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Actimmune

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127780
Guideline Name	Actimmune
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic granulomatous disease

Product Name:Actimmune	
Diagnosis	Osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe, malignant osteopetrosis

Product Name:Actimmune	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name:Actimmune	
Diagnosis	Chronic Granulomatous Disease (CGD), Osteopetrosis, Primary Cutaneous Lymphomas

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Actimmune

Product Name:Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Actimmune	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Actimmune therapy

2 . Revision History

Date	Notes
7/10/2023	Updated formularies, simplified and combined criteria, updated indications, cleaned up criteria.

Adalimumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-173221
Guideline Name	Adalimumab
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

- Failure to a 3 month trial of ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses confirmed by claims history or submission of medical records
- History of intolerance or contraindication to one non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

AND

4.2.2 If the request is for a non-preferred adalimumab product, ONE of the following:

- Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) [please specify intolerance or contraindication]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

1.2 Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.3 Prescribed by or in consultation with a rheumatologist

AND

1.4 If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

AND

1.5 If the request is for a non-preferred adalimumab product, ONE of the following:

- Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) [please specify intolerance or contraindication]

OR

2 - ALL of the following:

2.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2.3 Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

AND

2.5 If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab),

Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL)

	2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 ALL of the following:

4.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

4.2.1.2 ONE of the following:

4.2.1.2.1 Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

4.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

4.2.1.3 ONE of the following:

4.2.1.3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

4.2.1.3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

4.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

4.2.2 History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

4.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 Failure to ONE of the following conventional drugs or classes at maximally indicated doses, as confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

OR

4.2.2 History of intolerance or contraindication to ALL of the following conventional drugs or classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (generic Imuran)
- 6-mercaptopurine (generic Purinethol)
- Methotrexate

OR

4.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), ustekinumab]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical

reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*	
Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records

OR

4.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission medical records [e.g., Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib)]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 Failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records

OR

4.2.2 History of intolerance or contraindication to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify intolerance or contraindication)

OR

4.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., Bimzelx (bimekizumab-bkzx), Cosentyx (secukinumab)]

AND

5 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as ONE of the following:

- Intermediate
- Posterior
- Panuveitis

AND

3 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Ophthalmologist

AND

5 - ONE of the following:

5.1 Patient is currently on Adalimumab therapy as confirmed by claims history or submission of medical records

OR

5.2 BOTH of the following:

5.2.1 ONE of the following:

5.2.1.1 Failure to at least ONE corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose, as confirmed by claims history or submission of medical records

OR

5.2.1.2 History of intolerance or contraindication to at least ONE corticosteroid (e.g., prednisolone, prednisone) (please specify intolerance or contraindication)

AND

5.2.2 ONE of the following:

5.2.2.1 Failure to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at maximally indicated dose, as confirmed by claims history or submission of medical records

OR

5.2.2.2 History of intolerance or contraindication to at least ONE systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) (please specify intolerance or contraindication)

AND

6 - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*

Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background

Product Name:Humira, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, Adalimumab (all products)	
Diagnosis	RA, PJIA, PsA, Plaque Psoriasis, AS, CD, Ulcerative Colitis, HS, UV
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Adalimumab therapy

AND

2 - Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]^ **AND** **3** - If the request is for a non-preferred adalimumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred adalimumab products (please document reason/special circumstances)*	
Notes	*If approving a non-preferred adalimumab, please enter 1) The group authorization CSPREFADAL (for NY EPP and NY use: CSNYADAL) 2) An authorization for the non-preferred adalimumab at GPI-12 level See PDL links in Background ^ Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
2/19/2025	Updated formularies. Replaced Stelara with ustekinumab. Added ste p therapy bypass in HS section

Adbry

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161233
Guideline Name	Adbry
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 Failure to TWO of the following therapeutic classes of topical therapies, confirmed by claims history or submission of medical records:

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.2 History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium, high or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.3 Patient is currently on Adbry therapy as confirmed by claims history or submission of medical records

AND

3 - ONE of the following:

3.1 Failure to Dupixent confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to Dupixent (please specify intolerance or contraindication)

OR

3.3 Patient is currently on Adbry therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is NOT receiving Adbry in combination with EITHER of the following:

- Biologic immunomodulator [e.g., Dupixent (dupilumab)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

5 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name:Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Adbry therapy

AND

2 - Patient is NOT receiving Adbry in combination with either of the following:

- Biologic immunomodulator [e.g., Dupixent (dupilumab)]
- Janus kinas inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

3 - Prescribed by ONE of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1. Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05

	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1

Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
11/25/2024	Added GPI 9027308045D530

ADHD Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206556
Guideline Name	ADHD Products
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:generic amphetamine/dextroamphetamine salts (generic Adderall), generic amphetamine/dextroamphetamine salts ER (generic Adderall XR), generic methylphenidate ER tabs (generic Concerta), generic methylphenidate ER cp24 20mg, 30mg, and 40mg (generic Ritalin LA), generic methylphenidate ER tabs (generic Metadate ER), generic methylphenidate tabs (generic Ritalin), generic methylphenidate ER (CD) caps (generic Metadate CD), generic dexmethylphenidate, generic dexmethylphenidate ER, generic dextroamphetamine ER, generic dextroamphetamine 5 mg and 10 mg	
Diagnosis	Requests for Patients Greater Than or Equal to the Maximum Age Edit of 18 Years
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD)

OR

2 - Patient has depression

OR

3 - Patient has narcolepsy

OR

4 - Patient has other hypersomnia of central origin

OR

5 - Patient has Autism Spectrum Disorder

OR

6 - Patient has mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

OR

7 - Patient has fatigue associated with medical illness in palliative or end of life care

OR

8 - Patient has fatigue associated with multiple sclerosis

OR

9 - BOTH of the following:

9.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

9.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

Product Name:generic lisdexamfetamine capsules, generic lisdexamfetamine chewable tablets	
Diagnosis	Patient is greater than 18 years
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is greater than 18 years of age

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of ONE of the following:

2.1.1.1 Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

OR

2.1.1.2 Depression

OR

2.1.1.3 Narcolepsy

OR

2.1.1.4 Other hypersomnia of central origin

OR

2.1.1.5 Autism Spectrum Disorder

OR

2.1.1.6 Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

OR

2.1.1.7 Fatigue associated with medical illness in patients in palliative or end of life care

OR

2.1.1.8 Fatigue associated with multiple sclerosis

OR

2.1.1.9 Both of the following:

2.1.1.9.1 The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2.1.1.9.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

2.1.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

2.1.2.3 History of, or potential for, a substance abuse disorder

OR

2.2 Diagnosis of Binge Eating Disorder (BED)

Product Name:generic lisdexamfetamine capsules, generic lisdexamfetamine chewable tablets	
Diagnosis	Patient is 18 years or younger
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or younger

AND

2 - Diagnosis of ONE of the following:

2.1 Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

OR

2.2 Binge Eating Disorder (BED)

OR

2.3 Depression

OR

2.4 Narcolepsy

OR

2.5 Other hypersomnia of central origin

OR

2.6 Autism Spectrum Disorder

OR

2.7 Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

OR

2.8 Fatigue associated with medical illness in patients in palliative or end of life care

OR

2.9 Fatigue associated with multiple sclerosis

OR

2.10 Both of the following:

2.10.1 The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2.10.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

Product Name:(All) Brand Adderall, generic amphetamine/dextroamphetamine, Brand Adderall XR, generic amphetamine/dextroamphetamine ER, Brand Intuniv, generic guanfacine ER, generic methylphenidate ER tab, generic methylphenidate ER (CD), Brand Concerta, generic methylphenidate ER OSM, (generic Concerta), Brand Ritalin, generic methylphenidate tablet, generic methylphenidate ER (LA), Brand Ritalin LA, Brand Strattera, generic atomoxetine, Brand Vyvanse chewable tablets, Brand Vyvanse capsules, generic lisdexamfetamine chewable tablet, generic lisdexamfetamine capsules, Adhansia XR, Adzenys XR-ODT, Brand Aptensio XR, generic methylphenidate ER cap, Cotempla XR-ODT, Brand Daytrana, generic methylphenidate patch, Brand Desoxyn, generic methamphetamine, Brand Dexedrine, generic dextroamphetamine ER, Dyanavel XR, Brand Evekeo, Evekeo ODT, generic amphetamine, Brand Focalin, generic dexmethylphenidate, Brand Focalin XR, generic dexmethylphenidate ER, Jornay PM, Brand Kapvay, generic clonidine ER, Brand Methylin, generic methylphenidate chew tabs, generic methylphenidate soln, Brand Mydayis, Brand Procentra, generic dextroamphetamine soln, Quillichew ER, Quillivant XR, Brand Zenzedi, generic dextroamphetamine, Brand Relexxii, Brand Methylphenidate ER OSM, generic methylphenidate ER OSM (generic Relexxii), Qelbree, Azstarys, Xelstrym, generic amphetamine/dextroamphetamine 3-bead ER, amphetamine ER susp, Brand Metadate CD, Onyda XR

Diagnosis	Members Less than the FDA Approved Minimum Age*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD)

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information

- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The child is unresponsive to, or has had an inadequate response to behavioral therapy

AND

3 - The child is experiencing moderate-severe continuing disturbance in function despite behavioral therapy

AND

4 - ONE of the following**:

4.1 If the request is for a preferred product, the patient has history of ONE of the following:

4.1.1 Failure to THREE preferred alternatives, as confirmed by claims history or submission of medical records (In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to ALL of the preferred products for the patient's age as confirmed by claims history or submission of medical records)

OR

4.1.2 Contraindication or intolerance to THREE preferred alternatives (In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to ALL of the preferred products for the patient's age) (please specify contraindication or intolerance)

OR

4.2 If the request is for a non-preferred product, non-preferred criteria must also be met***

Notes	*See Table 1 in background section for FDA approved min ages. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html. Prior

	trials of formulary/PDL alternatives must sufficiently demonstrate that t he formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. ***For non-preferred criteria, please reference the Non-Preferred secti on below.

Product Name:Onyda XR	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

3 - BOTH of the following:

3.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

AND

3.2 ONE of the following

- Failure to clonidine ER tablet (generic Kapvay) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to clonidine ER tablet (generic Kapvay) (please specify contraindication or intolerance)

Product Name:Qelbree	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

3 - ALL of the following:

3.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

AND

3.2 ONE of the following:

3.2.1 Failure to ALL of the following, as confirmed by claims history or submission of medical records:

- guanfacine ER (generic Intuniv)
- atomoxetine (generic Strattera)
- clonidine ER (generic Kapvay)

OR

3.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- guanfacine ER (generic Intuniv)
- atomoxetine (generic Strattera)
- clonidine ER (generic Kapvay)

AND

3.3 ONE of the following:

3.3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Amphetamine/dextroamphetamine extended-release capsule (generic Adderall XR)
- Methylphenidate extended-release tablet (generic Concerta)
- Methylphenidate extended-release capsule (generic Metadate CD)
- Methylphenidate 20 mg (milligrams), 30 mg, 40 mg extended-release capsule (generic Ritalin LA)
- Dexmethylphenidate ER capsule (generic Focalin XR)
- Lisdexamfetamine dimesylate capsule (generic Vyvanse)

OR

3.3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Amphetamine/dextroamphetamine extended-release capsule (generic Adderall XR)
- Methylphenidate extended-release tablet (generic Concerta)
- Methylphenidate extended-release capsule (generic Metadate CD)
- Methylphenidate 20 mg, 30 mg, 40 mg extended-release capsule (generic Ritalin LA)
- Dexmethylphenidate ER capsule (generic Focalin XR)
- Lisdexamfetamine dimesylate capsule (generic Vyvanse)

OR

3.3.3 Physician attestation that use of a stimulant medication is not appropriate for the patient

Product Name:Brand Adderall, Brand Adderall XR, Adhansia XR, Adzenys XR-ODT, Brand Aptensio XR, generic methylphenidate ER cap (generic Aptensio XR), Brand Concerta,

Cotempla XR-ODT, Brand Daytrana, generic methylphenidate patch, Brand Desoxyn, generic methamphetamine, Brand Dexedrine, Dyanavel XR, Brand Evekeo, Evekeo ODT, generic amphetamine, Brand Focalin, Brand Focalin XR, Brand Intuniv, Jornay PM, Brand Methylin, generic methylphenidate chew tabs, generic methylphenidate soln, generic methylphenidate ER (LA) 10 mg and 60 mg caps, Brand Mydayis, Brand Procentra, generic dextroamphetamine soln, Quillichew ER, Quillivant XR, Brand Relexxii, Brand Methylphenidate ER OSM, generic methylphenidate ER OSM (generic Relexxii), Brand Ritalin, Brand Ritalin LA, Brand Strattera, Brand Zenzedi, generic dextroamphetamine 2.5mg and 7.5mg and 15 mg and 20 mg and 30 mg, Azstarys, Xelstrym, generic amphetamine/dextroamphetamine 3-bead ER, amphetamine ER susp, Brand Metadate CD	
Diagnosis	Non-Preferred*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

3 - If the request is non-preferred*, ALL of the following:

3.1 The patient has a history of ONE of the following:

3.1.1 Failure to a majority (not more than three) of the preferred* formulary/PDL alternatives for the given diagnosis, as confirmed by claims history or submission of medical records (In instances where there are fewer than three preferred alternatives, the patient must have a history of failure to ALL of the preferred products for the patient's age as confirmed by claims history or submission of medical records)

OR

3.1.2 Contraindication or intolerance to a majority (not more than three) of the preferred*

formulary/PDL alternatives for the given diagnosis (In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to ALL of the preferred products for the patient's age) (please specify contraindication or intolerance)

AND

3.2 If the request is for a multi-source brand medication, ONE of the following:

3.2.1 The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

OR

3.2.2 The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

OR

3.2.3 The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

OR

3.2.4 Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

AND

3.3 ONE of the following:

3.3.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

3.3.2 BOTH of the following:

3.3.2.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3.3.2.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

Notes	*PDL link https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.

Product Name:Brand Vyvanse capsules, Brand Vyvanse tablet	
Diagnosis	ADHD/ADD
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

3 - ALL of the following:

3.1 Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

AND

3.2 ONE of the following:

3.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

3.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

3.2.3 BOTH of the following:

3.2.3.1 History of, or potential for, a substance abuse disorder

AND

3.2.3.2 One of the following:

- Failure to atomoxetine (generic Strattera) as confirmed by claims history or submission of medical records

- History of intolerance or contraindication to atomoxetine (generic Strattera) (please specify intolerance or contraindication)

AND

3.3 ONE of the following*:

3.3.1 The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

OR

3.3.2 The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

OR

3.3.3 The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

OR

3.3.4 Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

Notes	*Generic Vyvanse became available 9/2023. Requests for members currently on brand Vyvanse should be evaluated for use of the GENERIC, unless the provider provides specific rationale for ongoing use of the brand.

Product Name:Brand Vyvanse capsules, Brand Vyvanse tablet	
Diagnosis	Non-ADHD/ADD Diagnoses
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

3 - ONE of the following:

3.1 ALL of the following:

3.1.1 ONE of the following diagnoses:

3.1.1.1 Depression

OR

3.1.1.2 Narcolepsy

OR

3.1.1.3 Other hypersomnia of central origin

OR

3.1.1.4 Autism Spectrum Disorder

OR

3.1.1.5 Mental fatigue secondary to traumatic brain injury (e.g., post-concussion syndrome)

OR

3.1.1.6 Fatigue associated with medical illness in patients in palliative or end of life care

OR

3.1.1.7 Fatigue associated with multiple sclerosis

OR

3.1.1.8 BOTH of the following:

3.1.1.8.1 The use of this drug is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3.1.1.8.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

3.1.2 ONE of the following:

3.1.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

3.1.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
- Methylphenidate extended-release tablet or capsule (e.g., generic Concerta or Metadate CD)
- Dexmethylphenidate ER capsule (generic Focalin XR)

OR

3.1.2.3 History of or potential for a substance abuse disorder

AND

3.1.3 ONE of the following*:

3.1.3.1 The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

OR

3.1.3.2 The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

OR

3.1.3.3 The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

OR

3.1.3.4 Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

OR

3.2 BOTH of the following:

3.2.1 Diagnosis of Binge Eating Disorder (BED)

AND

3.2.2 ONE of the following*:

3.2.2.1 The multi-source brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic equivalent (specify the adverse reaction, allergy or sensitivity)

OR

3.2.2.2 The multi-source brand is being requested due to a therapeutic failure with the generic equivalent, as documented by submission of medical records

OR

3.2.2.3 The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

OR

3.2.2.4 Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstances)

Notes	*Generic Vyvanse became available 9/2023. Requests for members currently on brand Vyvanse should be evaluated for use of the GENERIC, unless the provider provides specific rationale for ongoing use of the brand.

2 . Background

Benefit/Coverage/Program Information

Table 1: FDA Approved Minimum Age Table

Product name	FDA Approved Minimum Age
All products NOT listed below	6 years of age
Adderall (amphetamine/dextroamphetamine salts)	3 years of age
Dexedrine (dextroamphetamine)	3 years of age
Evekeo ODT/Evekeo (amphetamine) tablet	3 years of age
Mydayis (mixed amphetamine salts) ER capsule	13 years of age
ProCentra (dextroamphetamine) solution	3 years of age
Zenzedi (dextroamphetamine) tablet	3 years of age

3 . Revision History

Date	Notes
3/3/2025	Updated GPIs. Added Onyda XR

Aemcolo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125324
Guideline Name	Aemcolo
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Aemcolo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of travelers' diarrhea

AND

2 - ONE of the following:

2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Azithromycin (generic Zithromax)
- Ciprofloxacin (generic Cipro)
- Levofloxacin (generic Levaquin)
- Ofloxacin (generic Floxin)

2 . Revision History

Date	Notes
5/4/2023	Removed old CO cag and replaced with new. Removed AZ, this LOB no longer applies to CORE policy

Afinitor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155803
Guideline Name	Afinitor
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Neuroendocrine tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Neuroendocrine tumors of gastrointestinal origin
- Neuroendocrine tumors of lung origin
- Neuroendocrine tumors of thymic origin

AND

1.2 Disease is progressive

AND

1.3 ONE of the following:

- Disease is unresectable
- Disease is locally advanced
- Disease is metastatic

AND

1.4 If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

OR

2 - ALL of the following:

2.1 Diagnosis of neuroendocrine tumors of pancreatic origin

AND

2.2 ONE of the following:

- Used for the management of recurrent, locoregional advanced disease and/or metastatic disease
- Used as preoperative therapy of locoregional insulinoma with or without diazoxide

AND

2.3 If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Neuroendocrine Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal cell cancer, Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell cancer/kidney cancer

AND

2 - Disease is ONE of the following:

- Relapsed
- Stage IV disease

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Renal cell cancer, Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex-Associated Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex (TSC)-associated renal cell carcinoma

AND

2 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex-Associated Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO

Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA)

AND

2 - Used as adjuvant treatment

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Waldenströms macroglobulinemia
- Lymphoplasmacytic lymphoma

AND

2 - One of the following:

- Disease is non-responsive to primary treatment
- Disease is progressive
- Disease has relapsed

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Waldenströms Macroglobulinemia or Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - One of the following:

2.1 Disease is recurrent

OR

2.2 Disease is metastatic

AND

3 - Disease is hormone receptor positive (HR+) [i.e., estrogen-receptor-positive (ER+) or progesterone-receptor-positive (PR+)]

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - One of the following:

5.1 Patient is a postmenopausal woman

OR

5.2 BOTH of the following:

- Patient is a premenopausal woman
- Patient is being treated with ovarian ablation/suppression

OR

5.3 Patient is male

AND

6 - Used in combination with one of the following:

6.1 Exemestane if progressed within 12 months or on a non-steroidal aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole)]

OR

6.2 Fulvestrant

OR

6.3 Tamoxifen

AND

7 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of classic Hodgkin lymphoma

AND

2 - Disease is refractory to at least 3 prior lines of therapy

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, or lymphangioleiomyomatosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following soft tissue sarcoma subtypes:

1.1 Locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)

OR

1.2 Recurrent angiomyolipoma

OR

1.3 Lymphangioleiomyomatosis

AND

2 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	PEComa (perivascular epitheliod cell tumor), recurrent angiomyolipoma, or lymphangioleiomyomatosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of thymic carcinoma
- Diagnosis of thymoma

AND

2 - ONE of the following:

2.1 First-line therapy as a single agent for those who cannot tolerate first-line combination regimens

OR

2.2 Second-line therapy as a single agent

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records

- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Thymic Carcinoma or Thymoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Follicular carcinoma, Oncocytic carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2 - ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

3 - ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine treatment

AND

5 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Follicular carcinoma, Oncocytic carcinoma, or papillary carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is recurrent or progressive

AND

3 - Surgery and/or radiation is not possible

AND

4 - One of the following:

- Used in combination with bevacizumab (Avastin, Mvasi, etc.)
- Used in combination with octreotide acetate LAR

AND

5 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records

- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with letrozole

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis complex associated partial-onset seizures

AND

2 - Used as adjunctive therapy

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Tuberous Sclerosis Complex associated Partial-Onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of osteosarcoma

AND

2 - Disease is ONE of the following:

- Relapsed/Refractory
- Metastatic

AND

3 - Used as second-line therapy

AND

4 - Used in combination with Nexavar (sorafenib)

AND

5 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Osteosarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Rosai-Dorfman Disease
- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

AND

2 - Presence of phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation

AND

3 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Histiocytic Neoplasms

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)

AND

2 - Disease is one of the following:

- Unresectable
- Progressive
- Metastatic
- Gross residual (R2 resection)
- Tumor rupture

AND

3 - Disease has progressed after single agent therapy with ALL of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)

- Stivarga (regorafenib)
- Qinlock (ripretinib)

AND

4 - Used in combination with ONE of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)

AND

5 - If the request is for Torpenz, ONE of the following:

- Failure to everolimus (generic Afinitor) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to everolimus (generic Afinitor) (please specify contraindication or intolerance)

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Afinitor, generic everolimus, Torpenz, Brand Afinitor Disperz, generic everolimus TBSO	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/24/2024	Added step thru everolimus for Torpenz

Afrezza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123673
Guideline Name	Afrezza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New York

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Afrezza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Forced Expiratory Volume (FEV1) within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

AND

4 - Afrezza will not be approved in patients with ONE of the following:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months)
- With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

Product Name:Afrezza	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in Forced Expiratory Volume (FEV1)

AND

2 - Patient continues to be unable to self-inject short-acting insulin due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria)

AND

3 - Patient continues to not smoke cigarettes

2 . Revision History

Date	Notes
3/23/2023	Updated revised GPIs. Combined Markets in Scope

Agamree

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155757
Guideline Name	Agamree
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Agamree	
Diagnosis	Duchenne Muscular Dystrophy
Guideline Type	Prior Authorization
Approval Criteria	

1 - Published clinical evidence shows Agamree is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Agamree is not medically necessary for treatment of Duchenne muscular dystrophy	
Notes	All requests for authorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Com munity Plan Pharmacy Appeals team for consideration.

2 . Revision History

Date	Notes
9/23/2024	New Guideline

Akeega

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164692
Guideline Name	Akeega
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington • Medicaid - Community & State New Mexico • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Akeega	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Deleterious or suspected deleterious BRCA-mutated (BRCAm)

AND

3 - Used in combination with prednisone

Product Name:Akeega	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Akeega therapy

Product Name:Akeega	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Akeega	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Akeega therapy	

2 . Revision History

Date	Notes
2/4/2025	Added IN formulary. No change to clinical criteria.

Alecensa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151387
Guideline Name	Alecensa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is anaplastic lymphoma kinase (ALK)-positive

AND

3 - One of the following:

3.1 Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

OR

3.2 Used as adjuvant treatment following tumor resection

Product Name:Alecensa	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic Erdheim-Chester Disease

AND

2 - Used as targeted therapy anaplastic lymphoma kinase (ALK)-fusion

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

Product Name:Alecensa	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma (ALCL)

AND

2 - Used as second-line or initial palliative intent therapy and subsequent therapy

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

4 - Anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of large B-Cell lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from NSCLC

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Presence of anaplastic lymphoma kinase (ALK) translocation

Product Name:Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, T-Cell Lymphomas, B-Cell Lymphomas, Central Nervous System (CNS) Cancers, Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name:Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alecensa therapy

2 . Revision History

Date	Notes

8/13/2024	Added criteria for adjuvant treatment following tumor resection of ALK-positive NSCLC per FDA label. Updated references.

Alecensa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151387
Guideline Name	Alecensa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is anaplastic lymphoma kinase (ALK)-positive

AND

3 - One of the following:

3.1 Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

OR

3.2 Used as adjuvant treatment following tumor resection

Product Name:Alecensa	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic Erdheim-Chester Disease

AND

2 - Used as targeted therapy anaplastic lymphoma kinase (ALK)-fusion

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

Product Name:Alecensa	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma (ALCL)

AND

2 - Used as second-line or initial palliative intent therapy and subsequent therapy

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

4 - Anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of large B-Cell lymphoma

AND

2 - Disease is ONE of the following:

- Relapsed
- Refractory

AND

3 - Anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from NSCLC

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alecensa	
Diagnosis	Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Presence of anaplastic lymphoma kinase (ALK) translocation

Product Name:Alecensa	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, T-Cell Lymphomas, B-Cell Lymphomas, Central Nervous System (CNS) Cancers, Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alecensa therapy

Product Name:Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Alecensa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alecensa therapy

2 . Revision History

Date	Notes

8/13/2024	Added criteria for adjuvant treatment following tumor resection of ALK-positive NSCLC per FDA label. Updated references.

Alfa Interferons

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158354
Guideline Name	Alfa Interferons
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Will be used as part of a combination antiviral treatment regimen

Product Name:Pegasys	
Diagnosis	Diagnoses Other Than Hepatitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Chronic myeloid leukemia (CML)
- Hairy cell leukemia
- Erdheim-Chester disease (ECD)
- Myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF)
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma

Product Name:Pegasys	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Pegasys	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pegasys therapy

2 . Revision History

Date	Notes
10/31/2024	Removed Intron A

Alfa Interferons

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158354
Guideline Name	Alfa Interferons
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

Product Name:Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient does not have decompensated liver disease (defined as Child-Pugh Class B or C)

AND

3 - Will be used as part of a combination antiviral treatment regimen

Product Name:Pegasys	
Diagnosis	Diagnoses Other Than Hepatitis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Chronic myeloid leukemia (CML)
- Hairy cell leukemia
- Erdheim-Chester disease (ECD)
- Myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF)
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma

Product Name:Pegasys	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Pegasys	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pegasys therapy

2 . Revision History

Date	Notes
10/31/2024	Removed Intron A

Alinia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117334
Guideline Name	Alinia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:generic nitazoxanide, Brand Alinia	
Diagnosis	Diarrhea caused by Giardia lamblia
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giardiasis

AND

2 - ONE of the following:

2.1 Failure to metronidazole, as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to metronidazole (please specify contraindication or intolerance)

Product Name:generic nitazoxanide, Brand Alinia	
Diagnosis	Diarrhea caused by Cryptosporidium parvum
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cryptosporidiosis

2 . Revision History

Date	Notes
11/30/2022	Updated T/F criteria, updated auth duration of giardiasis.

Alunbrig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157619
Guideline Name	Alunbrig
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alunbrig	
Diagnosis	Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Presence of ALK (anaplastic lymphoma kinase) translocation

Product Name:Alunbrig

Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic Erdheim-Chester Disease

AND

2 - Used as targeted therapy (anaplastic lymphoma kinase) ALK-fusion

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

Product Name:Alunbrig	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from NSCLC

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alunbrig	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

AND

4 - Used as palliative intent therapy or second-line and subsequent therapy

Product Name:Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma/Uterine Neoplasms, Histiocytic Neoplasms, Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alunbrig therapy

Product Name:Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alunbrig therapy

2 . Revision History

Date	Notes

10/30/2024	Added Anaplastic Large Cell Lymphoma

Alunbrig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157619
Guideline Name	Alunbrig
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent
- Advanced

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alunbrig	
Diagnosis	Soft Tissue Sarcoma/Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Presence of ALK (anaplastic lymphoma kinase) translocation

Product Name:Alunbrig

Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic Erdheim-Chester Disease

AND

2 - Used as targeted therapy (anaplastic lymphoma kinase) ALK-fusion

AND

3 - Disease is ONE of the following:

- Relapsed
- Refractory

Product Name:Alunbrig	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from NSCLC

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Alunbrig	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

AND

4 - Used as palliative intent therapy or second-line and subsequent therapy

Product Name:Alunbrig	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma/Uterine Neoplasms, Histiocytic Neoplasms, Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Alunbrig therapy

Product Name:Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Alunbrig	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Alunbrig therapy

2 . Revision History

Date	Notes

10/30/2024	Added Anaplastic Large Cell Lymphoma

Ampyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-133253
Guideline Name	Ampyra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Brand Ampyra, generic dalfampridine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of multiple sclerosis

2 . Revision History

Date	Notes
9/19/2023	Updated criteria to only require diagnosis to allow for DX2RX.

Anthelmintics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155824
Guideline Name	Anthelmintics
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Generic albendazole, Emverm	
Diagnosis	Enterobius vermicularis (pinworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Enterobius vermicularis (pinworm)

AND

2 - ONE of the following:

2.1 Failure of over-the-counter pyrantel pamoate confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to over-the-counter pyrantel pamoate (please specify intolerance or contraindication)

Product Name:Generic albendazole	
Diagnosis	Taenia solium and Taenia saginata (Taeniasis or Cysticercosis/Neurocysticercosis)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Taeniasis or Cysticercosis/Neurocysticercosis

Product Name:Generic albendazole, Emverm	
Diagnosis	Echinococcosis (Tapeworm)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hydatid Disease [Echinococcosis (Tapeworm)]

Product Name:Emverm	
Diagnosis	Ancylostoma/Necatoriasis (Hookworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

Product Name:Generic albendazole	
Diagnosis	Ancylostoma/Necatoriasis (Hookworm)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ancylostoma/Necatoriasis (Hookworm)

Product Name:Generic albendazole, Emverm	
Diagnosis	Ascariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ascariasis (Roundworm)

Product Name:Generic albendazole, Emverm	
Diagnosis	Toxocariasis (Roundworm)

Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Toxocariasis (Roundworm)

Product Name:Generic albendazole, Emverm	
Diagnosis	Trichinellosis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Trichinellosis

Product Name:Generic albendazole, Emverm	
Diagnosis	Trichuriasis (Whipworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Trichuriasis (Whipworm)

Product Name:Generic albendazole, Emverm	
Diagnosis	Capillariasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Capillariasis

Product Name:Generic albendazole, Emverm	
Diagnosis	Baylisascaris
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Baylisascaris

Product Name:Generic albendazole	
Diagnosis	Clonorchiasis (Liver flukes)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Clonorchiasis (Liver flukes)

Product Name:Generic albendazole	
Diagnosis	Gnathostomiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gnathostomiasis

Product Name:Generic albendazole	
Diagnosis	Strongyloidiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Strongyloidiasis

Product Name:Generic albendazole	
Diagnosis	Loiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Loiasis

Product Name:Generic albendazole	
Diagnosis	Opisthorchiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Opisthorchiasis

Product Name:Generic albendazole	
Diagnosis	Anisakiasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Anisakiasis

Product Name:Generic albendazole	
Diagnosis	Microsporidiosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Microsporidiosis not caused by Enterocytozoon bieneusi or Vittaforma corneae

2 . Revision History

Date	Notes
9/24/2024	Clarified spelling of Opisthorchiasis

Anticonvulsants

Prior Authorization Guideline

Guideline ID	GL-161382
Guideline Name	Anticonvulsants
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Aptiom, Briviact tabs/oral soln, Xcopri	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of partial-onset seizures

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Fycompa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Diagnosis of partial-onset seizures with or without secondarily generalized seizures

OR

2.1.2 ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:generic lacosamide tabs/oral soln, Brand Vimpat tabs/oral soln	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Diagnosis of partial onset seizures

OR

2.1.2 ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran

Product Name:Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

OR

3 - BOTH of the following:

3.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

3.2 History of greater than or equal to 8 week trial of at least TWO generic anticonvulsants (e.g., divalproex, lamotrigine, topiramate, valproic acid)

Product Name:Brand Onfi, generic clobazam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome
- Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)
- Diagnosis of Dravet syndrome

AND

2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

Product Name:generic rufinamide, Brand Banzel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of seizures associated with Lennox-Gastaut syndrome

Product Name:generic tiagabine, Brand Gabitril	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of partial-onset seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Felbamate (generic Felbatol)
- Rufinamide (generic Banzel)

AND

2.4 Prescriber provides a reason or special circumstance the patient cannot use clobazam (generic Onfi) tablets or suspension

OR

3 - ALL of the following:

3.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

3.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

3.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

3.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

4 - ALL of the following:

- Diagnosis of Dravet syndrome

- Patient is currently taking Diacomit
- Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

Product Name:Brand Sabril powd pack, Vigadrone powd pack, generic vigabatrin powd pack	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of infantile spasms

OR

3 - ALL of the following:

3.1 Diagnosis of complex partial seizures

AND

3.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

3.3 Not used as primary treatment

AND

3.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Brand Sabril tablets, Vigadrone tablets, generic vigabatrin tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of Dravet syndrome and currently taking clobazam

Product Name:Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with Dravet syndrome

AND

2.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

OR

3 - ALL of the following:

3.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

3.2 ONE of the following:

3.2.1 Failure of a greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)

- Valproic acid (e.g., generic Depakene)

OR

3.2.2 History of intolerance or contraindication to ALL of the following (any release formulation qualifies) (please specify intolerance or contraindication):

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)

Product Name:Ztalmy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with genetic testing

AND

2.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)

- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

2 . Revision History

Date	Notes
12/5/2024	Updated GPIs

Anticonvulsants

Prior Authorization Guideline

Guideline ID	GL-161382
Guideline Name	Anticonvulsants
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Aptiom, Briviact tabs/oral soln, Xcopri	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of partial-onset seizures

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Fycompa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Diagnosis of partial-onset seizures with or without secondarily generalized seizures

OR

2.1.2 ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:generic lacosamide tabs/oral soln, Brand Vimpat tabs/oral soln	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Diagnosis of partial onset seizures

OR

2.1.2 ALL of the following:

- Diagnosis of primary generalized tonic-clonic seizures
- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.2 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies) confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran

Product Name:Epidiolex	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of seizures associated with Dravet syndrome or tuberous sclerosis complex

OR

3 - BOTH of the following:

3.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

3.2 History of greater than or equal to 8 week trial of at least TWO generic anticonvulsants (e.g., divalproex, lamotrigine, topiramate, valproic acid)

Product Name:Brand Onfi, generic clobazam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of seizures associated with Lennox-Gastaut syndrome
- Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)
- Diagnosis of Dravet syndrome

AND

2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

Product Name:generic rufinamide, Brand Banzel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of seizures associated with Lennox-Gastaut syndrome

Product Name:generic tiagabine, Brand Gabitril	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of partial-onset seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Sympazan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

2.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Felbamate (generic Felbatol)
- Rufinamide (generic Banzel)

AND

2.4 Prescriber provides a reason or special circumstance the patient cannot use clobazam (generic Onfi) tablets or suspension

OR

3 - ALL of the following:

3.1 Diagnosis of refractory partial onset seizures (four or more uncontrolled seizures per month after an adequate trial of at least two antiepileptic drugs)

AND

3.2 BOTH of the following:

- Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)
- Not used as primary treatment

AND

3.3 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

AND

3.4 Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

OR

4 - ALL of the following:

- Diagnosis of Dravet syndrome

- Patient is currently taking Diacomit
- Prescriber provides a reason or special circumstance the patient cannot use generic clobazam tablets or suspension

Product Name:Brand Sabril powd pack, Vigadrone powd pack, generic vigabatrin powd pack	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of infantile spasms

OR

3 - ALL of the following:

3.1 Diagnosis of complex partial seizures

AND

3.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

3.3 Not used as primary treatment

AND

3.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Brand Sabril tablets, Vigadrone tablets, generic vigabatrin tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Used as adjunctive therapy (defined as accessory treatment used in combination to enhance primary treatment)

AND

2.3 Not used as primary treatment

AND

2.4 History of greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)
- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

Product Name:Diacomit	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - Diagnosis of Dravet syndrome and currently taking clobazam

Product Name:Fintepla	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with Dravet syndrome

AND

2.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Levetiracetam (e.g., generic Keppra)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

OR

3 - ALL of the following:

3.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

3.2 ONE of the following:

3.2.1 Failure of a greater than or equal to 8 week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)

- Valproic acid (e.g., generic Depakene)

OR

3.2.2 History of intolerance or contraindication to ALL of the following (any release formulation qualifies) (please specify intolerance or contraindication):

- Divalproex (e.g., generic Depakote)
- Lamotrigine (e.g., generic Lamictal)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)

Product Name:Ztalmy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy for a seizure disorder

OR

2 - ALL of the following:

2.1 Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with genetic testing

AND

2.2 History of greater than or equal to 8-week trial of at least TWO of the following (any release formulation qualifies), confirmed by claims history or submitted medical records:

- Carbamazepine (e.g., generic Tegretol)
- Divalproex (e.g., generic Depakote)
- Gabapentin (e.g., generic Neurontin)
- Lamotrigine (e.g., generic Lamictal)
- Levetiracetam (e.g., generic Keppra)

- Oxcarbazepine (e.g., generic Trileptal)
- Phenytoin (e.g., generic Dilantin)
- Pregabalin (e.g., generic Lyrica)
- Topiramate (e.g., generic Topamax)
- Valproic acid (e.g., generic Depakene)
- Zonisamide (generic Zonegran)

2 . Revision History

Date	Notes
12/5/2024	Updated GPIs

Antipsoriatic Agents

Prior Authorization Guideline

Guideline ID	GL-173218
Guideline Name	Antipsoriatic Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:generic calcitriol ointment	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of psoriasis

AND

2 - ONE of the following:

2.1 Failure to TWO medium to high potency corticosteroid topical treatments (see Background) as confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to TWO medium to high potency corticosteroid topical treatments (see Background) (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Calcipotriene cream
- Calcipotriene ointment

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Calcipotriene cream
- Calcipotriene ointment

2 . Background

Benefit/Coverage/Program Information

Table 1. Relative Potency of Selected Topical Corticosteroid Products

Drug	Dosage Form	Strength
Super-High Potency (group 1)		
Augmented betamethasone dipropionate (Diprolene)	Gel, Ointment, lotion	0.05%
Clobetasol propionate (Clobex, Olux, Temovate, Temovate E)	Cream, Ointment, Gel, Solution, Lotion, Shampoo, Spray Aerosol, Foam Aerosol	0.05%
Fluocinonide (Vanos)	Cream	0.1%
Flurandrenolide (Cordran)	Tape (roll)	4 mcg/cm^2
Halobetasol propionate (Ultravate, Lexette)	Lotion, Cream, Ointment, Foam	0.05%
High Potency (group 2)		
Amcinonide (Amcort)	Ointment	0.1%
Augmented betamethasone dipropionate (Diprolene, Diprolene AF)	Cream, Lotion, Ointment	0.05%
Betamethasone dipropionate	Lotion, Ointment	0.05%
Clobetasol propionate (Impoyz)	Cream	0.025%
Desoximetasone (Topicort)	Cream, Ointment, Spray	0.25%,
	Gel	0.05%
Diflorasone diacetate (Psorcon)	Cream, Ointment	0.05%
Fluocinonide (Lidex, Lidex E)	Cream, Gel, Ointment, Solution	0.05%
Halcinonide (Halog)	Cream, Ointment, Solution	0.1%

Halobetasol propionate (Bryhali)	Lotion	0.01%
High Potency (group 3)		
Amcinonide (Amcort)	Cream, Lotion	0.1%
Betamethasone valerate (Valisone)	Ointment	0.1%
Desoximetasone (Topicort)	Cream, ointment	0.05%
Diflorasone diacetate (Florone, Psorcon)	Cream	0.05%
Fluocinonide (Lidex-E)	Cream	0.05%
Fluticasone propionate (Cutivate)	Ointment	0.005%
Mometasone furoate (Elocon)	Ointment	0.1%
Triamcinolone acetonide (Aristocort HP, Kenalog, Triderm)	Cream, ointment	0.5%
Medium Potency (group 4)		
Betamethasone dipropionate (sernivo)	Spray	0.05%
Clocortolone pivalate (Cloderm)	Cream	0.1%
Fluocinolone acetonide (Synalar)	Cream, Ointment	0.025%
Flurandrenolide (Cordran)	Ointment	0.05%
Fluticasone propionate (Cutivate)	Cream, Lotion	0.05%
Hydrocortisone valerate (Westcort)	Ointment	0.2%
Mometasone furoate (Elocon)	Cream, lotion, Solution	0.1%
Triamcinolone acetonide (Aristocort, Kenalog)	Cream, Lotion Ointment	0.1%
	Ointment	0.05%

3 . Revision History

Date	Notes
2/18/2025	Removed calcipotriene cream and ointment as targets for guideline. Added a step through either calcipotriene cream or ointment.

Antipsychotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164575
Guideline Name	Antipsychotics
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:generic risperidone tabs/soln, Brand Risperdal tabs/soln, generic quetiapine, Brand Seroquel, generic ziprasidone, Brand Geodon, Brand Zyprexa, generic olanzapine, generic clozapine, Brand Clozaril, Cobenfy, Brand Abilify tabs/soln, generic aripiprazole tabs/soln, Abilify Maintena, Invega Sustenna, Perseris, Brand Risperdal Consta, generic risperidone ER IM injection, Aristada, Aristada Initio, generic paliperidone ER, Brand Invega, generic risperidone ODT, aripiprazole ODT, aripiprazole soln, generic olanzapine ODT, Brand Zyprexa Zydis, Fanapt, generic quetiapine ER, Brand Seroquel XR, Brand Latuda, Rexulti, Brand Saphris, Secuado, Vraylar, Versacloz, generic clozapine ODT, generic asenapine, Invega Hafyera, Lybalvi, Invega Trinza, Caplyta, Abilify Mycite, generic lurasidone, Uzedy, Abilify Asimtufii, Fanapt Titration Pack, Rykindo, Erzofri	
Diagnosis	Minimum Age Edit*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is unresponsive to other treatment modalities, unless contraindication (i.e., other medications or behavioral modification attempted)

AND

2 - The patient has tried and failed ALL available preferred** atypical antipsychotics that are Food and Drug Administration (FDA) approved for the patient's age

AND

3 - ONE of the following:

3.1 Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Autism
- Bipolar disorder

OR

3.2 Patient displays symptoms of aggression as a symptom of developmental delay, Tourette's syndrome or chronic tics, oppositional defiant disorder, or conduct disorder

Notes	*See Table 1 in Background for UHC C&S Minimum Age Edits. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Brand Risperdal soln, generic risperidone soln	
Diagnosis	Maximum Age Edit*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 BOTH of the following:

1.2.1 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- Clinical pharmacology
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

1.2.2 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The drug is prescribed within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - ONE of the following:

3.1 The patient is unable to swallow the oral solid preferred** alternatives

OR

3.2 ONE of the following:

3.2.1 Failure to a majority (not more than 3) of the oral solid preferred** alternatives as confirmed by claims history or submission of medical records

OR

3.2.2 History of contraindication or intolerance to a majority (not more than 3) of the oral solid preferred** alternatives (please specify contraindication or intolerance)

Notes	*See Table 2 in Background for UHC C&S Maximum Age Edits. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Abilify Maintena	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral aripiprazole

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Aristada, Aristada Initio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral aripiprazole

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - ONE of the following:

2.1 Patient has been established on once-a-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Sustenna) for at least 4 months

OR

2.2 Patient has been established on every-three-month paliperidone palmitate extended-release injectable suspension (e.g., Invega Trinza) for at least one three-month cycle

Product Name:Invega Sustenna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral paliperidone or oral risperidone

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Invega Trinza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - Patient has been established on Invega Sustenna for at least 4 consecutive months prior to initiating Invega Trinza

Product Name:Perseris	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral risperidone

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Brand Risperdal Consta, generic risperidone ER IM injection	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral risperidone

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Abilify Asimtufii	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral aripiprazole

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Uzedy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia
- Schizoaffective disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral risperidone

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Rykindo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

AND

2 - ONE of the following:

2.1 Patient is non-adherent with oral atypical antipsychotic dosage forms

OR

2.2 Patient has established tolerability with oral risperidone

OR

2.3 Patient is unable to take oral solid alternatives

Product Name:Abilify MyCite	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient has ONE of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder
- Autism
- Major depressive disorder
- Tourette's

AND

1.2 Submission of medical records documenting the patient is currently prescribed aripiprazole and tolerates the medication

AND

1.3 Submission of medical records documenting the patient's adherence to aripiprazole is less than 80% within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100)

AND

1.4 ALL of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:

- Utilization of a pill box
- Utilization of a smart phone reminder (ex. alarm, application, or text reminder)
- Involving family members or friends to assist
- Coordinating timing of dose to coincide with dosing of another daily medication

AND

1.5 Submission of medical records documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole

AND

1.6 Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence

AND

1.7 Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer

AND

1.8 ONE of the following:

1.8.1 History of failure to TWO of the following as confirmed by claims history or submission of medical records:

- Abilify Maintena
- Invega Sustenna
- Risperidone ER injection (generic Risperdal Consta)
- Aristada
- Perseris

OR

1.8.2 History of contraindication, intolerance, reason, or special circumstance they cannot use ALL of the following (please specify contraindication, intolerance, reason, or special circumstance):

- Abilify Maintena
- Invega Sustenna
- Risperidone ER injection (generic Risperdal Consta)
- Aristada
- Perseris

OR

2 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

3 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Product Name:Abilify MyCite	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient is clinically stable on Abilify MyCite

AND

2 - Submission of medical records documenting that the use of Abilify MyCite has increased adherence to 80% or more

AND

3 - Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent

Product Name:Vraylar	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient has a diagnosis of ONE of the following:

- Mania or mixed episodes associated with Bipolar Disorder
- Major depressive disorder (MDD)

AND

1.2 ONE of the following:

1.2.1 Failure to THREE preferred* alternatives, one of which must be aripiprazole, as confirmed by claims history or submission of medical records

OR

1.2.2 History of contraindication or intolerance to THREE preferred* alternatives, one of which must be aripiprazole (please specify contraindication or intolerance)

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

2.2 ONE of the following:

2.2.1 Failure to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone, as confirmed by claims history or submission of medical records

OR

2.2.2 History of contraindication or intolerance to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone (please specify contraindication or intolerance)

OR

3 - BOTH of the following:

3.1 Patient has a diagnosis of depressive episodes associated with Bipolar I Disorder (bipolar depression)

AND

3.2 ONE of the following:

3.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Fluoxetine used in combination with olanzapine
- Lurasidone
- Quetiapine

OR

3.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Fluoxetine used in combination with olanzapine
- Lurasidone
- Quetiapine

OR

4 - ONE of the following:

4.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

4.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Cobenfy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient has a diagnosis of schizophrenia or schizoaffective disorder

AND

1.2 ONE of the following:

1.2.1 Failure to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone, as confirmed by claims history or submission of medical records

OR

1.2.2 History of contraindication or intolerance to THREE preferred atypical antipsychotics*, which must include both aripiprazole and lurasidone (please specify contraindication or intolerance)

OR

2 - ONE of the following:

2.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Brand Risperdal tabs/soln, Brand Seroquel, Brand Geodon, Brand Zyprexa, Brand Clozaril, Brand Abilify tabs/soln, generic paliperidone ER, Brand Invega, generic risperidone ODT, aripiprazole ODT, aripiprazole soln, generic olanzapine ODT, Brand Zyprexa Zydis, Fanapt, Brand Seroquel XR, Brand Latuda, Rexulti, Brand Saphris, Secuado, Versacloz, generic clozapine ODT, generic asenapine, Lybalvi, Caplyta, Fanapt Titration Pack, Erzofri	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 Patient must demonstrate failure to a majority (not more than 3) of the preferred* formulary/preferred drug list (PDL) alternatives, one of which must be aripiprazole, for the given diagnosis as confirmed by claims history or submission of medical records (Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)

OR

1.1.2 Patient must demonstrate intolerance to a majority (not more than 3) of the preferred* formulary/PDL alternatives, one of which must be aripiprazole, for the given diagnosis (please specify intolerance) (Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request)

OR

1.1.3 There are no preferred* formulary alternatives for the requested drug

AND

1.2 If the request is for a multi-source brand medication, ONE of the following:

1.2.1 The multi-source brand is being requested because of an adverse reaction, allergy or sensitivity to a generic equivalent (specify the adverse reaction, allergy, or sensitivity)

OR

1.2.2 The multi-source brand is being requested due to an incomplete response with the generic equivalent as documented by submission of medical records

OR

1.2.3 The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient

OR

1.2.4 Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient (document special clinical circumstance)

AND

1.3 ONE of the following:

1.3.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.3.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium

- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

1.4 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

OR

2 - The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

3 - The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Caplyta	
Diagnosis	Requests Exceeding Quantity Limit*
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The requested dose falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

5 - Physician has provided rationale for needing to exceed the quantity limit of one capsule per day, at a maximum dose of 42 mg (milligrams) (NOTE: The treatment effect of Caplyta at doses higher than 42 mg daily versus placebo was NOT statistically significant in clinical trials)	
Notes	*Caplyta requests should be reviewed using the Non-Preferred criteria . This section is for Caplyta quantity limit requests only.

2 . Background

Benefit/Coverage/Program Information
Table 1. UHC C&S Plan Minimum Age Edits: Based on FDA-approved uses, prior authorization is required for antipsychotic medications for members less than the following ages: • Abilify Discmelt, Abilify oral solution – 6 years of age • Abilify Maintena – 18 years of age • Abilify MyCite – 18 years of age • Abilify oral tablets – 6 years of age • Abilify Asimtufii – 18 years of age • Aristada – 18 years of age • Caplyta – 18 years of age • Clozaril – 18 years of age • Cobenfy – 18 years of age • Erzofri - 18 years of age • Fanapt- 18 years of age • Geodon – 18 years of age • Invega – 12 years of age • Invega Sustenna – 18 years of age • Invega Trinza – 18 years of age • Invega Hafyera – 18 years of age • Latuda – 10 years of age • Lybalvi – 18 years of age • Perseris – 18 years of age • Rexulti – 18 years of age • Risperdal – 5 years of age • Risperdal Consta – 18 years of age • Rykindo – 18 years of age • Saphris – 10 years of age • Secuado – 18 years of age • Seroquel, Seroquel XR – 10 years of age • Uzedy – 18 years of age • Vraylar – 18 years of age • Zyprexa – 13 years of age

- Zyprexa Zydis – 6 years of age

Table 2.

UHC C&S Plan Maximum Age Edits: Prior authorization is required for atypical antipsychotic claims for members greater than the following ages:

- Risperidone oral solution: 7 years of age

3 . Revision History

Date	Notes
1/31/2025	Added Erzofri

Apokyn

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127844
Guideline Name	Apokyn
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Apokyn, generic apomorphine hcl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Apokyn will be used as intermittent treatment for OFF episodes

AND

3 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

AND

4 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

5 - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

6 - ONE of the following:

6.1 Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes) confirmed by claims history or submitted medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)

- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

OR

6.2 History of contraindication or intolerance to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (contraindication/intolerance must be from two different classes; please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name:Brand Apokyn, generic apomorphine hcl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
7/11/2023	Updated T/F criteria language.

Aqneursa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165150
Guideline Name	Aqneursa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Aqneursa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes

AND

3 - Medication is being used to treat neurological manifestations of NPC

AND

4 - Medication is not being used in combination with Miplyffa (arimoclomol)

AND

5 - Medication is prescribed by or in consultation with a provider with expertise in the treatment of NPC

Product Name:Aqneursa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Aqneursa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales)

AND

2 - Medication is not being used in combination with Miplyffa (arimoclomol)

AND

3 - Medication is prescribed by or in consultation with a provider with expertise in the treatment of Niemann-Pick disease type C (NPC)

2 . Revision History

Date	Notes
2/13/2025	Updated formularies. Added criteria that Aqneursa is not taken in co mbination with Miplyffa

Arcalyst

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127433
Guideline Name	Arcalyst
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

Product Name:Arcalyst	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

AND

2 - Disease is in remission (e.g., diary score of less than 0.5 [reflecting no fever, skin rash and bone pain], acute phase reactants [less than 0.5 mg/dL CRP (milligrams per deciliter C-Reactive protein)], absence of objective skin rash, no radiological evidence of active bone lesions)

Product Name:Arcalyst	
Diagnosis	Pericarditis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent pericarditis (RP)

Product Name:Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), Pericarditis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Arcalyst therapy

2 . Revision History

Date	Notes
6/30/2023	Removed RMH and ACUAZ formularies.

Arikayce

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123308
Guideline Name	Arikayce
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting respiratory cultures positive for MAC within the previous 6 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Product Name:Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 ALL of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with

available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

AND

3 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

2 . Revision History

Date	Notes
3/16/2023	Updated language about referring to claims history.

Arikayce

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123308
Guideline Name	Arikayce
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting respiratory cultures positive for MAC within the previous 6 months

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting the patient has been receiving a multidrug background regimen containing at least TWO of the following agents for a minimum of 6 consecutive months within the past 12 months:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

AND

4 - Patient will continue to receive a multidrug background regimen

AND

5 - Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

AND

6 - In vitro susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than or equal to 64 micrograms per milliliter (mcg/mL)

AND

7 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

Product Name:Arikayce	
Diagnosis	Refractory Mycobacterium avium complex (MAC) lung disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Documentation that the patient has achieved negative respiratory cultures

OR

1.2 ALL of the following:

1.2.1 Patient has not achieved negative respiratory cultures while on Arikayce

AND

1.2.2 Physician attestation that patient has demonstrated clinical benefit while on Arikayce

AND

1.2.3 In vitro susceptibility testing of most recent (within 6 months) positive culture with

available susceptibility testing documents that the Mycobacterium avium complex (MAC) isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of less than 64 micrograms per milliliter (mcg/mL)

AND

1.2.4 Patient has NOT received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) or prescription claims history documenting that the patient continues to receive a multidrug background regimen containing at least TWO of the following agents:

- Macrolide antibiotic (e.g., azithromycin, clarithromycin)
- Ethambutol
- Rifamycin antibiotic (e.g., rifampin, rifabutin)

AND

3 - Prescribed by or in consultation with one of the following:

- Infectious disease specialist
- Pulmonologist

2 . Revision History

Date	Notes
3/16/2023	Updated language about referring to claims history.

Attruby

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-199189
Guideline Name	Attruby
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Attruby	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - One of the following:

2.1 Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 All of the following:

- Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis
- Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*
- Absence of light chain amyloidosis

AND

3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Physician attests that the patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

AND

5 - One of the following:

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

6 - Prescribed by or in consultation with a cardiologist

AND

7 - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

Notes	*May require prior authorization and notification

Product Name:Attruby	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Attruby (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

AND

2 - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Prescribed by or in consultation with a cardiologist

AND

4 - Patient is not receiving Attruby in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Onpattro (patisiran), Tegsedi (inotersen), Vyndaqel/Vyndamax (tafamadis), or Wainua (eplontersen)]

2 . Revision History

Date	Notes
2/25/2025	Updated formularies in scope. No change to clinical criteria.

Augtyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155853
Guideline Name	Augtyro
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Augtyro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is ROS1-positive

Product Name:Augtyro	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor(s)

AND

3 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic
- Unresectable

Product Name:Augtyro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Augtyro therapy

Product Name:Augtyro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Augtyro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Augtyro therapy	

2 . Revision History

Date	Notes
9/24/2024	Added criteria for Solid Tumors.

Augtyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155853
Guideline Name	Augtyro
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Augtyro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is ROS1-positive

Product Name:Augtyro	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor(s)

AND

3 - Disease is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic
- Unresectable

Product Name:Augtyro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Augtyro therapy

Product Name:Augtyro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Augtyro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Augtyro therapy	

2 . Revision History

Date	Notes
9/24/2024	Added criteria for Solid Tumors.

Austedo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-180196
Guideline Name	Austedo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Austedo*	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

AND

2 - ONE of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Notes	*Austedo XR not applicable to this guideline

Product Name:Austedo*	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Austedo therapy	
Notes	*Austedo XR not applicable to this guideline

Product Name:Austedo*	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chorea associated with Huntington's Disease **AND** **2** - Prescribed by or in consultation with ONE of the following: • Neurologist • Psychiatrist	
Notes	*Austedo XR not applicable to this guideline

Product Name:Austedo*	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Austedo therapy	
Notes	*Austedo XR not applicable to this guideline

2 . Revision History

Date	Notes
2/19/2025	Updated formularies

Ayvakit

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154680
Guideline Name	Ayvakit
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

2.1 Submission of medical records or claims history confirming patient has unresectable, recurrent, or metastatic disease after failure on approved therapies (e.g., imatinib, sunitinib, dasatinib, regorafenib, ripretinib)

OR

2.2 BOTH of the following:

2.2.1 Disease is ONE of the following:

- Unresectable
- Resectable with significant morbidity
- Metastatic
- Recurrent
- Limited progression
- Gross residual disease (R2 resection)
- Residual disease with significant morbidity

AND

2.2.2 Presence of a platelet-derived growth factor receptor alpha (PDGFRA) exon mutation, including 18 D842V mutation

Product Name:Ayvakit	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of a FIP1L1-PDGFRA (platelet-derived growth factor receptor alpha) rearrangement

AND

3 - Presence of a PDGFRA D842V mutation

Product Name:Ayvakit	
Diagnosis	Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Advanced systemic mastocytosis
- Aggressive systemic mastocytosis
- Systemic mastocytosis with an associated hematological neoplasm
- Mast cell leukemia
- Indolent systemic mastocytosis

AND

2 - Platelet count is greater than or equal to 50 x 10^9/liter

Product Name:Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Myeloid/Lymphoid Neoplasms, Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ayvakit therapy

Product Name:Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ayvakit	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ayvakit therapy

2 . Revision History

Date	Notes
9/10/2024	Updated wording of systemic mastocytosis criteria per NCCN without change to clinical intent.

Azole Antifungals

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147440
Guideline Name	Azole Antifungals
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Systemic Fungal Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

OR

2 - BOTH of the following:

2.1 Diagnosis of coccidioidomycosis

AND

2.2 ONE of the following:

2.2.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

OR

2.2.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

Product Name:Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test

- Fungal culture
- Nail biopsy

Product Name:Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Fingernails
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Three months have elapsed since completion of initial therapy for fingernail onychomycosis

AND

2 - Documentation of positive clinical response to therapy

Product Name:Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of toenail onychomycosis confirmed by ONE of the following:

- KOH (potassium hydroxide) test
- Fungal culture
- Nail biopsy

Product Name:Brand Sporanox capsules, generic itraconazole capsules	
Diagnosis	Onychomycosis Toenails
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Nine months have elapsed since completion of initial therapy for toenail onychomycosis

AND

2 - Documentation of positive clinical response to therapy

Product Name:Brand Sporanox oral solution, generic itraconazole oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Oropharyngeal candidiasis
- Esophageal candidiasis

Product Name:Brand Vfend tablets, generic voriconazole tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

2 - ALL of the following:

2.1 Diagnosis of candidemia

AND

2.2 Patient is non-neutropenic

AND

2.3 ONE of the following:

2.3.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

OR

2.3.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

OR

3 - BOTH of the following:

3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

3.2 ONE of the following:

3.2.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

OR

3.2.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

OR

4 - Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

5 - Diagnosis of Fusarium spp. infection including Fusarium solani

OR

6 - Diagnosis of Exserohilum species infection

Product Name:Brand Vfend susp, generic voriconazole susp	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of invasive aspergillosis including Aspergillus fumigatus

OR

1.2 ALL of the following:

1.2.1 Diagnosis of Candidemia

AND

1.2.2 Patient is non-neutropenic

AND

1.2.3 ONE of the following:

1.2.3.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

OR

1.2.3.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

OR

1.3 BOTH of the following:

1.3.1 ONE of the following diagnoses:

- Candida infection in the abdomen
- Candida infection in the kidney
- Candida infection in the bladder wall
- Candida infection in wounds
- Disseminated Candida infections in skin
- Esophageal candidiasis

AND

1.3.2 ONE of the following:

1.3.2.1 Failure to fluconazole (generic Diflucan) as confirmed by claims history or submission of medical records

OR

1.3.2.2 History of contraindication, intolerance, or resistance to fluconazole (generic Diflucan) (please specify intolerance, contraindication, or resistance)

OR

1.4 Diagnosis of Scedosporium apiospermum infection (asexual form of Pseudallescheria boydii)

OR

1.5 Diagnosis of Fusarium spp. infection including Fusarium solani

OR

1.6 Diagnosis of Exserohilum species infection

AND

2 - Physician has provided rationale for the patient needing to use voriconazole oral suspension instead of voriconazole tablets

Product Name:Brand Noxafil tablets, generic posaconazole tablets	
Diagnosis	Prophylaxis of Aspergillus or Candida Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

2 - ONE of the following conditions:

2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

2.1.1 Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)

OR

2.1.2 Hematologic malignancies with prolonged neutropenia from chemotherapy [e.g., acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name:Brand Noxafil tablets, generic posaconazole tablets	
Diagnosis	Treatment of Invasive Aspergillosis
Approval Length	84 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - ONE of the following:

2.1 Failure to voriconazole (generic Vfend) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication, intolerance, or resistance to voriconazole (generic Vfend) (please specify intolerance, contraindication, or resistance)

Product Name:Brand Noxafil suspension, generic posaconazole suspension, Noxafil delayed release suspension packets	
Diagnosis	Prophylaxis of Aspergillus or Candida Infections
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by ONE of the following:

- Aspergillus
- Candida

AND

2 - ONE of the following conditions:

2.1 Patient is at high risk of infections due to severe immunosuppression from ONE of the following conditions:

2.1.1 Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)

OR

2.1.2 Hematologic malignancies with prolonged neutropenia from chemotherapy [e.g., acute myeloid leukemia (AML), myelodysplastic syndromes (MDS)]

OR

2.2 Patient has a prior fungal infection requiring secondary prophylaxis

Product Name:Brand Noxafil suspension, generic posaconazole suspension	
Diagnosis	Oropharyngeal Candidiasis (OPC)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of oropharyngeal candidiasis (OPC)

AND

2 - ONE of the following:

2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Fluconazole (generic Diflucan)
- Itraconazole (generic Sporanox)

OR

2.2 History of contraindication, intolerance, or resistance to BOTH of the following (please specify intolerance, contraindication, or resistance):

- Fluconazole (generic Diflucan)

- Itraconazole (generic Sporanox)

Product Name:Cresemba	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of invasive aspergillosis

AND

1.2 ONE of the following:

1.2.1 Failure to voriconazole (generic Vfend) as confirmed by claims history or submission of medical records

OR

1.2.2 History of contraindication, intolerance, or resistance to voriconazole (generic Vfend) (please specify intolerance, contraindication, or resistance)

OR

2 - Diagnosis of invasive mucormycosis

Product Name:Tolsura	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

2 - ONE of the following:

2.1 Failure to itraconazole capsules (generic Sporanox) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to itraconazole capsules (generic Sporanox) (please specify intolerance or contraindication)

Product Name:Brand Sporanox capsules, generic itraconazole capsules, Brand Sporanox oral solution, generic itraconazole oral solution, Brand Vfend tablets, generic voriconazole tablets, Brand Vfend suspension, generic voriconazole suspension, Brand Noxafil tablets, generic posaconazole tablets, Brand Noxafil oral suspension, generic posaconazole oral suspension, Noxafil delayed release suspension packets, Cresemba, Tolsura	
Diagnosis	Infectious Diseases Society of America (IDSA) Recommended Regimens
Approval Length	Based on provider and IDSA recommended treatment durations, up to 12 months
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is recognized for treatment of the diagnosis by the Infectious Diseases Society of America (IDSA)

2 . Revision History

Date	Notes
5/15/2024	Updated GPIs (removed obsolete posaconazole tab; added new Cre semba 74.5mg)

Balversa

Prior Authorization Guideline

Guideline ID	GL-150786
Guideline Name	Balversa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	

1 . Criteria

Product Name:Balversa	
Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urothelial carcinoma

AND

2 - ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of FGFR3 genetic alterations

AND

4 - Disease has progressed on or after at least one line of prior systemic therapy [e.g., platinum-based chemotherapy (e.g., cisplatin, carboplatin), immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)]

AND

5 - One of the following:

5.1 Patient has received prior systemic therapy containing an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, avelumab)

OR

5.2 Patient is not eligible for immune checkpoint inhibitor therapy (e.g., pembrolizumab, nivolumab, avelumab)

Product Name:Balversa

Diagnosis	Urothelial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Balversa therapy

Product Name:Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Balversa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Balversa therapy

2 . Revision History

Date	Notes
8/1/2024	Annual review. Removed coverage for FGFR2 genetic alterations. Ad ded that first line of prior systemic therapy should contain an immune checkpoint inhibitor, if eligible. Updated background and references.

Baxdela

Prior Authorization Guideline

Guideline ID	GL-121352
Guideline Name	Baxdela
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name:Baxdela	
Diagnosis	Community-Acquired Bacterial Pneumonia
Approval Length	10 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

3.3 One of the following:

3.3.1 Failure to three of the following antibiotics or antibiotic regimens as confirmed by claims history or submission of medical records:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

OR

3.3.2 History of intolerance or contraindication to all of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication)

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name:Baxdela	
Diagnosis	Acute Bacterial Skin and Skin Structure Infections
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - All of the following:

3.1 One of the following diagnoses:

3.1.1 Both of the following

3.1.1.1 Acute bacterial skin and skin structure infections

AND

3.1.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.1.2 Both of the following:

3.1.2.1 Empirical treatment of patients with acute bacterial skin and skin structure infections

AND

3.1.2.2 Presence of MRSA infection is likely

AND

3.2 ONE of the following:

3.2.1 Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records

OR

3.2.2 History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

AND

3.3 One of the following:

3.3.1 Failure to one of the following antibiotics as confirmed by claims history or submitted medical records:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

3.3.2 History of intolerance or contraindication to all of the following (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

4 - All of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infections

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Baxdela

AND

4.3 One of the following:

4.3.1 Failure to three of the following antibiotics as confirmed by claims history or submitted medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

OR

4.3.2 History of intolerance or contraindication to all of the following antibiotics (please specify intolerance or contraindication):

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)

- Clindamycin

Product Name:Baxdela	
Diagnosis	Off-Label Uses
Approval Length	Based on provider and IDSA recommended treatment durations, up to 6 months.
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

2 . Revision History

Date	Notes
2/27/2023	Updated trial/failure language and notes.

Belbuca_Butrans

Prior Authorization Guideline

Guideline ID	GL-161160
Guideline Name	Belbuca_Butrans
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Cancer related pain/Hospice/End of Life Related Pain
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is being treated for one of the following:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

- Hospice related pain
- End of life related pain

AND

2 - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

Notes	If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic buprenorphine patches, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12-month authorization should be entered for generic buprenorphine patches.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Non-cancer related pain/Non-hospice/Non-end of life care pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to BOTH of the following:

1.1 Patient has been screened for substance abuse/opioid dependence

AND

1.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - BOTH of the following:

3.1 Patient has been screened for underlying depression and/or anxiety

AND

3.2 If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 The patient has a history of failure to a trial of tramadol IR (immediate release) as confirmed by claims history or submission of medical records

OR

4.2 The patient has a contraindication or intolerance to tramadol IR (please specify contraindication or intolerance)

OR

4.3 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

OR

4.4 Patient is new to plan and currently established on Belbuca or Butrans for at least the past 30 days

AND

5 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), BOTH of the following:

5.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

AND

5.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

AND

6 - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

Notes	If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic buprenorphine patches, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for generic buprenorphine patches.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Non-cancer related pain/Non-hospice/Non-end of life care pain

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

AND

2 - Documented rationale for not tapering and discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attests to BOTH of the following:

3.1 Patient has been screened for substance abuse/opioid dependence

AND

3.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

4 - If the request is for Belbuca or Brand Butrans, the prescriber provides a reason or special circumstance the patient cannot use generic buprenorphine patches

Notes	If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the patient is currently taking the requested long-acting opioid for at

	least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried generic bu prenorphine patches, a denial should be issued and a maximum 60-d ay authorization may be authorized one time for the requested drug/st rength combination up to the requested quantity for transition to an alt ernative treatment. Additionally, a 6 month authorization should be ent ered for generic buprenorphine patches.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the FDA (Food and Drug Administration) maximum dose per day, where an FDA maximum dose per day exists	
Notes	Approval durations: 12 months for cancer related pain/hospice/end of life related pain. 6 months for non-cancer related pain/non-hospice/non-end of life relat ed pain.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Cancer related pain/Hospice/End of Life Related Pain
Approval Length	12 month(s)
Guideline Type	Morphine Milligram Equivalents (MME)
Approval Criteria **1** - Patient has one of the following: • Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)	

• Hospice pain • End of life diagnosis	
Notes	The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Non-cancer related pain/Non-hospice/Non-End of Life Related Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalents (MME)

Approval Criteria

1 - Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - BOTH of the following:

3.1 Patient has been screened for underlying depression and/or anxiety

AND

3.2 If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 Opioid medication doses of less than 90 MME (Morphine Milligram Equivalents) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

OR

4.2 Patient is new to plan and currently established on the requested MME for at least the past 30 days

Notes	Authorization will be issued for 6 months for non-cancer related pain/non-hospice/non-end of life related pain up to the current requested MME plus 90 MME. If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.

Product Name:Belbuca, generic buprenorphine patches, Brand Butrans	
Diagnosis	Non-cancer related pain/Non-hospice/Non-End of Life Related Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalents (MME)

Approval Criteria

1 - Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

2 - Documented rationale for not tapering and discontinuing opioid if treatment goals are not being met

AND **3** - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)	
Notes	Authorization will be issued for 6 months for non-cancer related pain/non-hospice/non-end of life related pain up to the current requested MME plus 90 MME If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.

2 . Revision History

Date	Notes
11/21/2024	Updated language to clarify "cancer" is Cancer-related pain

Benefit Determination Mifeprex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123261
Guideline Name	Benefit Determination Mifeprex
Formulary	• Medicaid - Community & State Florida MMA • Medicaid - Community & State Indiana • Medicaid - Community & State Kansas • Medicaid - Community & State Louisiana • Medicaid - Community & State Michigan • Medicaid - Community & State Mississippi • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Texas • Medicaid - Community & State Virginia • Medicaid - Community & State Arizona • Medicaid - Community & State Nebraska

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name:Brand Mifeprex, generic mifepristone	
Approval Length	1 month(s)
Guideline Type	Benefit Determination

Approval Criteria

1 - Provider attests patient requires treatment for purposes identified in the Hyde amendment and any applicable state laws and regulations

AND

2 - Submission of all necessary state form(s) and/or certification document(s)

2 . Revision History

Date	Notes
3/15/2023	Added KS and changed GL type to " benefit determination

Benlysta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159289
Guideline Name	Benlysta
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic lupus erythematosus

AND

2 - Patient is currently receiving standard immunosuppressive therapy [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is NOT receiving Benlysta in combination with any of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Product Name:Benlysta SQ	
Diagnosis	Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is currently receiving standard immunosuppressive therapy for systemic lupus erythematosus [e.g., hydroxychloroquine, chloroquine, prednisone, azathioprine, methotrexate]

AND

3 - Patient does NOT have severe active central nervous system lupus

AND

4 - Patient is NOT receiving Benlysta in combination with any of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

Product Name:Benlysta SQ	
Diagnosis	Systemic Lupus Erythematosus, Active Lupus Nephritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Benlysta therapy

AND

2 - Patient is NOT receiving Benlysta in combination with any of the following:

- Targeted Immunomodulator [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Kineret (anakinra)]
- Lupkynis (voclosporin)
- Saphnelo (anifrolumab-fnia)

2 . Revision History

Date	Notes
11/5/2024	Updated coverage criteria for SLE removing documentation of the pr esence of antibodies. Updated not used in combination from biologic DMARD to targeted immunomodulator without change in clinical inte nt.

Benznidazole

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124041
Guideline Name	Benznidazole
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Benznidazole	
Approval Length	60 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Chagas disease (American trypanosomiasis) due to Trypanosoma cruzi

2 . Revision History

Date	Notes
3/31/2023	Updated formularies

Berinert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147422
Guideline Name	Berinert
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Berinert	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

AND

4 - ONE of the following:

4.1 Failure of Ruconest as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to Ruconest (please specific intolerance or contraindication)

OR

4.3 Patient is currently on Berinert therapy as confirmed by claims history or submission of medical records

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name:Berinert	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Berinert therapy

AND

2 - Prescribed for the acute treatment of HAE (hereditary angioedema) attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Firazyr, Ruconest)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
5/23/2024	Update to types of genetic variant(s) and diagnostic criteria with nor mal C1 inhibitor levels in initial auth section and minor update in reau th section.

Besremi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159211
Guideline Name	Besremi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Besremi	
Diagnosis	Polycythemia Vera
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of polycythemia vera

Product Name:Besremi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Besremi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Besremi therapy	

2 . Revision History

Date	Notes
11/4/2024	New program

Biltricide

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-119737
Guideline Name	Biltricide
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:Brand Biltricide, generic praziquantel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following: **1.1** Infections due to schistosoma **OR** **1.2** Infections due to the liver trematodes (flukes), Clonorchis sinensis/Opisthorchis viverrini (i.e., clonorchiasis or opisthorchiasis)

2 . Revision History

Date	Notes
1/5/2023	No clinical changes. Updated formularies.

Bimzelx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-173201
Guideline Name	Bimzelx
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Bimzelx	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 ONE of the following:

1.2.1 ALL of the following:

1.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

1.2.1.2 ONE of the following:

1.2.1.2.1 Failure of ONE of the following topical therapy classes confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

AND

1.2.1.3 ONE of the following:

- Failure of a 3 month trial of methotrexate, at the maximally indicated doses, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Orencia (abatacept), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast), ustekinumab]

AND

1.3 Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab]

AND

1.4 ONE of the following:

1.4.1 Failure to two of the following preferred products confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

1.4.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

1.5 ONE of the following:

- Failure to Cosentyx (secukinumab) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

AND

1.6 Prescribed by or in consultation with a dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderate to severe plaque psoriasis

AND

2.3 Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept),

adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab] **AND** **2.4** Prescribed by or in consultation with a dermatologist

Notes	*See PDL links in Background

Product Name:Bimzelx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Cosentyx (secukinumab), adalimumab, Simponi (golimumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept), ustekinumab]

AND

3 - One of the following:

3.1 BOTH of the following:

3.1.1 ONE of the following:

3.1.1.1 Failure to two of the following as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

3.1.1.2 History of intolerance or contraindication to all of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

3.1.2 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

OR

3.2 Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept),

adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast), ustekinumab]

AND

5 - Prescribed by or in consultation with a rheumatologist or dermatologist

Notes	*See PDL links in Background

Product Name:Bimzelx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - One of the following:

- Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)]

AND

3 - One of the following:

3.1 One of the following:

3.1.1 Failure of ALL of the following as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Cosentyx (secukinumab)

OR

3.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Cosentyx (secukinumab)

OR

3.2 Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx (secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*See PDL links in Background

Product Name:Bimzelx	
Diagnosis	Non-radiographic Axial Spondyloarthritis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - One of the following:

- Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g. Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)]

AND

3 - One of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)
- Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx (secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*See PDL links in Background

Product Name:Bimzelx	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - ONE of the following:

- Failure to at least one oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to at least one oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify contraindication or intolerance)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., adalimumab, Cosentyx (secukinumab)]

AND

3 - ONE of the following:

3.1 ONE of the following:

3.1.1 Failure to both of the following preferred products confirmed by claims history or submission of medical records

- One of the preferred adalimumab products*
- Cosentyx (secukinumab)

OR

3.1.2 History of contraindication or intolerance to both of the following preferred products (please specify contraindication or intolerance)

- One of the preferred adalimumab products*
- Cosentyx (secukinumab)

OR

3.2 Patient is currently on Bimzelx therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*See PDL links in Background

Product Name:Bimzelx	
Diagnosis	Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis, Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Bimzelx therapy **AND** **2** - Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*	
Notes	*Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL links: CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
2/17/2025	Updated Cosentyx step in PsO section. Removed requirement that o ne of the steps in PsO must be adalimumab. Changed references of brand Stelara to generic ustekinumab. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Ad ded criteria for hidradenitis suppurativa.

Bonjesta and Diclegis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120212
Guideline Name	Bonjesta and Diclegis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:generic doxylamine/pyridoxine, Brand Diclegis, Bonjesta	
Approval Length	9 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of nausea and vomiting associated with pregnancy

AND

2 - Documented failure or contraindication to lifestyle modifications (e.g., diet, avoidance of triggers)

AND

3 - ONE of the following:

3.1 Failure to a five day trial of over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly), as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to over-the-counter doxylamine taken together with pyridoxine (i.e., not a combined dosage form, but separate formulations taken concomitantly) (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
1/17/2023	Updated T/F criteria, cleaned up GPI and product name list and indic ation.

Bosulif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145975
Guideline Name	Bosulif
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Bosulif	
Diagnosis	Chronic Myelogenuous/Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of chronic myeloid leukemia

AND

2 - One of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Bosulif therapy

Product Name:Bosulif	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

Product Name:Bosulif	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have a diagnosis of myeloid/lymphoid neoplasms with eosinophilia

AND

2 - Presence of ABL1 (gene) rearrangement

Product Name:Bosulif	
Diagnosis	Chronic Myelogenuous/Myeloid Leukemia, Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Bosulif therapy

Product Name:Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Bosulif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Bosulif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Bosulif therapy	

2 . Revision History

Date	Notes
4/22/2024	Added Bosulif capsules

Braftovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156203
Guideline Name	Braftovi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Presence of BRAF V600E mutation

AND

3 - Disease is one of the following:

- Unresectable
- Metastatic

AND

4 - Used in combination with Mektovi (binimetinib)

AND

5 - ONE of the following:

5.1 Patient has a contraindication or history of intolerance to ONE of the following regimens (please specify contraindication or intolerance)

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

5.2 Provider attests that the patient is not an appropriate candidate for either of the following regimens

- Tafinlar (dabrafenib) plus Mekinist (trametinib)

- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

5.3 For continuation of prior Braftovi therapy

Product Name:Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with Mektovi (binimetinib)

Product Name:Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon cancer

AND

2 - Presence of BRAF V600E mutation

AND

3 - Disease is one of the following:

- Advanced
- Metastatic

AND

4 - Patient has received prior therapy

AND

5 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name:Braftovi	
Diagnosis	Colon Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name:Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rectal cancer

AND

2 - Presence of BRAF V600E mutation

AND

3 - Disease is one of the following:

- Advanced
- Metastatic

AND

4 - Patient has received prior therapy

AND

5 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name:Braftovi	
Diagnosis	Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with ONE of the following:

- Erbitux (cetuximab)
- Vectibix (panitumumab)

Product Name:Braftovi	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Presence of BRAF V600E mutation

AND

3 - Disease is one of the following:

- Advanced
- Recurrent
- Metastatic

AND

4 - Used in combination with Mektovi (binimetinib)

AND

5 - ONE of the following:

5.1 Patient has a contraindication or history of intolerance to the following regimen (please specify contraindication or intolerance):

- Tafinlar (dabrafenib) plus Mekinist (trametinib)

OR

5.2 Provider attests that the patient is not an appropriate candidate for the following regimen:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)

OR

5.3 For continuation of prior Braftovi therapy

Product Name:Braftovi	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Braftovi therapy

AND

2 - Used in combination with Mektovi (binimetinib)

Product Name:Braftovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Braftovi

Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Braftovi therapy

2 . Revision History

Date	Notes
9/25/2024	Add step thru section for melanoma and NSCLC

Brexafemme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123228
Guideline Name	Brexafemme
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Brexafemme	
Diagnosis	Vulvovaginal candidiasis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvovaginal candidiasis (VVC)

AND

2 - ONE of the following:

2.1 Confirmed azole resistance demonstrated by culture and susceptibility testing

OR

2.2 BOTH of the following:

2.2.1 Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

AND

2.2.2 Failure of a 7-day course of oral fluconazole therapy defined as 100 mg (milligrams), 150 mg, or 200 mg taken orally every third day for a total of 3 doses (days 1,4, and 7), confirmed by claims history or submission of medical records, for the current episode of VVC

AND

3 - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

Product Name:Brexafemme	
Diagnosis	Recurrent vulvovaginal candidiasis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)

AND

2 - ONE of the following:

2.1 Confirmed azole resistance demonstrated by culture and susceptibility testing

OR

2.2 BOTH of the following:

2.2.1 Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

AND

2.2.2 Failure of a maintenance course of oral fluconazole confirmed by claims history or submission of medical records defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months

AND

3 - Prescribed by or in consultation with ONE of the following:

- Infectious disease physician
- Obstetrician/Gynecologist

2 . Revision History

Date	Notes

3/14/2023	Added criteria for Recurrent vulvovaginal candidiasis.

Bronchitol

Prior Authorization Guideline

Guideline ID	GL-124637
Guideline Name	Bronchitol
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Used in conjunction with standard CF therapies [e.g., chest physiotherapy, bronchodilators, antibiotics, anti-inflammatory therapy (e.g., ibuprofen, oral/inhaled corticosteroids)]

AND

3 - Patient has passed the Bronchitol Tolerance Test

Product Name:Bronchitol	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bronchitol therapy

2 . Revision History

Date	Notes
4/13/2023	Updated formularies, added GPI.

Brukinsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154620
Guideline Name	Brukinsa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Brukinsa	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Diagnosis of follicular lymphoma (FL)
- Disease is relapsed or refractory
- Patient has received at least two or more lines of systemic therapy
- Brukinsa will be used in combination with obinutuzumab

OR

2 - ALL of the following:

2.1 Diagnosis of ONE of the following:

- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Nodal marginal zone lymphoma

AND

2.2 Disease is relapsed, refractory, or progressive

AND

2.3 Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

OR

3 - ALL of the following:

3.1 Diagnosis of splenic marginal zone lymphoma

AND

3.2 Disease is relapsed or refractory

AND

3.3 Patient has received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab)

OR

4 - Diagnosis of mantle cell lymphoma (MCL)

Product Name:Brukinsa	
Diagnosis	Waldenström's Macroglobulinemia (WM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström's macroglobulinemia (WM)

Product Name:Brukinsa	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)

Product Name:Brukinsa	
Diagnosis	B-Cell Lymphomas, Waldenström's Macroglobulinemia (WM), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Product Name:Brukinsa	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Disease is relapsed, refractory, or progressive

Product Name:Brukinsa	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Brukinsa therapy

Product Name:Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brukinsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Brukinsa therapy

2 . Revision History

Date	Notes

9/9/2024	Annual review. Clinical coverage criteria added for follicular lymphoma and hairy cell leukemia. Updated B-cell lymphoma formatting. Updated background and reference.

Buphenyl

Prior Authorization Guideline

Guideline ID	GL-134097
Guideline Name	Buphenyl
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Brand Buphenyl oral powder, generic sodium phenylbutyrate oral powder	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs)

Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs) **AND** **2** - Prescriber provides a reason or special circumstance the patient cannot use sodium phenylbutyrate (generic Buphenyl) powder for oral solution	

Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets	

2 . Revision History

Date	Notes
10/2/2023	Removed RMHP Formulary

Buphenyl

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134097
Guideline Name	Buphenyl
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Brand Buphenyl oral powder, generic sodium phenylbutyrate oral powder	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs)

Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of urea cycle disorders (UCDs) **AND** **2** - Prescriber provides a reason or special circumstance the patient cannot use sodium phenylbutyrate (generic Buphenyl) powder for oral solution	

Product Name:Brand Buphenyl tablets, generic sodium phenylbutyrate tablets	
Diagnosis	Urea Cycle Disorders (UCDs)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Buphenyl (sodium phenylbutyrate) tablets	

2 . Revision History

Date	Notes
10/2/2023	Removed RMHP Formulary

Buprenorphine for Opioid Dependence

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161688
Guideline Name	Buprenorphine for Opioid Dependence
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Zubsolv, Brand Suboxone sublingual film	
Approval Length	12 month(s)*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a DSM-V-TR (diagnostic and statistical manual, fifth edition, text revision) diagnosis of opioid use disorder

AND

2 - The patient must have a reason or special circumstance that they cannot use BOTH of the following (please specify reason or special circumstance):

- Buprenorphine/naloxone sublingual film (generic Suboxone sublingual film)
- Buprenorphine/naloxone sublingual tablet

Notes	*Up to 24 mg per day of buprenorphine, or equivalent dosing of an alt ernative medication, will be authorized

Product Name:Zubsolv, Brand Suboxone sublingual film	
Approval Length	12 month(s)*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has been prescribed a buprenorphine product for the purpose of opioid use disorder maintenance therapy

AND

2 - The patient must have a reason or special circumstance that they cannot use BOTH of the following (please specify reason or special circumstance):

- Buprenorphine/naloxone sublingual film (generic Suboxone sublingual film)
- Buprenorphine/naloxone sublingual tablet

Notes	*Up to 24 mg per day of buprenorphine, or equivalent dosing of an alt ernative medication, will be authorized

Product Name:Zubsolv, Brand Suboxone sublingual film, generic buprenorphine/naloxone sublingual film, generic buprenorphine/naloxone sublingual tablet, or generic buprenorphine sublingual tablet

Diagnosis	Exceeding 24mg of buprenorphine or equivalent
Approval Length	Authorization length will be issued for requested duration of therapy, not to exceed 12 months
Guideline Type	Drug Utilization Review

Approval Criteria

1 - Physician has provided rationale for needing to exceed the 24mg buprenorphine daily limit

Product Name:Zubsolv, Brand Suboxone sublingual film, generic buprenorphine/naloxone sublingual film, generic buprenorphine/naloxone sublingual tablet, or generic buprenorphine sublingual tablet	
Approval Length	Authorization length will be issued for requested duration of therapy, not to exceed 12 months
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

OR

1.2 Physician has provided rationale for requiring the specific quantity requested

2 . Revision History

Date	Notes
12/5/2024	All strengths of sublingual films are now preferred, updated product li st and step thru criteria

Bylvay

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156270
Guideline Name	Bylvay
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed molecular diagnosis of progressive familial intrahepatic cholestasis (PFIC)

AND

2 - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)

AND

3 - Patient is experiencing moderate to severe pruritus associated with PFIC

AND

4 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

AND

5 - Patient has had an inadequate response to at least TWO other conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, sertraline)

AND

6 - Prescribed by a gastroenterologist or hepatologist

Product Name:Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis, and less sleep disturbance)

AND

2 - Prescribed by a gastroenterologist or hepatologist

Product Name:Bylvay	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis Alagille syndrome (ALGS)

AND

2 - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation

AND

3 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory

AND

4 - Patient is experiencing moderate to severe pruritis associated with ALGS

AND

5 - Patient has had an inadequate response to at least TWO other conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, sertraline).

AND

6 - Prescribed by a gastroenterologist or hepatologist

Product Name:Bylvay	
Diagnosis	Alagille Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Bylvay therapy (e.g., reduced serum bile acids, improved pruritis)

AND

2 - Prescribed by a gastroenterologist or hepatologist

2 . Revision History

Date	Notes

9/25/2024	Updated examples of conventional treatment and initial authorization durations

C&S Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Clinical Review

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-205199
Guideline Name	C&S Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Clinical Review
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State Rhode Island • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Indiana • Medicaid - Community & State Michigan • Medicaid - Community & State Florida MMA • Medicaid - Community & State Nebraska

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Diagnosis	Exception to Policy Limitations for Medicaid Patients Less Than 21 Years of Age^
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 The use of the requested medication is for an indicated diagnosis that is supported by the Food and Drug Administration (FDA)

AND

1.1.2 The use of the requested medication is NOT for experimental or investigational purposes

OR

1.2 The use of the requested medication is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology

AND

2 - The requested medication is medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition (health problem)

AND

3 - Prescriber attests the requested medication is an accepted method for treatment (medical practice)

AND

4 - Prescriber attests the requested medication is the least costly treatment of equally effective choices

AND

5 - Prescriber attests the requested medication is safe and effective

AND

6 - The requested medication is prescribed within the dosing guidelines from ONE of the following:

6.1 The manufacturer

OR

6.2 ONE of the following compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary

AND

7 - If for a non-preferred medication*, submission of documentation of failure to, contraindication to, or intolerance to 3 preferred alternatives, confirmed by claims history or submission of medical records. Submission of documentation showing preferred alternatives used to treat the condition were ineffective or inappropriate (must include regimen, duration, treatment goals, and response to treatment)

AND

8 - If the request is for a multi-source brand medication, submission of the adverse reaction, allergy, or sensitivity to a generic or an authorized generic

AND

9 - If the request is for a brand medication with an authorized generic, ONE of the following:

9.1 Submission of documentation of the adverse reaction, allergy, or sensitivity to a generic or an authorized generic

OR

9.2 Submission of documentation of an incomplete response with a generic/authorized generic equivalent

OR

9.3 Submission of documentation due to transition to a generic/authorized generic equivalent could result in destabilization of the beneficiary

OR

9.4 Submission of documentation due to special clinical circumstances precluding the use of a generic/authorized generic equivalent of the brand medication

AND

10 - If the request is for a generic when brand medication is preferred formulation, ONE of the following:

10.1 Submission of documentation of the adverse reaction, allergy, or sensitivity to brand medication

OR

10.2 Submission of documentation of an incomplete response with brand medication

OR **10.3** Submission of documentation due to transition to a brand medication could result in destabilization of the beneficiary **OR** **10.4** Submission of documentation due to special clinical circumstances precluding the use of a brand medication	
Notes	*PDL links are listed in Background. ^ This criteria does not apply to CSFLD and ACUFLEC. Note: ACUFLEC does not have Rx benefits. ^ This criteria does NOT apply to ACUNE/ ACUNEEL1

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html Pennsylvania CHIP : https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP IN: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html MI: https://www.uhcprovider.com/en/health-plans-by-state/michigan-health-plans/mi-comm-plan-home/mi-cp-pharmacy.html FL: https://www.uhcprovider.com/en/health-plans-by-state/florida-health-plans/fl-comm-plan-home/fl-cp-pharmacy.html NE: https://www.uhcprovider.com/en/health-plans-by-state/nebraska-health-plans/ne-comm-plan-home/ne-cp-pharmacy.html

3 . Revision History

Date	Notes
2/28/2025	Combined all formularies with same criteria. Updated exclusion notes .

Cablivi

Prior Authorization Guideline

Guideline ID	GL-86323
Guideline Name	Cablivi
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2021
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name:Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)	

AND

2 - Cablivi was initiated as a bolus intravenous injection administered by a healthcare provider in combination with plasma exchange therapy

AND

3 - Cablivi will be used in combination with immunosuppressive therapy (e.g., corticosteroids)

AND

4 - Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange

Product Name:Cablivi	
Diagnosis	Acquired thrombotic thrombocytopenic purpura (aTTP)
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for a new (different) episode requiring the re-initiation of plasma exchange for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) (Documentation of date of prior episode and documentation date of new episode required)

2 . Revision History

Date	Notes
5/3/2021	Copy of NY

Cabometyx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163721
Guideline Name	Cabometyx
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Cabometyx	
Diagnosis	Kidney cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Stage IV or relapsed renal cell carcinoma (RCC)
- Hereditary leiomyomatosis and RCC (HLRCC)

Product Name:Cabometyx	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

AND

3 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

Product Name:Cabometyx	
Diagnosis	Hepatocellular Carcinoma

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Used as subsequent-line systemic therapy

AND

3 - ONE of the following:

- Patient has liver-confined, unresectable disease and is not a transplant candidate
- Patient has extrahepatic/metastatic disease and deemed ineligible for resection, transplant, or locoregional therapy

Product Name:Cabometyx	
Diagnosis	Bone cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Osteosarcoma
- Ewing Sarcoma (including mesenchymal chondrosarcoma)

AND

2 - Disease is ONE of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second line therapy

Product Name:Cabometyx	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Patient has ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/metastatic disease

AND

3 - Disease has progressed on ALL of the following:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)

Product Name:Cabometyx	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used as second-line or subsequent treatment

Product Name:Cabometyx	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease has progressed following prior VEGFR-targeted therapy

AND

4 - Disease is radioactive iodine-refractory or ineligible

Product Name:Cabometyx	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following soft tissue sarcoma subtypes:

- Alveolar soft part sarcoma (ASPS)
- Atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLPS)
- Clear cell sarcoma
- Extraskeletal myxoid chondrosarcoma

AND

2 - Used as subsequent line of therapy for advanced/metastatic disease

Product Name:Cabometyx	
Diagnosis	Renal Cell Carcinoma (RCC), Non-Small Cell Lung Cancer (NSCLC), Hepatocellular Carcinoma, Osteosarcoma, Ewing Sarcoma, Gastrointestinal Stromal Tumors (GIST), Kidney Cancer, Endometrial Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cabometyx therapy

Product Name:Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Cabometyx	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cabometyx therapy

2 . Revision History

Date	Notes
1/14/2025	Consolidated sections and updated coverage criteria for kidney cancer and renal cell carcinoma into kidney cancer. Consolidated sections and updated coverage criteria for ewing sarcoma and osteosarcoma into bone cancer. Added criteria for soft tissue sarcoma per NCCN guideline. Updated coverage criteria for hepatocellular carcinoma and endometrial carcinoma.

Calquence

Prior Authorization Guideline

Guideline ID	GL-127058
Guideline Name	Calquence
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Calquence	
Diagnosis	Mantle cell lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Patient has received at least one prior therapy for MCL [e.g., Rituxan (rituximab)]

Product Name:Calquence	
Diagnosis	Chronic lymphocytic leukemia/small lymphocytic lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma

Product Name:Calquence	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Nodal Marginal Zone Lymphoma
- Extranodal Marginal Zone Lymphoma (EMZL) of the stomach
- Splenic Marginal Zone Lymphoma

- Extranodal Marginal Zone Lymphoma of Nongastric Sites (Non-cutaneous)

AND

2 - Disease is recurrent, relapsed, refractory, or progressive

Product Name:Calquence	
Diagnosis	Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma

AND

2 - ONE of the following:

- Patient did not respond to primary therapy
- Disease is relapsed or progressive

Product Name:Calquence	
Diagnosis	Mantle cell lymphoma (MCL), Chronic lymphocytic leukemia/small lymphocytic lymphoma, B-Cell Lymphomas, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient does not show evidence of progressive disease while on Calquence therapy

Product Name:Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Calquence	
Diagnosis	National Comprehensive Cancer Network (NCCN) Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Calquence therapy	

2 . Revision History

Date	Notes
6/27/2023	Updated criteria for B-Cell Lymphomas. Added GPI for Calquence tabs.

Camzyos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134084
Guideline Name	Camzyos
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Heart failure is classified as ONE of the following:

- New York Heart Association (NYHA) class II heart failure
- NYHA class III heart failure

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has a Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - One of the following:

5.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)
- Disopyramide

OR

5.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)

- Disopyramide

AND

6 - Camzyos is prescribed by, or in consultation with, a cardiologist

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as supported by ONE of the following:

- Reduction in NYHA (New York Heart Association) class
- No worsening in NYHA class

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50%

AND

3 - Camzyos is prescribed by, or in consultation with, a cardiologist

2 . Revision History

Date	Notes
10/2/2023	Simplified diagnosis criteria.

Camzyos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134084
Guideline Name	Camzyos
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Heart failure is classified as ONE of the following:

- New York Heart Association (NYHA) class II heart failure
- NYHA class III heart failure

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has a Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - One of the following:

5.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)
- Disopyramide

OR

5.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
- Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil)

- Disopyramide

AND

6 - Camzyos is prescribed by, or in consultation with, a cardiologist

Product Name:Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as supported by ONE of the following:

- Reduction in NYHA (New York Heart Association) class
- No worsening in NYHA class

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50%

AND

3 - Camzyos is prescribed by, or in consultation with, a cardiologist

2 . Revision History

Date	Notes
10/2/2023	Simplified diagnosis criteria.

Caprelsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159286
Guideline Name	Caprelsa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Caprelsa	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.2 ONE of the following:

- Unresectable locoregional disease that is symptomatic or progressing
- Asymptomatic recurrent or persistent distant metastatic disease if unresectable and progressing
- Recurrent or persistent distant metastases if symptomatic disease or progression

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2.2 ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease

- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

Product Name:Caprelsa	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name:Caprelsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Caprelsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	

2 . Revision History

Date	Notes
11/5/2024	Updated criteria for medullary thyroid carcinoma

Caprelsa

Prior Authorization Guideline

Guideline ID	GL-159286
Guideline Name	Caprelsa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Caprelsa	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.2 ONE of the following:

- Unresectable locoregional disease that is symptomatic or progressing
- Asymptomatic recurrent or persistent distant metastatic disease if unresectable and progressing
- Recurrent or persistent distant metastases if symptomatic disease or progression

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2.2 ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease

- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

Product Name:Caprelsa	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Caprelsa therapy

Product Name:Caprelsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Caprelsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Caprelsa therapy	

2 . Revision History

Date	Notes
11/5/2024	Updated criteria for medullary thyroid carcinoma

Carbaglu

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128532
Guideline Name	Carbaglu
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Brand Carbaglu, generic carglumic acid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hyperammonemia due to ONE of the following:

- N-acetylglutamate synthase (NAGS) deficiency
- Propionic acidemia (PA)
- Methylmalonic acidemia (MMA)

Product Name:Brand Carbaglu, generic carglumic acid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
7/24/2023	Updated formularies, cleaned up reauth criteria.

Cayston

Prior Authorization Guideline

Guideline ID	GL-123583
Guideline Name	Cayston
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New York

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Cayston	
Diagnosis	Cystic Fibrosis (CF)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - ONE of the following:

2.1 Failure to tobramycin solution for inhalation (generic Bethkis) confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to tobramycin solution for inhalation (generic Bethkis) (please specify intolerance or contraindication)

2 . Revision History

Date	Notes
3/21/2023	Updated trial and failure language. Combined all LOB's.

Cerdelga and Zavesca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135076
Guideline Name	Cerdelga and Zavesca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gaucher disease type 1

AND

2 - Patient is ONE of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name:Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Zavesca, generic miglustat, Yargesa	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate type 1 Gaucher disease

AND

2 - Patient is unable to receive enzyme replacement therapy due to ONE of the following conditions:

2.1 Allergy or hypersensitivity to enzyme replacement therapy

OR

2.2 Poor venous access

OR

2.3 Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)

Product Name:Brand Zavesca, generic miglustat, Yargesa	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

10/17/2023	Brought all applicable Core formularies into this guideline. Added Yar gesa product.

Cerdelga and Zavesca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135076
Guideline Name	Cerdelga and Zavesca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gaucher disease type 1

AND

2 - Patient is ONE of the following as detected by a Food and Drug Administration (FDA)-cleared test:

- CYP2D6 extensive metabolizer
- CYP2D6 intermediate metabolizer
- CYP2D6 poor metabolizer

Product Name:Cerdelga	
Diagnosis	Gaucher Disease Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Zavesca, generic miglustat, Yargesa	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate type 1 Gaucher disease

AND

2 - Patient is unable to receive enzyme replacement therapy due to ONE of the following conditions:

2.1 Allergy or hypersensitivity to enzyme replacement therapy

OR

2.2 Poor venous access

OR

2.3 Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)

Product Name:Brand Zavesca, generic miglustat, Yargesa	
Diagnosis	Mild to Moderate Type 1 Gaucher Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

10/17/2023	Brought all applicable Core formularies into this guideline. Added Yar gesa product.

CGRP

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-180190
Guideline Name	CGRP
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Ajovy, Emgality 120mg	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month
- Provider attests this is the patient's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - ONE of the following:

3.1 Failure (after a trial of at least two months), to TWO of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan (generic Atacand)*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 History of intolerance or contraindication to TWO of the following prophylactic therapies or classes (please specify intolerance or contraindication):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*

- Candesartan (generic Atacand)*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti (eptinezumab-jjmr)]

Notes	*Timolol and candesartan are non-preferred and should not be include d in denial to provider. **OnabotulinumtoxinA (generic Botox) is a medical benefit and should not be included in denial to provider.

Product Name:Aimovig	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 4 to 7 migraine days per month and at least ONE of the following:

- Less than 15 headache days per month

- Provider attests this is the patient's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - ONE of the following:

3.1 Failure (after a trial of at least two months), to TWO of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan (generic Atacand)*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 History of intolerance or contraindication to TWO of the following prophylactic therapies or classes (please specify intolerance or contraindication):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan (generic Atacand)*
- Divalproex sodium [generic Depakote/Depakote ER (extended-release)]
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - ONE of the following:

4.1 Failure (after a trial of at least three months), to BOTH of the following as documented by claims history or submission of medical records:

- Ajovy
- Emgality [120 mg (milligram) strength]

OR

4.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Ajovy
- Emgality (120 mg strength)

AND

5 - Medication will not be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Ajovy, Emgality, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

Notes	*Timolol and candesartan are non-preferred and should not be include d in denial to provider. **OnabotulinumtoxinA (generic Botox) is a medical benefit and should not be included in denial to provider.

Product Name:Aimovig, Ajovy, Emgality 120mg	
Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

Product Name:Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

AND

3 - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Ajovy, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

Product Name:Emgality 100mg	
Diagnosis	Episodic Cluster Headache
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will NOT be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines [e.g., Aimovig, Ajovy, Nurtec ODT (orally disintegrating tablet), Qulipta, Vyepti]

2 . Revision History

Date	Notes
2/19/2025	Updated formularies. Updated prophylactic therapy drug list and requ irement contraindication/intolerance count from all to two. Updated B otox note

Chantix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138245
Guideline Name	Chantix
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Brand Chantix, varenicline, apo-varenicline	
Approval Length	6 Month(s)*
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has not exceeded 180 days of therapy in the last 12 months	

AND

2 - Treatment is being requested for tobacco cessation

AND

3 - ONE of the following:

3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Nicotine replacement patches OTC (over the counter) (e.g., Nicoderm CQ-OTC)
- Nicotine gum OTC (e.g., Nicorette gum-OTC)
- Nicotine lozenge OTC (e.g., Nicorette lozenge-OTC)

OR

3.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance)

- Nicotine replacement patches OTC (over the counter) (e.g., Nicoderm CQ-OTC)
- Nicotine gum OTC (e.g., Nicorette gum-OTC)
- Nicotine lozenge OTC (e.g., Nicorette lozenge-OTC)

AND

4 - ONE of the following:

4.1 Failure to bupropion as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to bupropion (please specify contraindication or intolerance)

Notes	*Authorization will be issued for 6 months, not to exceed 180 days of t herapy per 12 months.

2 . Revision History

Date	Notes
12/28/2023	Updated benefit coverage section to remove RMHCAID, RMHCHP, RMHWRP plans and updated GPI list.

Cholbam

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127064
Guideline Name	Cholbam
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Cholbam	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of a bile acid synthesis disorder

AND

1.2 Bile acid synthesis disorder is due to single enzyme defects (SEDs)

OR

2 - ALL of the following:

2.1 Diagnosis of a peroxisomal disorder including Zellweger spectrum disorders

AND

2.2 Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption

AND

2.3 Cholbam is being used as adjunctive treatment

Product Name:Cholbam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cholbam therapy as evidenced by BOTH of the following:

1.1 Improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]) **AND** **1.2** Absence of complete biliary obstruction

2 . Revision History

Date	Notes
7/3/2023	Revised initial and reauth criteria based upon policy updates.

Cialis and Chewtadzy for BPH

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156304
Guideline Name	Cialis and Chewtadzy for BPH
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Chewtadzy 5mg, Brand Cialis 5 mg, generic tadalafil 5 mg	
Diagnosis	Benign prostatic hyperplasia (BPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of benign prostatic hyperplasia (BPH)

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Alpha Blockers: (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Alpha Blockers: (e.g., tamsulosin, alfuzosin ER, doxazosin, or terazosin)
- 5-alpha reductase inhibitors (e.g., finasteride)

AND

3 - Dose does not exceed 5 mg (milligrams) once daily

AND

4 - If the request is for Chewtadzy, ONE of the following:

- Failure to tadalafil 5 mg (generic Cialis 5 mg) confirmed by claims history or submission of medical records
- History of intolerance or contraindication to tadalafil 5 mg (generic Cialis 5 mg) (please specify intolerance or contraindication)

2 . Revision History

Date	Notes
9/26/2024	Added Chewtadzy

Cibinqo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147160
Guideline Name	Cibinqo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Cibinqo	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high, or very-high potency topical corticosteroid* [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.1.1.2 History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium, high, or very-high potency topical corticosteroid* [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)]
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

AND

2.1.2 ONE of the following:

2.1.2.1 BOTH of the following:

2.1.2.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.]

AND

2.1.2.1.2 Physician attests that the patient was not adequately controlled with the documented systemic drug product

OR

2.1.2.2 Physician attests that systemic treatment with BOTH of the following FDA (Food and Drug Administration)-approved chronic atopic dermatitis therapies is inadvisable (document drug and contraindication rationale):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-V-TR) 300.29 for specific phobia diagnostic criteria]

OR

2.2 Patient is currently on Cibinqo therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Cibinqo in combination with any of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]

- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Notes	*See list of "Relative Potencies of Topical Corticosteroids" in Table 1 of the Background.

Product Name:Cibinqo	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cibinqo therapy

AND

2 - Patient is NOT receiving Cibinqo in combination with any of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5

Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

3 . Revision History

Date	Notes
5/13/2024	Clarified language regarding steroid potency.

Cimzia

Prior Authorization Guideline

Guideline ID	GL-180187
Guideline Name	Cimzia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Cimzia	
Diagnosis	Crohn’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active Crohn's disease

AND

1.2 ONE of the following:

1.2.1 Failure to ONE of the following confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

OR

1.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- Azathioprine (Imuran)
- 6-mercaptopurine (Purinethol)
- Methotrexate (Rheumatrex, Trexall)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., adalimumab, ustekinumab, Skyrizi (risankizumab)]

AND

1.3 ONE of the following:

1.3.1 Failure to ONE of the following as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

OR

1.3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active Crohn’s disease

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine], at the maximally indicated doses, confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.3 ONE of the following:

1.3.1 Failure to ALL of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

OR

1.3.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of methotrexate, at the maximally indicated dose, confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.3 ONE of the following:

1.3.1 Failure to TWO of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

OR

1.3.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 ONE of the following:

1.2.1 Failure of TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

1.3 ONE of the following:

1.3.1 Failure to BOTH of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products*

OR

1.3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products*

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderate to severe plaque psoriasis

AND

1.2 ONE of the following:

1.2.1 ALL of the following:

1.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.2.1.2 ONE of the following:

1.2.1.2.1 Failure to ONE of the following topical therapies, confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.2.1.3 ONE of the following:

1.2.1.3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose, confirmed by claims history or submitted medical records

OR

1.2.1.3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

1.3 ONE of the following:

1.3.1 Failure to TWO of the following preferred products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

1.3.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz

(ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] **AND** **1.5** Prescribed by or in consultation with a dermatologist **OR** **2** - ALL of the following: **2.1** Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records **AND** **2.2** Diagnosis of moderate to severe plaque psoriasis **AND** **2.3** Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)] **AND** **2.4** Prescribed by or in consultation with a dermatologist	
Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of non-radiographic axial spondyloarthritis

AND

1.2 ONE of the following:

1.2.1 Failure of TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

AND

1.3 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of contraindication or intolerance to Cosentyx (please specify contraindication or intolerance)

AND

1.4 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of non-radiographic axial spondyloarthritis

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Cosentyx (secukinumab), Rinvoq (upadacitinib), Taltz (ixekizumab)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Product Name:Cimzia	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)

AND

1.2 ONE of the following:

1.2.1 Failure to ALL of the following as confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

OR

1.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

AND

1.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Cimzia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)

AND

2.3 Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See PDL links in Background

Product Name:Cimzia	
Diagnosis	Crohn's Disease, Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Non-Radiographic Axial Spondyloarthritis, Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cimzia therapy

AND **2** - Patient is NOT receiving Cimzia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast)]*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
2/19/2025	Updated formularies. Replaced Ilumya with ustekinumab as a step th erapy option in PsO and added ustekinumab as ST option in CD and PsA. Replaced Stelara with ustekinumab throughout

Cinryze

Prior Authorization Guideline

Guideline ID	GL-147158
Guideline Name	Cinryze
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Cinryze	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by one of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for the prophylaxis of HAE attacks

AND

3 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro)

AND

4 - Prescriber attests that the patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Cinryze

AND

5 - One of the following:

5.1 Failure to Haegarda confirmed by claims history or submitted medical records

OR

5.2 History of intolerance or contraindication to Haegarda (please specify intolerance or contraindication)

OR

5.3 Patient is currently on Cinryze therapy confirmed by claims history or submitted medical records

AND

6 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name:Cinryze	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cinryze therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Cinryze therapy

AND

3 - Prescribed for the prophylaxis of HAE attacks

AND

4 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Haegarda, Orladeyo, Takhzyro)

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
5/8/2024	Update to diagnostic criteria for HAE with normal C1 inhibitor levels. Simplified reauthorization criteria.

Ciprodex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124233
Guideline Name	Ciprodex
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Brand Ciprodex, generic ciprofloxacin/dexamethasone	
Approval Length	1 Month
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 The patient has a perforated tympanic membrane or tympanostomy tubes

OR

1.2 The patient has had an inadequate response, intolerance or contraindication to ONE preferred alternative confirmed by claims history or submission of medical records (please specify intolerance or contraindication if applicable).

2 . Revision History

Date	Notes
4/11/2023	Updated product names. Revised trial and failure criteria.

Colony Stimulating Factors

Prior Authorization Guideline

Guideline ID	GL-180198
Guideline Name	Colony Stimulating Factors
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Leukine, Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - ONE of the following:

3.1 The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

3.2 Both of the following:

3.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

AND

3.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records

- History of contraindication, intolerance or adverse event to Zarxio (please specify contraindication, intolerance, or adverse event)

Product Name:Leukine, Zarxio	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - ONE of the following:

2.1 Patient achieved complete remission after induction therapy

OR

2.2 Patient is receiving consolidation chemotherapy

OR

2.3 Patient is receiving fludarabine, cytarabine with or without idarubicin for relapsed or refractory disease

OR

2.4 Patient is receiving cladribine, cytarabine with or without mitoxantrone or idarubicin for relapsed or refractory disease

AND

3 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - One of the following:

2.1 Patient achieved complete remission after induction therapy

OR

2.2 Patient is receiving consolidation chemotherapy

OR

2.3 Patient is receiving fludarabine, cytarabine with or without idarubicin for relapsed or refractory disease

OR

2.4 Patient is receiving cladribine, cytarabine with or without mitoxantrone or idarubicin for relapsed or refractory disease

AND

3 - Prescribed by or in consultation with a hematologist or oncologist

AND

4 - ONE of the following:

4.1 The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

4.2 Both of the following:

4.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

AND

4.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of contraindication, intolerance or adverse effect to Zarxio (please specify contraindication, intolerance, or adverse effect)

Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy.
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 One of the following:

- Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer
- Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer
- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

OR

1.2 Both of the following:

1.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN

AND

1.2.2 Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as:

- Persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin > 2.0)
- Renal dysfunction (creatinine clearance < 50)
- Age greater than 65 years receiving full chemotherapy dose intensity

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Granix, Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy.
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 One of the following:

- Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer
- Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer
- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

OR

1.2 Both of the following:

1.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN

AND

1.2.2 Patient has one or more risk factors for chemotherapy-induced febrile neutropenia such as:

- Persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin > 2.0)
- Renal dysfunction (creatinine clearance < 50)
- Age greater than 65 years receiving full chemotherapy dose intensity

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - ONE of the following:

3.1 The request is for Granix vial, Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

3.2 Both of the following:

3.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

AND

3.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of contraindication, intolerance, or adverse effect to Zarxio (please specify contraindication, intolerance, or adverse effect)

Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 One of the following:

- Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer
- Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer

- Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of febrile neutropenia (FN)

OR

1.2 Both of the following:

1.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN

AND

1.2.2 Patient has one or more risk factors for chemotherapy-induced febrile neutropenia:

- Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours)
- Liver dysfunction (bilirubin > 2.0)
- Renal dysfunction (creatinine clearance < 50)
- Age greater than 65 years receiving full chemotherapy dose intensity

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - BOTH of the following:

3.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

AND

3.2 One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records

- History of intolerance, contraindication, or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)

OR

1.1.1.2 Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling

OR

1.1.1.3 Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)

AND

1.1.2 ONE of the following:

1.1.2.1 Patient has a documented history of a neutropenic event (febrile neutropenia or low

neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

OR

1.1.2.2 Patient has a documented history of neutropenic event from a previous course of chemotherapy

OR

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

AND

1.2.1.2 Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

OR

1.2.2 Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Granix, Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)

OR

1.1.1.2 Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling

OR

1.1.1.3 Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)

AND

1.1.2 ONE of the following:

1.1.2.1 Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

OR

1.1.2.2 Patient has a documented history of neutropenic event from a previous course of chemotherapy

OR

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

AND

1.2.1.2 Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

OR

1.2.2 Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - ONE of the following:

3.1 The request is for Granix vial, Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

3.2 Both of the following:

3.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

AND

3.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia (FN)
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting)

OR

1.1.1.2 Patient is receiving myelosuppressive anticancer drug(s) with a non-curative intent and use of secondary prophylaxis is in accordance with the United States Food and Drug Administration approved labeling

OR

1.1.1.3 Patient is receiving myelosuppressive anticancer drug(s) for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)

AND

1.1.2 One of the following:

1.1.2.1 Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received

OR

1.1.2.2 Patient has a documented history of neutropenic event from a previous course of chemotherapy

OR

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Patient is receiving myelosuppressive anticancer drug(s) given with non-curative intent

AND

1.2.1.2 Patient has a documented history of neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen after a trial of dose reduction

OR

1.2.2 Patient is receiving myelosuppressive anticancer drug(s) where primary prophylaxis is indicated

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - BOTH of the following:

3.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

AND

3.2 One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

Product Name:Leukine, Neulasta, Neulasta Onpro, Zarxio, Udenyca, Udenyca Onbody	
Diagnosis	Treatment of Febrile Neutropenia (FN)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of febrile neutropenia (FN)

AND

2 - Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days

AND

3 - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years or age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration
- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

AND

4 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Treatment of Febrile Neutropenia (FN)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of febrile neutropenia (FN)

AND

2 - Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days

AND

3 - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years of age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration

- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

AND

4 - Prescribed by or in consultation with a hematologist or oncologist

AND

5 - One of the following:

5.1 The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

5.2 Both of the following:

5.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi or Releuko than experienced with Zarxio

AND

5.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo	
Diagnosis	Treatment of Febrile Neutropenia (FN)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of febrile neutropenia (FN)

AND

2 - Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days

AND

3 - Patient has one or more risk factors for an infection-associated complication such as:

- Sepsis syndrome
- Greater than 65 years of age
- Absolute Neutrophil Count (ANC) less than 100/mcL
- Neutropenia expected to be greater than 10 days in duration
- Pneumonia
- Clinically documented infections including invasive fungal infection
- Hospitalization at the time of fever
- Prior episode(s) of FN

AND

4 - Prescribed by or in consultation with a hematologist or oncologist

AND

5 - Both of the following:

5.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

AND

5.2 One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

Product Name:Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) [i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count (ANC) less than or equal to 500 neutrophils/microliter]

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe chronic neutropenia (SCN) [i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count (ANC) less than or equal to 500 neutrophils/microliter]

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - ONE of the following:

3.1 The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

3.2 Both of the following:

3.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi,or Releuko than experienced with Zarxio

AND

3.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

Product Name:Leukine, Neulasta, Zarxio, Udenyca, Udenyca Onbody	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name:Neupogen, Nivestym, Nypozi, Releuko	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - ONE of the following:

3.1 The request is for Neupogen vial, Nivestym vial, or Releuko vial AND the requested dose is less than 0.3 milliliters

OR

3.2 Both of the following:

3.2.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neupogen, Nivestym, Nypozi, or Releuko than experienced with Zarxio

AND

3.2.2 One of the following:

- Failure to Zarxio as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Zarxio (please specify intolerance, contraindication or adverse effect)

Product Name:Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

AND

3 - BOTH of the following:

3.1 Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend or Ziextenzo than experienced with Neulasta or Udenyca/Udenyca Onbody

AND

3.2 One of the following:

- Failure to Neulasta or Udenyca/Udenyca Onbody as confirmed by claims history or submission of medical records
- History of intolerance, contraindication or adverse effect to Neulasta or Udenyca/Udenyca Onbody (please specify intolerance, contraindication or adverse effect)

2 . Revision History

Date	Notes
2/20/2025	Updated formularies. Added Nypozi

Combination Basal Insulin/GLP-1 Receptor Agonist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147166
Guideline Name	Combination Basal Insulin/GLP-1 Receptor Agonist
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Soliqua	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Inadequately controlled on ONE of the following as confirmed by claims history or submission of medical records:

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Trulicity (dulaglutide), Victoza (liraglutide), Bydureon BCise (exenatide extended-release), Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide)]
- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

Product Name:Xultophy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - Inadequately controlled on ONE of the following as confirmed by claims history or submission of medical records:

- GLP-1 (glucagon-like peptide-1) receptor agonist [e.g. Victoza (liraglutide injection), Ozempic (semaglutide), Rybelsus (semaglutide)]
- Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

AND

3 - One of the following:

3.1 Failure to Soliqua as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Soliqua (please specify contraindication or intolerance)

Product Name:Xultophy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xultophy therapy	

2 . Revision History

Date	Notes
5/13/2024	Updated GLP-1 examples

Cometriq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127884
Guideline Name	Cometriq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medullary carcinoma

OR

2 - ALL of the following:

2.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic cell carcinoma
- Papillary carcinoma

AND

2.2 Disease is progressive after treatment with ONE of the following as confirmed by claims history or submission of medical records:

- Lenvima (lenvatinib)
- Nexavar (sorafenib)

AND

2.3 Disease is at least ONE of the following:

- Symptomatic iodine-refractory
- Unresectable locoregional recurrent or persistent disease
- Distant metastatic disease

Product Name:Cometriq	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name:Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Positive for RET gene rearrangements

Product Name:Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cometriq therapy

Product Name:Cometriq

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Cometriq	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cometriq therapy

2 . Revision History

Date	Notes
7/12/2023	Updated diagnosis options for thyroid carcinoma, simplified numberin g, cleaned up criteria and indications.

Compounds and Bulk Powders

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124580
Guideline Name	Compounds and Bulk Powders
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Compounds or Bulk Powders	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - The requested drug component is a covered medication

AND

2 - ONE of the following:

2.1 The requested drug component is to be administered for an FDA (Food and Drug Administration)-approved indication

OR

2.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - If a drug included in the compound requires prior authorization and/or step therapy, all drug specific clinical criteria must also be met

AND

4 - If the drug component is no longer available commercially, it must not have been withdrawn for safety reasons

AND

5 - ONE of the following:

5.1 A unique vehicle is required

OR

5.2 A unique dosage form is required for a commercially available product due to patient's age, weight, or inability to take a solid dosage form

OR

5.3 A unique formulation is required for a commercially available product due to an allergy or intolerance to an inactive ingredient in the commercially available product

OR

5.4 There is a shortage of the commercially available product per the FDA Drug Shortage database or the ASHP (American Society of Health-System Pharmacists) Current Drug Shortages tracking log

AND

6 - Coverage for compounds and bulk powders will NOT be approved for any of the following:

6.1 For topical compound preparations (e.g., creams, ointments, lotions, or gels to be applied to the skin for transdermal, transcutaneous, or any other topical route), if the requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use (see Table 1 in Background section)

OR

6.2 If the requested compound contains topical fluticasone, topical fluticasone will NOT be approved unless both of the following are met:

6.2.1 Topical fluticasone is intended to treat a dermatologic condition (scar treatments are considered cosmetic and will not be covered)

AND

6.2.2 Patient has a contraindication to all commercially available topical fluticasone formulations

OR

6.3 Requested compound contains any ingredients when used for cosmetic purposes (see Table 2 in Background section)

OR

6.4 Requested compound contains any ingredient(s) which are on the FDA's Do Not Compound List (see Table 3 in Background section)

2 . Background

Benefit/Coverage/Program Information
Table 1: Example topical compound preparations that contain any FDA approved ingredient that are not FDA approved for TOPICAL use, including but NOT LIMITED TO the following: (1) Ketamine (2) Gabapentin (3) Flurbiprofen (topical ophthalmic use not included) (4) Ketoprofen (5) Morphine (6) Nabumetone (7) Oxycodone (8) Cyclobenzaprine

(9) Baclofen

(10) Tramadol

(11) Hydrocodone

(12) Meloxicam

(13) Amitriptyline

(14) Pentoxifylline

(15) Orphenadrine

(16) Piroxicam

(17) Levocetirizine

(18) Amantadine

(19) Oxytocin

(20) Sumatriptan

(21) Chorionic gonadotropin (human)

(22) Clomipramine

(23) Dexamethasone

(24) Hydromorphone

(25) Methadone

(26) Papaverine

(27) Mefenamic acid

(28) Promethazine

(29) Succimer DMSA

(30) Tizanidine

(31) Apomorphine

(32) Carbamazepine

(33) Ketorolac

(34) Dimercaptopropane-sulfonate

(35) Dimercaptosuccinic acid

(36) Duloxetine

(37) Fluoxetine

(38) Bromfenac (topical ophthalmic use not included)

(39) Nepafenac (topical ophthalmic use not included)

Table 2: Example compounds that contain ingredients for cosmetic purposes:

(1) Hydroquinone

(2) Acetyl hexapeptide-8

(3) Tocopheryl Acid Succinate

(4) PracaSil TM-Plus

(5) Chrysaderm Day Cream

(6) Chrysaderm Night Cream

(7) PCCA Spira-Wash

(8) Lipopen Ultra

(9) Versapro

(10) Fluticasone

(11) Mometasone

(12) Halobetasol

(13) Betamethasone

(14) Clobetasol

(15) Triamcinolone

(16) Minoxidil

(17) Tretinoin

(18) Dexamethasone

(19) Spironolactone

(20) Cycloserine

(21) Tamoxifen

(22) Sermorelin

(23) Mederma Cream

(24) PCCA Cosmetic HRT Base

(25) Sanare Scar Therapy Cream

(26) Scarcin Cream

(27) Apothederm

(28) Stera Cream

(29) Copasil

(30) Collagenase

(31) Arbutin Alpha

(32) Nourisil

(33) Freedom Cepapro

(34) Freedom Silomac Andydrous

(35) Retinaldehyde

(36) Apothederm

Table 3: Example ingredients on the FDA's Do Not Compound List:

(1) 3,3′,4′,5-tetrachlorosalicylanilide

(2) Adenosine phosphate

(3) Adrenal cortex

(4) Alatrofloxacin mesylate

(5) Aminopyrine

(6) Astemizole

(7) Azaribine

(8) Benoxaprofen

(9) Bithionol

(10) Camphorated oil

(11) Carbetapentane citrate

(12) Casein, iodinated

(13) Cerivastatin sodium

(14) Chlormadinone acetate

(15) Chloroform

(16) Cisapride

(17) Defenfluramine hydrochloride

(18) Diamthazole dihydrochloride

(19) Dibromsalan

(20) Dihydrostreptomycin sulfate

(21) Dipyrone

(22) Encainide hydrochloride

(23) Etretinate

(24) Fenfluramine hydrochloride

(25) Flosequinan

(26) Glycerol, iodinated

(27) Grepafloxacin

(28) Mepazine

(29) Metabromsalan

(30) Methapyrilene

(31) Methopholine

(32) Methoxyflurane

(33) Mibefradil dihydrochloride

(34) Nomifensine maleate

(35) Novobiocin sodium

(36) Oxyphenisatin acetate

(37) Oxyphenisatin

(38) Pemoline

(39) Pergolide mesylate

(40) Phenacetin

(41) Phenformin hydrochloride

(42) Phenylpropanolamine

(43) Pipamazine

(44) Potassium arsenite

(45) Propoxyphene

(46) Rapacuronium bromide

(47) Rofecoxib

(48) Sibutramine hydrochloride

(49) Sparteine sulfate

(50) Sulfadimethoxine

(51) Sweet spirits of nitre

(52) Tegaserod maleate

(53) Temafloxacin hydrochloride

(54) Terfenadine

(55) Ticrynafen

(56) Tribromsalan

(57) Trichloroethane

(58) Troglitazone

(59) Trovafloxacin mesylate:

(60) Urethane

(61) Valdecoxib

(62) Zomepirac sodium

3 . Revision History

Date	Notes
4/12/2023	Updated formularies.

Constipation Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152614
Guideline Name	Constipation Agents
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:generic lubiprostone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Diagnosis of opioid-induced constipation in an adult with chronic, non-cancer pain

OR

1.1.2 Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer diagnosis or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

1.2 ONE of the following:

1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

OR

2 - BOTH of the following:

2.1 Diagnosis of chronic idiopathic constipation

AND

2.2 ONE of the following:

2.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose

- Polyethylene glycol (Miralax)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

OR

3 - ALL of the following:

3.1 Diagnosis of irritable bowel syndrome with constipation

AND

3.2 Patient was female at birth

AND

3.3 ONE of the following:

3.3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

3.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

Product Name:Brand Amitiza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 Diagnosis of opioid-induced constipation in an adult with chronic, non-cancer pain

OR

1.1.2 Diagnosis of opioid-induced constipation in patients with chronic pain related to prior cancer diagnosis or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

1.2 ONE of the following:

1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

1.3 ONE of the following:

1.3.1 Failure to Movantik as confirmed by claims history or submission of medical records

OR

1.3.2 History of intolerance or contraindication to Movantik (please specify intolerance or contraindication)

AND

1.4 ONE of the following:

1.4.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

1.4.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

OR

2 - ALL of the following:

2.1 Diagnosis of chronic idiopathic constipation

AND

2.2 ONE of the following:

2.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose

- Polyethylene glycol (Miralax)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

2.3 ONE of the following:

2.3.1 Failure to Motegrity as confirmed by claims history or submission of medical records

OR

2.3.2 History of intolerance or contraindication to Motegrity (please specify intolerance or contraindication)

AND

2.4 ONE of the following:

2.4.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

2.4.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

OR

3 - ALL of the following:

3.1 Diagnosis of irritable bowel syndrome with constipation

AND

3.2 Patient was female at birth

AND

3.3 ONE of the following:

3.3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

3.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

3.4 ONE of the following:

3.4.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

3.4.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Linzess	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic idiopathic constipation

AND

1.2 ONE of the following:

1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

1.3 ONE of the following:

1.3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

1.3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

AND

1.4 ONE of the following:

1.4.1 Failure to Motegrity as confirmed by claims history or submission of medical records

OR

1.4.2 History of intolerance or contraindication to Motegrity (please specify intolerance or contraindication)

OR

2 - ALL of the following:

2.1 Diagnosis of irritable bowel syndrome with constipation

AND

2.2 ONE of the following:

2.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

2.3 ONE of the following:

2.3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

2.3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

OR

3 - BOTH of the following:

3.1 Diagnosis of functional constipation

AND

3.2 One of the following:

3.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

3.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication)

- Lactulose
- Polyethylene glycol (Miralax)

Product Name:Trulance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic idiopathic constipation

AND

1.2 ONE of the following:

1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

1.3 ONE of the following:

1.3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

1.3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

AND

1.4 ONE of the following:

1.4.1 Failure to Motegrity as confirmed by claims history or submission of medical records

OR

1.4.2 History of intolerance or contraindication to Motegrity (please specify intolerance or contraindication)

OR

2 - ALL of the following:

2.1 Diagnosis of irritable bowel syndrome with constipation

AND

2.2 ONE of the following:

2.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

2.3 ONE of the following:

2.3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

2.3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Motegrity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic constipation

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - ONE of the following:

3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Movantik	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of opioid-induced constipation in a patient being treated for chronic, non-cancer pain

OR

1.2 Diagnosis of opioid-induced constipation in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - ONE of the following:

3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Symproic	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of opioid-induced constipation in a patient being treated for chronic, non-cancer pain

OR

1.2 Diagnosis of opioid-induced constipation in a patient with chronic pain related to prior cancer diagnosis or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - ONE of the following:

3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

AND

4 - ONE of the following:

4.1 Failure to Movantik as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to Movantik (please specify intolerance or contraindication)

Product Name:Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - Patient was female at birth

AND

3 - ONE of the following:

3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

4 - ONE of the following:

4.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Lactulose
- Polyethylene glycol (Miralax)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Lactulose
- Polyethylene glycol (Miralax)

AND

3 - ONE of the following:

3.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

Product Name:Brand Amitiza, generic lubiprostone, Ibsrela, Linzess, Motegrity, Movantik, Symproic, Trulance, Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
8/26/2024	Added criteria for functional constipation.

Continuous Glucose Monitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157017
Guideline Name	Continuous Glucose Monitors
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/3/2024

1 . Criteria

Product Name:Continuous Glucose Monitors, sensors, and transmitters (all brands)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of diabetes

AND

2 - One of the following:

2.1 Patient is on an intensive insulin regimen (3 or more insulin injections per day or uses continuous subcutaneous insulin infusion pump)

OR

2.2 One of the following:

- Patient has a history of a level 3 hypoglycemic event
- Patient has a history of more than one level 2 hypoglycemia events that persist despite multiple attempts to adjust medication(s) or modify diabetes treatment plan

AND

3 - Patient regularly monitors blood glucose 4 or more times per day

AND

4 - If the request is for a Guardian Connect (all components), Guardian 3 (all components), Guardian 4 (all components), or Freestyle Libre 3 (all components), ONE of the following:

4.1 BOTH of the following:

4.1.1 Patient has a physical or mental limitation that makes utilization of Dexcom G6 and Dexcom G7 unsafe, inaccurate, or otherwise not feasible (e.g., manual dexterity; document limitation)

AND

4.1.2 Patient has a physical or mental limitation that makes utilization of the preferred Freestyle Libre product unsafe, inaccurate, or otherwise not feasible (e.g., manual dexterity; document limitation)

OR **4.2** Provider submits documentation why the patient requires use of the Guardian Connect, Guardian 3, Guardian 4, or Freestyle Libre 3 for treatment of diabetes

Product Name:Continuous Glucose Monitors, sensors, and transmitters (all brands)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response	

2 . Revision History

Date	Notes
10/3/2024	Removed ACUCO formulary.

Copiktra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127436
Guideline Name	Copiktra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

AND

2 - Disease is relapsed or refractory

AND

3 - ONE of the following:

3.1 Failure to at least TWO prior therapies for CLL/SLL confirmed by claims history or submitted medical records. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.]

OR

3.2 History of intolerance or contraindication to at least TWO prior therapies for CLL/SLL. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.] (please specify intolerance or contraindication)

Product Name:Copiktra	
Diagnosis	Chronic Lymphocytic Leukemia (CLL) / Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name:Copiktra	
Diagnosis	T-cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Hepatosplenic T-cell lymphoma
- Breast implant-associated anaplastic large cell lymphoma
- Peripheral T-cell lymphomas

AND

2 - Disease is relapsed or refractory

AND

3 - ONE of the following:

3.1 Failure to at least TWO prior systemic therapies confirmed by claims history or submitted medical records

OR

3.2 History of intolerance or contraindication to at least TWO prior systemic therapies (please specify intolerance or contraindication)

Product Name:Copiktra	
Diagnosis	T-cell Lymphomas

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Copiktra therapy

Product Name:Copiktra	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Copiktra	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Copiktra therapy

2 . Revision History

Date	Notes
6/30/2023	Updated formularies, cleaned up criteria.

Copper Chelating Agents

Prior Authorization Guideline

Guideline ID	GL-149080
Guideline Name	Copper Chelating Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Brand Depen Titratabs, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe active rheumatoid arthritis

Product Name:Brand Depen Titratabs, generic penicillamine tablets	
Diagnosis	Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Depen Titratabs, generic penicillamine tablets	
Diagnosis	Wilson’s disease, Cystinuria
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Wilson’s disease (i.e., hepatolenticular degeneration)
- Cystinuria

Product Name:Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

OR

2.2 History of intolerance to BOTH of the following (please specify intolerance):

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

Product Name:Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Cystinuria

- Severe active rheumatoid arthritis

AND

2 - ONE of the following:

2.1 Failure to penicillamine tablets (generic Depen Titratabs) as confirmed by claims history or submission of medical records

OR

2.2 History of intolerance to penicillamine tablets (generic Depen Titratabs) (please specify intolerance)

Product Name:Brand Cuprimine, generic penicillamine capsules	
Diagnosis	Wilson's disease, Cystinuria, Severe active rheumatoid arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Syprine, generic trientine hcl 250 mg capsules	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

Product Name:Brand Syprine, generic trientine hcl 250 mg capsules	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:trientine hcl 500 mg capsules	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- penicillamine tablets (generic Depen Titratabs)
- trientine 250 mg capsules (generic Syprine)

Product Name:trientine hcl 500 mg capsules	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/27/2024	Updated trial/failure requirements for Cuprimine, Syprine, and trientine 500 mg capsules.

Corlanor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158162
Guideline Name	Corlanor
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Symptomatic Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Worsening heart failure in a diagnosis of stable, symptomatic, chronic [e.g., New York Heart Association (NYHA) class II, III, or IV] heart failure

AND

1.2 Patient has a left ventricular ejection fraction (EF) less than or equal to 35%

AND

1.3 The patient is in sinus rhythm

AND

1.4 Patient has a resting heart rate greater than or equal to 70 beats per minute

AND

1.5 ONE of the following:

1.5.1 Patient is on a stabilized dose and receiving concomitant therapy with maximum tolerated beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) as confirmed by claims history or submission of medical records

OR

1.5.2 Patient has a contraindication or intolerance to beta-blocker therapy (please specify contraindication or intolerance)

AND

1.6 ONE of the following:

1.6.1 Patient is on a stabilized dose and receiving concomitant therapy with Farxiga (includes combination products containing dapagliflozin) as confirmed by claims history or submission of medical records

OR

1.6.2 Patient has a contraindication or intolerance to SGLT2 (sodium-glucose co-transporter 2) inhibitor therapy (please specify contraindication or intolerance)

AND

1.7 ONE of the following:

1.7.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, as confirmed by claims history or submission of medical records:

1.7.1.1 Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

OR

1.7.1.2 Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

1.7.1.3 Angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto)

OR

1.7.2 Patient has a contraindication or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify contraindication or intolerance)

AND

1.8 ONE of the following:

1.8.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g., eplerenone, spironolactone) as confirmed by claims history or submission of medical records

OR

1.8.2 Patient has a contraindication or intolerance to aldosterone antagonist therapy (please specify contraindication or intolerance)

AND

1.9 Prescribed by or in consultation with a cardiologist

OR

2 - ALL of the following:

2.1 Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM)

AND

2.2 Patient is in sinus rhythm

AND

2.3 Patient has an elevated heart rate

AND

2.4 Prescribed by or in consultation with a cardiologist

OR

3 - Patient is currently established on Corlanor therapy

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Inappropriate Sinus Tachycardia (IST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following

1.1 Diagnosis of inappropriate sinus tachycardia (IST)

AND

1.2 Patient is in sinus rhythm

AND

1.3 One of the following:

- Patient has tried and failed or had an inadequate response to a beta blocker (e.g., carvedilol, metoprolol succinate, bisoprolol) as confirmed by claims history or submission of medical records
- Patient has a contraindication or intolerance to beta-blocker therapy (please specify contraindication or intolerance)

AND

1.4 Prescribed by or in consultation with a cardiologist

OR

2 - Patient is currently established on Corlanor therapy

Product Name:Brand Corlanor, generic ivabradine	
Diagnosis	Symptomatic Chronic Heart Failure, Inappropriate Sinus Tachycardia (IST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Corlanor therapy	

2 . Revision History

Date	Notes
10/29/2024	Added generic ivabradine. Updated product names.

Cosentyx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-180202
Guideline Name	Cosentyx
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab), Enbrel (etanercept)]

OR

4.2.1.2 ALL of the following:

4.2.1.2.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

4.2.1.2.2 ONE of the following:

- Failure of ONE of the following confirmed by claims history or submitted medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

AND

4.2.1.2.3 ONE of the following:

- Failure of a 3 month trial of methotrexate, at the maximally indicated doses, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

AND

4.2.2 ONE of the following:

4.2.2.1 Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

Notes	*See PDL links in Background

Product Name:Cosentyx	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

OR

4.2.1.2 History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

OR

4.2.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib), Enbrel (etanercept)]

AND

4.2.2 ONE of the following:

- Failure of BOTH of the following confirmed by claims history or submitted medical records: One of the preferred adalimumab products*, Enbrel (etanercept)
- History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, Enbrel (etanercept)

Notes	*See PDL links in Background

Product Name:Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a rheumatologist OR dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

- Failure of a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab),

ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Rinvoq (upadacitinib), Enbrel (etanercept)]

AND

4.2.2 ONE of the following:

4.2.2.1 Failure to TWO of the following confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

Notes	*See PDL links in Background

Product Name:Cosentyx	
Diagnosis	Non-radiographic axial spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

OR

4.2 ONE of the following:

4.2.1 Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

OR

4.2.2 History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

4.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab)]

Product Name:Cosentyx	
Diagnosis	Enthesitis-Related Arthritis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active enthesitis-related arthritis

AND

2 - ONE of the following:

2.1 Failure to TWO NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

2.3 Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), adalimumab, Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Cosentyx	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

AND

2 - ONE of the following:

- Failure to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to at least ONE oral antibiotic (e.g., doxycycline, clindamycin, rifampin) (please specify contraindication or intolerance)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of hidradenitis suppurativa as confirmed by claims history or submitted medical records [e.g., adalimumab, Bimzelx (bimekizumab-bkzx)].

AND

3 - ONE of the following:

- Failure to at least one of the preferred adalimumab products* as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to one of the preferred adalimumab products* (please specify contraindication or intolerance)
- Patient is currently on Cosentyx therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator

[e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] **AND** **5** - Prescribed by or in consultation with a dermatologist

Notes	*See PDL links in Background

Product Name:Cosentyx	
Diagnosis	Plaque Psoriasis, Ankylosing Spondylitis, Psoriatic Arthritis (PsA), Non-radiographic Axial Spondyloarthritis, Enthesitis-Related Arthritis, Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cosentyx therapy

AND

2 - Patient is NOT receiving Cosentyx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information

PDL Links:

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
2/20/2025	Updated formularies. Removed reference to brand Stelara. Removed Ilumya step in PsO section – and added preferred ustekinumab as step therapy option in PsO and PsA. Removed requirement that one of the steps in PsO must be adalimumab. Updated step therapy bypass in HS section to bypass oral antibiotic therapy for patients with a history of targeted immunomodulator therapy and bypass for adalimumab section for current utilizers.

Cotellic

Prior Authorization Guideline

Guideline ID	GL-163858
Guideline Name	Cotellic
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - ONE of the following:

2.1 Patient has unacceptable toxicities to Tafinlar (dabrafenib)/Mekinist (trametinib) on the basis of agent side-effect profile

OR

2.2 Disease is one of the following:

- Relapsed greater than 3 months after treatment discontinuation
- Unresectable
- Metastatic

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Circumscribed glioma
- Glioblastoma
- Limited brain metastases
- Extensive brain metastases

AND

2 - Disease is BRAF V600E positive

AND

3 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Melanoma, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following histiocytic neoplasms:

- Langerhans cell histiocytosis
- Erdheim-Chester disease

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

Product Name:Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cotellic therapy	

2 . Revision History

Date	Notes
1/15/2025	Updated melanoma, central nervous system cancers, and histiocytic neoplasms criteria

Cotellic

Prior Authorization Guideline

Guideline ID	GL-163858
Guideline Name	Cotellic
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - ONE of the following:

2.1 Patient has unacceptable toxicities to Tafinlar (dabrafenib)/Mekinist (trametinib) on the basis of agent side-effect profile

OR

2.2 Disease is one of the following:

- Relapsed greater than 3 months after treatment discontinuation
- Unresectable
- Metastatic

AND

3 - Disease is positive for ONE of the following mutations:

- BRAF V600E
- BRAF V600K

AND

4 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Circumscribed glioma
- Glioblastoma
- Limited brain metastases
- Extensive brain metastases

AND

2 - Disease is BRAF V600E positive

AND

3 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Melanoma, Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

AND

2 - Used in combination with Zelboraf (vemurafenib)

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following histiocytic neoplasms:

- Langerhans cell histiocytosis
- Erdheim-Chester disease

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cotellic therapy

Product Name:Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Cotellic	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Cotellic therapy	

2 . Revision History

Date	Notes
1/15/2025	Updated melanoma, central nervous system cancers, and histiocytic neoplasms criteria

Cuvrior

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148686
Guideline Name	Cuvrior
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • • •

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Cuvrior	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease

AND

2 - Patient is de-coppered [i.e., serum non-ceruloplasmin copper (NCC) level greater than or equal to 25 and less than or equal to 150 mcg/L (micrograms/liter)]

AND

3 - Patient is tolerant to penicillamine

AND

4 - Prescriber provides a reason or special circumstance why the patient cannot use penicillamine tablets (generic Depen Titratabs)

AND

5 - ONE of the following:

5.1 Failure to trientine 250 mg capsules (generic Syprine) as confirmed by claims history or submission of medical records

OR

5.2 History of intolerance to trientine 250 mg capsules (generic Syprine) (please specify intolerance)

AND

6 - Prescribed by a hepatologist

Product Name:Cuvrior	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Cuvrior therapy (e.g., increased 24-hour urinary copper excretion from baseline, normalization of serum free copper, prevention of or improvement in symptoms)

AND

2 - Prescribed by a hepatologist

2 . Revision History

Date	Notes
6/26/2024	Updated language on why pt must switch from preferred penicillamine agent, added step through trientine 250 mg capsules, added prescriber requirement, and updated initial/reauth durations to 12 months.

Cystaran, Cystadrops

Prior Authorization Guideline

Guideline ID	GL-164695
Guideline Name	Cystaran, Cystadrops
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Nebraska • Medicaid - Community & State New Mexico • Medicaid - Community & State Indiana • Medicaid - Community & State Pennsylvania

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Cystaran, Cystadrops	
Diagnosis	Cystinosis
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystinosis	

2 . Revision History

Date	Notes
2/4/2025	Adding Indiana and PA Medicaid formularies. No change to clinical cr iteria.

Daliresp

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165155
Guideline Name	Daliresp
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

2 . Revision History

Date	Notes
2/13/2025	Updated formularies. Removed all criteria except diagnosis check

Danziten

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-173219
Guideline Name	Danziten
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Danziten	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myeloid leukemia

Product Name:Danziten	
Diagnosis	Acute Lymphoblastic Leukemia (Ph+B-ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL)

Product Name:Danziten	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor

Product Name:Danziten	
Diagnosis	Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia (Ph+B-ALL), Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Danziten therapy

Product Name:Danziten	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Danziten	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Danziten therapy

2 . Revision History

Date	Notes

2/18/2025	New program

Daraprim

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126766
Guideline Name	Daraprim
Formulary	• Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting ONE of the following:	

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 One of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm^3 if initiating prophylaxis or CD4 100-200 cells per mm^3 if reinstituting prophylaxis*

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-

sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]	
Notes	*Consider discontinuation of primary prophylaxis if CD4 > 200 cells/mm^3 for > 3 months after institution of combination antiretroviral therapy.

Product Name:Brand Daraprim*, generic pyrimethamine*	
Guideline Type	Reject 88 - Therapeutic Duplication
Approval Criteria **1** - There is a reason or special circumstances why the patient must be on Daraprim (pyrimethamine) commercial tablets and a compound containing pyrimethamine at the same time	
Notes	*Approval Length: 2 months (if deemed medically necessary for long-term use by the prescriber, authorization will be issued for 12 months)

2 . Revision History

Date	Notes
6/28/2023	Updated guideline name to remove formulary distinction. Clarified documentation requirement.

Daraprim

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126766
Guideline Name	Daraprim
Formulary	• Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Brand Daraprim, generic pyrimethamine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) documenting ONE of the following:	

1.1 Treatment of severe acquired toxoplasmosis, including toxoplasmic encephalitis

OR

1.2 Treatment of congenital toxoplasmosis

OR

1.3 Secondary prophylaxis of toxoplasmic encephalitis

OR

1.4 ALL of the following:

1.4.1 Primary pneumocystis pneumonia (PCP) prophylaxis in human immunodeficiency virus (HIV)-infected patients or as secondary prophylaxis in HIV-infected patients who have been treated for an acute episode of pneumocystis pneumonia

AND

1.4.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.4.3 One of the following:

1.4.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.4.3.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]

OR

1.5 ALL of the following:

1.5.1 Primary prophylaxis of toxoplasmic encephalitis

AND

1.5.2 Toxoplasma immunoglobulin G (IgG) positive

AND

1.5.3 CD4 (cluster of differentiation 4) less than or equal to 100 cells per mm^3 if initiating prophylaxis or CD4 100-200 cells per mm^3 if reinstituting prophylaxis*

AND

1.5.4 Will be used in combination with dapsone or atovaquone

AND

1.5.5 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.5.6 ONE of the following:

1.5.6.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.5.6.2 Evidence of moderately severe or life threatening-reaction to trimethoprim-

sulfamethoxazole (TMP-SMX) in the past [e.g., toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome]	
Notes	*Consider discontinuation of primary prophylaxis if CD4 > 200 cells/mm^3 for > 3 months after institution of combination antiretroviral therapy.

Product Name:Brand Daraprim*, generic pyrimethamine*	
Guideline Type	Reject 88 - Therapeutic Duplication
Approval Criteria **1** - There is a reason or special circumstances why the patient must be on Daraprim (pyrimethamine) commercial tablets and a compound containing pyrimethamine at the same time	
Notes	*Approval Length: 2 months (if deemed medically necessary for long-term use by the prescriber, authorization will be issued for 12 months)

2 . Revision History

Date	Notes
6/28/2023	Updated guideline name to remove formulary distinction. Clarified documentation requirement.

Daurismo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-181191
Guideline Name	Daurismo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

OR

1.2 Relapsed/refractory disease with ALL of the following:

1.2.1 Given as a component of repeating the initial successful induction regimen

AND

1.2.2 Late relapse (greater than or equal to 12 months since induction regimen)

AND

1.2.3 Initial therapy was not administered continuously

AND

1.2.4 Initial therapy was not stopped due to development of clinical resistance

AND

2 - Daurismo therapy to be given in combination with low-dose cytarabine

AND

3 - ONE of the following:

3.1 Patient is at least 75 years old

OR

3.2 Patient has significant comorbidities that preclude the use of intensive induction chemotherapy [e.g., severe cardiac disease, Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 2, baseline creatinine greater than 1.3 milligrams/deciliter]

Product Name:Daurismo	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Daurismo therapy

Product Name:Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Daurismo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Daurismo therapy	

2 . Revision History

Date	Notes
2/20/2025	Combined formularies. No changes to clinical criteria.

Daybue

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150910
Guideline Name	Daybue
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/3/2024

1 . Criteria

Product Name:Daybue	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Rett Syndrome (RTT) confirmed by ONE of the following:

1.1 ALL of the following clinical signs and symptoms:

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

1.2 Confirmed genetic mutation in the MECP2 gene

AND

2 - Prescribed by, or in consultation with, ONE of the following:

- Geneticist
- Pediatrician who specializes in childhood neurological or developmental disorders
- Neurologist

Product Name:Daybue	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Daybue therapy

2 . Revision History

Date	Notes
8/2/2024	Updated initial approval duration from 6 months to 12 months.

DEKAs Plus

Prior Authorization Guideline

Guideline ID	GL-135059
Guideline Name	DEKAs Plus
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:DEKAs Plus Ocean, DEKAs Plus	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria
1 - Diagnosis of cystic fibrosis

2 . Revision History

Date	Notes
10/16/2023	Updated formularies, cleaned up GPIs.

Descovy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-202203
Guideline Name	Descovy
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Mexico • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Descovy	
Diagnosis	Human Immunodeficiency Virus-1 (HIV-1)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of human immunodeficiency virus-1 (HIV-1)

AND

2 - ONE of the following:

2.1 Submission of medical records documenting a history of adverse event or intolerance to prior use of emtricitabine/tenofovir disoproxil fumarate (generic Truvada)

OR

2.2 Patient is currently on Descovy therapy

OR

2.3 Submission of medical records documenting an estimated GFR (glomerular filtration rate) below 90 mL/min (milliliters/minute)

OR

2.4 Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD (bone mineral density) T-score less than or equal to -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

OR

2.5 Submission of medical records documenting a prior low-trauma or non-traumatic fracture

OR

2.6 Patient is less than 20 years of age

OR

2.7 Submission of medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-scores] with evidence of progressive bone loss on serial DEXA (dual-energy X-ray absorptiometry) scan

Product Name:Descovy	
Diagnosis	Post-Exposure Prophylaxis (PEP)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of post-exposure prophylaxis (PEP)

Product Name:Descovy 200/25 mg	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis (PrEP)
Approval Length	Authorization will be issued for 12 months at GPI-14 level to approve only the 200/25mg strength
Guideline Type	Prior Authorization

Approval Criteria

1 - Request is for 200/25 mg strength

AND

2 - Used for HIV-1 pre-exposure prophylaxis (PrEP)

AND

3 - ONE of the following:

3.1 Submission of medical records documenting a history of adverse event or intolerance to prior use of emtricitabine/tenofovir disoproxil fumarate (generic Truvada)

OR

3.2 Submission of medical records documenting an estimated GFR (glomerular filtration rate) below 90 mL/min (milliliters/minute)

OR

3.3 Submission of medical records documenting a diagnosis of osteoporosis as defined by a BMD (bone mineral density) T-score less than or equal to -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-score]

OR

3.4 Submission of medical records documenting a prior low-trauma or non-traumatic fracture

OR

3.5 Patient is less than 20 years of age

OR

3.6 Submission of medical records documenting a diagnosis of osteopenia as defined by a BMD T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) [Provider must submit patient specific BMD T-scores] with evidence of progressive bone loss on serial DEXA (dual-energy X-ray absorptiometry) scan

2 . Revision History

Date	Notes

2/27/2025	Combined formularies, but removed NY and NY EPP from markets in scope as Descovy moving to open access for these markets. No cha nges to criteria.

Dificid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154715
Guideline Name	Dificid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Dificid	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Clostridioides difficile-associated diarrhea (CDAD) [previously known as Clostridium difficile-associated diarrhea]

AND

2 - ONE of the following:

2.1 Failure to one of the following:

- Firvanq (vancomycin) oral solution
- vancomycin 125 mg or 250 mg capsules
- vancomycin 25 mg/ml or 50 mg/ml oral solution

OR

2.2 History of intolerance or contraindication to all of the following: (please specify intolerance or contraindication)

- Firvanq (vancomycin) oral solution
- vancomycin 125 mg or 250 mg capsules
- vancomycin 25 mg/ml or 50 mg/ml oral solution

OR

2.3 For continuation of prior Dificid therapy

2 . Revision History

Date	Notes
9/10/2024	Updated step through agents due to PDL change

Dojolvi

Prior Authorization Guideline

Guideline ID	GL-148834
Guideline Name	Dojolvi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/3/2024

1 . Criteria

Product Name:Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming the diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) with at least two of the following diagnostic criteria:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- Genetic testing demonstrating one or more pathogenic mutations in a gene associated with long-chain fatty acid oxidation disorders (e.g., CPT2, ACADVL, HADHA, or HADHB)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) products

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management

AND

6 - If not diagnosed by newborn screening, patient has a history of clinical manifestations of long-chain fatty acid oxidation disorders LC-FAOD (e.g., rhabdomyolysis)

Product Name:Dojolvi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dojolvi therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management

2 . Revision History

Date	Notes
7/3/2024	New guideline

Dojolvi

Prior Authorization Guideline

Guideline ID	GL-148834
Guideline Name	Dojolvi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/3/2024

1 . Criteria

Product Name:Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming the diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) with at least two of the following diagnostic criteria:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- Genetic testing demonstrating one or more pathogenic mutations in a gene associated with long-chain fatty acid oxidation disorders (e.g., CPT2, ACADVL, HADHA, or HADHB)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) products

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management

AND

6 - If not diagnosed by newborn screening, patient has a history of clinical manifestations of long-chain fatty acid oxidation disorders LC-FAOD (e.g., rhabdomyolysis)

Product Name:Dojolvi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dojolvi therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.)

AND

2 - Patient is not receiving Dojolvi in combination with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by a board certified medical geneticist experienced in the treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

AND

4 - Target recommended daily dosage does not exceed 35% of the patient's total prescribed daily caloric intake (DCI)

AND

5 - Patient is receiving disease related dietary management

2 . Revision History

Date	Notes
7/3/2024	New guideline

Donepezil 23mg

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129311
Guideline Name	Donepezil 23mg
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:generic donepezil 23 mg	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to donepezil at a minimum dose of 10 mg (milligrams) daily for 90 days, as confirmed by claims history or submission of medical records **OR** **2** - History of contraindication or intolerance to donepezil 10 mg (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
8/3/2023	Updated formularies

Doptelet

Prior Authorization Guideline

Guideline ID	GL-180207
Guideline Name	Doptelet
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Doptelet	
Diagnosis	Thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - ONE of the following:

4.1 Failure to Mulpleta (lusutrombopag) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to Mulpleta (lusutrombopag) (please specify contraindication or intolerance)

Product Name:Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to at least ONE of the following as confirmed by claims history or submission of medical records:

- Corticosteroids
- Immunoglobulins

OR

2.1.1.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Corticosteroids
- Immunoglobulins

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to Promacta (eltrombopag) as confirmed by claims history or submission of medical records

OR

2.1.2.2 History of contraindication or intolerance to Promacta (eltrombopag) (please specify contraindication or intolerance)

OR

2.2 Patient is currently on Doptelet therapy

Product Name:Doptelet	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Doptelet therapy	

2 . Revision History

Date	Notes
2/20/2025	Updated formularies

DPP-4 Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-197191
Guideline Name	DPP-4 Inhibitors
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Alogliptin, Alogliptin/metformin, Alogliptin/pioglitazone, Brand Onglyza, generic saxagliptin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient has a diagnosis of type 2 diabetes mellitus	

AND

2 - One of the following:

2.1 Suboptimal response (i.e. suboptimal glycemic control) to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

Product Name:Alogliptin, Alogliptin/metformin, Alogliptin/pioglitazone, Brand Onglyza, generic saxagliptin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

Product Name:Nesina, Kazano, Oseni	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 Suboptimal response (i.e. suboptimal glycemic control) to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

AND

3 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use ONE of the following (please document reason/special circumstance):

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)

Product Name:Nesina, Kazano, Oseni	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use ONE of the following (please document reason/special circumstance):

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)

Product Name:Januvia, Janumet, Janumet XR, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Zituvimet, Zituvimet XR, Zituvio, Sitagliptin, Sitagliptin/metformin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 Suboptimal response (i.e. suboptimal glycemic control) to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 Failure to a 90 day trial with ONE of the following as confirmed by claims history or submission of medical records:

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)
- Saxagliptin (generic Onglyza)

OR

3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication)

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)
- Alogliptin/pioglitazone (authorized generic of Oseni)
- Saxagliptin (generic Onglyza)

Product Name:Januvia, Janumet, Janumet XR, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Zituvimet, Zituvimet XR, Zituvio, Sitagliptin, Sitagliptin/metformin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use ONE of the following (please document reason/special circumstance):

- Alogliptin (authorized generic of Nesina)
- Alogliptin/metformin (authorized generic of Kazano)

- Alogliptin/pioglitazone (authorized generic of Oseni)

2 . Revision History

Date	Notes
2/25/2025	Rhode Island market specific policy to maintain step thru generics fir st (metformin) per state directive. Added generic Onglyza to list of ste p therapy options. Separated preferred authorized generic with brand ed versions to ensure appropriate MSC M review would occur

Dry Eye Disease

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155385
Guideline Name	Dry Eye Disease
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Restasis Multidose, Brand Restasis, Cequa, Tyrvaya, Vevye, Miebo, Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to ONE of the following:

1.1 Moderate to severe keratoconjunctivitis sicca

OR

1.2 Moderate to severe dry eye disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery [e.g., LASIK (laser-assisted in situ keratomileusis)]

AND

3 - Failure to at least two OTC (over-the-counter) artificial tear products (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

AND

4 - ONE of the following:

4.1 Failure to cyclosporine emulsion 0.05% (generic Restasis) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to cyclosporine emulsion 0.05% (generic Restasis) (please specify contraindication or intolerance)

AND

5 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

AND

6 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

Product Name:Generic cyclosporine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Tear deficiency associated with ocular inflammation due to ONE of the following:

1.1 Moderate to severe keratoconjunctivitis sicca

OR

1.2 Moderate to severe dry eye disease

AND

2 - Not prescribed to manage dry eyes peri-operative elective eye surgery [e.g., LASIK (laser-assisted in situ keratomileusis)]

AND

3 - Failure to at least two OTC (over-the-counter) artificial tear products (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

AND

4 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

AND

5 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist
- Rheumatologist

Product Name:Restasis Multidose, Brand Restasis, generic cyclosporine, Xiidra, Cequa, Tyrvaya, Vevye, Miebo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated clinically significant improvement with therapy

AND

2 - Medication will not be used in combination with another prescription product for dry eye disease or keratoconjunctivitis sicca (e.g., Miebo, Restasis single dose-vials, Tyrvaya, Xiidra)

2 . Revision History

Date	Notes
9/20/2024	Updated criteria due to generic Restasis move to preferred, Xiidra m oved to non-preferred. Added language on concomitant therapy.

Duexis and Vimovo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127919
Guideline Name	Duexis and Vimovo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Duexis, generic ibuprofen/famotidine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

AND

2 - ONE of the following:

2.1 Failure to THREE combinations of preferred* NSAIDS, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred* H2-receptor antagonists, as confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to ALL preferred* NSAIDs and ALL preferred* H2-receptor antagonists (please specify contraindication or intolerance)

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination

Notes	*PDL links in Background

Product Name:Brand Vimovo, generic naproxen/esomeprazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

AND

2 - ONE of the following:

2.1 Failure to THREE combinations of preferred* NSAIDS, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred* proton pump inhibitors, as confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to ALL preferred* NSAIDs and ALL preferred* proton pump inhibitors (please specify contraindication or intolerance)

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination

Notes	*PDL links in Background

2 . Background

Benefit/Coverage/Program Information

PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
7/13/2023	Removed ACUAZ and RMH formularies. Updated PDL Links.

Duexis and Vimovo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127919
Guideline Name	Duexis and Vimovo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Duexis, generic ibuprofen/famotidine	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

AND

2 - ONE of the following:

2.1 Failure to THREE combinations of preferred* NSAIDS, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred* H2-receptor antagonists, as confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to ALL preferred* NSAIDs and ALL preferred* H2-receptor antagonists (please specify contraindication or intolerance)

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Duexis instead of taking individual products in combination

Notes	*PDL links in Background

Product Name:Brand Vimovo, generic naproxen/esomeprazole	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following risk factors for NSAID (non-steroidal anti-inflammatory drug)-induced adverse GI (gastrointestinal) events:

- Patient is greater than or equal to 65 years of age
- Prior history of peptic, gastric, or duodenal ulcer
- History of NSAID-related ulcer
- History of clinically significant GI bleeding
- Untreated or active H. Pylori (helicobacter pylori) gastritis
- Concurrent use of oral corticosteroids (e.g., prednisone, prednisolone, dexamethasone)
- Concurrent use of anticoagulants (e.g., warfarin, heparin)
- Concurrent use of antiplatelets (e.g., aspirin including low-dose, clopidogrel)

AND

2 - ONE of the following:

2.1 Failure to THREE combinations of preferred* NSAIDS, one of which must be celecoxib (generic Celebrex), taken concomitantly with preferred* proton pump inhibitors, as confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to ALL preferred* NSAIDs and ALL preferred* proton pump inhibitors (please specify contraindication or intolerance)

AND

3 - Physician has provided rationale for needing to use fixed-dose combination therapy with Vimovo instead of taking individual products in combination

Notes	*PDL links in Background

2 . Background

Benefit/Coverage/Program Information

PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
7/13/2023	Removed ACUAZ and RMH formularies. Updated PDL Links.

Duopa

Prior Authorization Guideline

Guideline ID	GL-164341
Guideline Name	Duopa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Duopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's disease

AND

2 - Patient experiences a wearing “off” phenomenon that cannot be managed by increasing the dose of oral levodopa

AND

3 - Has undergone or has planned placement of a procedurally-placed tube

AND

4 - Prescribed by or in consultation with a neurologist

Product Name:Duopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Duopa therapy

2 . Revision History

Date	Notes
1/27/2025	Updated initial auth criteria

Dupixent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164410
Guideline Name	Dupixent
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 Failure to TWO of the following therapeutic classes of topical therapies as confirmed by claims history or submission of medical records:

- One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.2 History of contraindication or intolerance to ALL of the following therapeutic classes of topical therapies (please specify contraindication or intolerance):

- One medium, high, or very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.3 Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Dupixent in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name:Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient is NOT receiving Dupixent in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name:Dupixent	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe asthma

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

- Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]
- Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

2.1.2 Dupixent will be used in combination with ONE of the following:

2.1.2.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)] (see Table 2 in Background)

OR

2.1.2.2 Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)] (see Table 2 in Background)
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

2.1.3 ONE of the following:

- Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter
- Patient is currently dependent on oral corticosteroids for the treatment of asthma

OR

2.2 BOTH of the following:

2.2.1 Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

AND

2.2.2 Dupixent will be used in combination with ONE of the following:

2.2.2.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick

(fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.2.2.2 Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent will be used in combination with ONE of the following:

2.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

2.2 Combination therapy including BOTH of the following:

- ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]
- ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by ALL of the following:

1.1.1 TWO or more of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

AND

1.1.2 ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus

- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

1.1.3 ONE of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

AND

1.1.4 ONE of the following:

1.1.4.1 Patient has required prior sinus surgery

OR

1.1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

OR

1.1.4.3 Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

OR

1.2 BOTH of the following:

- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Patient is currently on Dupixent therapy as confirmed by claims history or submission of medical records

AND

2 - Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone), as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Dupixent	
Diagnosis	Eosinophilic Esophagitis
Approval Length	6 month(s)*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis

AND

2 - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of 15 or more intraepithelial eosinophils per high power field (HPF) [or 60 eosinophils per mm^2 (square millimeters)]

AND

4 - Secondary causes of esophageal eosinophilia have been ruled out

AND

5 - Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least ONE of the following, as confirmed by claims history or submission of medical records:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

6 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Gastroenterologist

Notes	*If clinical criteria is met, enter a GPI-10 authorization with a MDD of 0 .3 mL.

Product Name:Dupixent	
Diagnosis	Eosinophilic Esophagitis
Approval Length	6 month(s)*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy as evidenced by improvement of at least ONE of the following from baseline:

- Symptoms (e.g., dysphagia, chest pain, heartburn)
- Histologic measures (e.g., esophageal intraepithelial eosinophil count)
- Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

AND

2 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

3 - Prescribed by or in consultation with a gastroenterologist or allergist

Notes	*If clinical criteria is met, enter a GPI-10 authorization with a MDD of 0 .3 mL.

Product Name:Dupixent	
Diagnosis	Prurigo Nodularis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prurigo nodularis

AND

2 - Patient has greater than or equal to 20 nodular lesions

AND

3 - ONE of the following:

3.1 Failure to at least one previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to all other prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin) (please specify contraindication or intolerance)

AND

4 - Patient is NOT receiving Dupixent in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]

- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name:Dupixent	
Diagnosis	Prurigo Nodularis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Dupixent therapy

AND

2 - Patient is NOT receiving Dupixent in combination with either of the following:

- Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
- Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist

- Immunologist

Product Name:Dupixent	
Diagnosis	Chronic Obstructive Pulmonary Disorder (COPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic Obstructive Pulmonary Disorder (COPD)

AND

2 - Submission of documentation (e.g., medical records, chart notes) of ALL of the following:

- Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7
- Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70%
- Patient has an eosinophilic phenotype defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level greater than or equal to 300 cells/µL

AND

3 - Uncontrolled or inadequately controlled COPD demonstrated by both of the following:

3.1 One of the following:

- Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
- One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

AND

3.2 COPD exacerbation(s) occurred while receiving maintenance therapy with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

4 - Symptoms of chronic productive cough for at least 3 months in the past year

AND

5 - Dupixent will be used as add-on maintenance therapy with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

6 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist

- Pulmonologist

Product Name:Dupixent	
Diagnosis	Chronic Obstructive Pulmonary Disorder (COPD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Dupixent therapy as demonstrated by at least one of the following:

- Reduction in the frequency of COPD exacerbations
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)
- Reduction in oral corticosteroid requirements

AND

2 - Dupixent will be used as add-on maintenance therapy with one of the following:

- Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
- Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

AND

3 - Patient is NOT receiving Dupixent in combination with any of the following:

- Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

2 . Background

Benefit/Coverage/Program Information

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05

	tridifloronide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium, and high daily doses of inhaled corticosteroids. Adults and adolescents (12 years of age and older)

Drug	Daily dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclomethasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	N/A	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3 . Revision History

Date	Notes
1/28/2025	Updated prescriber check language throughout to be consistent and allow for consultation

Duvyzat

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155454
Guideline Name	Duvyzat
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Duvyzat	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Diagnosis confirmed by the presence of a mutation in the DMD gene

AND

3 - Patient is 6 years of age or older

AND

4 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

5 - Patient has been or will be established on a stable corticosteroid regimen

AND

6 - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

AND

7 - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

AND

8 - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g.,

Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

Product Name:Duvyzat	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician attestation that patient would benefit from continued administration

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Patient continues to receive concomitant corticosteroid regimen

AND

4 - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

AND

5 - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

AND

6 - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

2 . Revision History

Date	Notes
9/23/2024	New guideline

Duvyzat

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155454
Guideline Name	Duvyzat
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Duvyzat	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Diagnosis confirmed by the presence of a mutation in the DMD gene

AND

3 - Patient is 6 years of age or older

AND

4 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

5 - Patient has been or will be established on a stable corticosteroid regimen

AND

6 - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

AND

7 - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

AND

8 - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g.,

Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

Product Name:Duvyzat	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Physician attestation that patient would benefit from continued administration

AND

2 - Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

AND

3 - Patient continues to receive concomitant corticosteroid regimen

AND

4 - Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD

AND

5 - Patient has not received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)]

AND

6 - Patient will not receive Duvyzat in combination with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]

2 . Revision History

Date	Notes
9/23/2024	New guideline

Effient

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-62717
Guideline Name	Effient
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2020

1 . Criteria

Product Name:Brand Effient, generic prasugrel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute coronary syndrome (ACS) [e.g., unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) or ST-segment elevation myocardial infarction (STEMI)]

AND

2 - Patient managed with percutaneous coronary intervention (PCI)

2 . Revision History

Date	Notes
2/27/2020	C&S 2020 IMPLENTATIONS

Egrifta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123713
Guideline Name	Egrifta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Egrifta SV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of human immunodeficiency virus (HIV)-associated lipodystrophy

2 . Revision History

Date	Notes
3/24/2023	No criteria changes. Combined Markets in Scope

Eliquis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-62718
Guideline Name	Eliquis
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2020

1 . Criteria

Product Name:Eliquis, Eliquis Starter Pack	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Atrial fibrillation

OR

1.2 Deep vein thrombosis

OR

1.3 Pulmonary embolism

OR

1.4 Knee replacement

OR

1.5 Hip replacement

OR

1.6 Presence of artificial hip/knee joint

2 . Revision History

Date	Notes
2/27/2020	C&S 2020 IMPLENTATIONS

Elmiron

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117347
Guideline Name	Elmiron
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Elmiron	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis

2 . Revision History

Date	Notes
11/30/2022	Updated formularies and indication box

Emflaza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161230
Guideline Name	Emflaza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Emflaza, generic deflazacort	
Diagnosis	Duchenne Muscular Dystrophy
Guideline Type	Prior Authorization
Approval Criteria	

1 - Published clinical evidence shows Emflaza is likely to produce equivalent therapeutic results as other available corticosteroids (e.g., prednisone); therefore, Emflaza is not medically necessary for treatment of Duchenne muscular dystrophy	
Notes	All requests for authorization will be denied by OptumRx and must be submitted through the appeals process to the UnitedHealthcare Com munity Plan Pharmacy Appeals team for consideration.

2 . Revision History

Date	Notes
11/25/2024	Updated GPIs and product list to add generic

Empaveli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148061
Guideline Name	Empaveli
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient will not be prescribed Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris)

OR

2.2 Patient is currently receiving another complement inhibitor (e.g., Fabhalta, Soliris, Ultomiris) which will be discontinued and Empaveli will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Empaveli therapy [e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH (lactate dehydrogenase), increased reticulocyte count, etc.]

AND

2 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) (e.g., Fabhalta, Soliris, Ultomiris)

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

2 . Revision History

Date	Notes
6/4/2024	In initial auth section, simplified criteria language for converting to ne w complement inhibitor therapy.

Empaveli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148061
Guideline Name	Empaveli
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient will not be prescribed Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris)

OR

2.2 Patient is currently receiving another complement inhibitor (e.g., Fabhalta, Soliris, Ultomiris) which will be discontinued and Empaveli will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Empaveli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Empaveli therapy [e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH (lactate dehydrogenase), increased reticulocyte count, etc.]

AND

2 - Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) (e.g., Fabhalta, Soliris, Ultomiris)

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

2 . Revision History

Date	Notes
6/4/2024	In initial auth section, simplified criteria language for converting to ne w complement inhibitor therapy.

Enbrel

Prior Authorization Guideline

Guideline ID	GL-180212
Guideline Name	Enbrel
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of rheumatoid arthritis confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

AND

1.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active rheumatoid arthritis

AND

2.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Product Name:Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Enbrel	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

AND

1.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name:Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of moderate to severe chronic plaque psoriasis

AND

1.2 ONE of the following:

1.2.1 ALL of the following:

1.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.2.1.2 ONE of the following:

1.2.1.2.1 Failure to one of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to all of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

1.2.1.3 ONE of the following:

1.2.1.3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

1.2.1.3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of plaque psoriasis as confirmed by claims

history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

1.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.4 Prescribed by or in consultation with a dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderate to severe chronic plaque psoriasis

AND

2.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Product Name:Enbrel	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 ONE of the following:

1.2.1 Failure to two non-steroidal anti-inflammatory drugs (NSAIDs: e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab)]

AND

1.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator

[e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - All of the following:

2.1 Patient is currently on Enbrel therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Product Name:Enbrel	
Diagnosis	Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (PJIA), Plaque Psoriasis, Ankylosing Spondylitis, Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Enbrel therapy **AND** **2** - Patient is NOT receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Revision History

Date	Notes
2/20/2025	Updated formularies. Replaced Stelara with ustekinumab throughout

Endari

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123716
Guideline Name	Endari
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of sickle cell disease
- Used to reduce acute complications of sickle cell disease

AND

2 - ONE of the following:

- Patient is using Endari with concurrent hydroxyurea therapy
- Patient is unable to take hydroxyurea due to a contraindication or intolerance (please specify contraindication or intolerance)

AND

3 - Patient has had 2 or more painful sickle cell crises within the past 12 months

Product Name:Endari	
Diagnosis	Sickle cell disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Endari therapy

2 . Revision History

Date	Notes

3/24/2023	Updated contraindication and intolerance language.

Enspryng

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160434
Guideline Name	Enspryng
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies

AND

3 - History of failure, contraindication, or intolerance to rituximab therapy

AND

4 - One of the following:

- History of one or more relapses that required rescue therapy during the previous 12 months
- History of two or more relapses that required rescue therapy during the previous 24 months

AND

5 - Prescribed by, or in consultation with, a neurologist

AND

6 - Patient is NOT receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]

Product Name:Enspryng

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Enspryng therapy

AND

2 - Prescribed by, or in consultation with, a neurologist

AND

3 - Patient is NOT receiving Enspryng in combination with any of the following:

- Disease modifying therapies for the treatment of multiple sclerosis [e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.]
- Complement inhibitors [e.g., Soliris (eculizumab), Ultomiris (ravulizumab), etc]
- Anti-IL6 (anti-interleukin-6) therapy [e.g., Actemra (tocilizumab)]
- B-cell depletion therapy [e.g., rituximab, Uplizna (inebilizumab)]

2 . Revision History

Date	Notes
11/11/2024	Updated examples of complement inhibitors

Entocort

Prior Authorization Guideline

Guideline ID	GL-120232
Guideline Name	Entocort
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:budesonide caps	
Diagnosis	Crohn’s Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Used for the treatment of Crohn’s disease

2 . Revision History

Date	Notes
1/17/2023	Updated guideline name, updated GPI and product name lists, updated criteria, fixed typo in indication.

Entresto

Prior Authorization Guideline

Guideline ID	GL-158342
Guideline Name	Entresto
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Entresto, Entresto Sprinkles	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Request is for continuation of therapy initiated during an inpatient stay

OR

2 - ALL of the following:

2.1 Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

AND

2.2 Prescribed by or in consultation with a cardiologist

AND

2.3 If the request is for Entresto Sprinkles, the prescriber has given a clinical reason or special circumstance why the patient is unable to use regular Entresto tablets

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 ONE of the following:

3.2.1 Ejection fraction is less than or equal to 40 percent

OR

3.2.2 BOTH of the following:

3.2.2.1 Ejection fraction is greater than 40 percent

AND

3.2.2.2 Patient has structural heart disease [i.e., left atrial enlargement (LAE) or left ventricular hypertrophy (LVH)]

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 Patient does not have a history of angioedema

AND

3.5 Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto*

AND

3.6 Patient is not concomitantly on aliskiren therapy

AND

3.7 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	*ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto.

Product Name:Entresto, Entresto Sprinkles

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg (milligrams)/103 mg twice daily or the maximum labeled dose for pediatric patients, or to a maximum dose as tolerated by the patient

AND

2 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/31/2024	Updated formularies. No clinical changes.

Entresto

Prior Authorization Guideline

Guideline ID	GL-158342
Guideline Name	Entresto
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Entresto, Entresto Sprinkles	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Request is for continuation of therapy initiated during an inpatient stay

OR

2 - ALL of the following:

2.1 Diagnosis of pediatric heart failure with systemic left ventricular systolic dysfunction which is symptomatic

AND

2.2 Prescribed by or in consultation with a cardiologist

AND

2.3 If the request is for Entresto Sprinkles, the prescriber has given a clinical reason or special circumstance why the patient is unable to use regular Entresto tablets

OR

3 - ALL of the following:

3.1 Diagnosis of heart failure (with or without hypertension)

AND

3.2 ONE of the following:

3.2.1 Ejection fraction is less than or equal to 40 percent

OR

3.2.2 BOTH of the following:

3.2.2.1 Ejection fraction is greater than 40 percent

AND

3.2.2.2 Patient has structural heart disease [i.e., left atrial enlargement (LAE) or left ventricular hypertrophy (LVH)]

AND

3.3 Heart failure is classified as ONE of the following:

- New York Heart Association Class II
- New York Heart Association Class III
- New York Heart Association Class IV

AND

3.4 Patient does not have a history of angioedema

AND

3.5 Patient will discontinue any use of concomitant ACE (angiotensin converting enzyme) Inhibitor or ARB (angiotensin II receptor blocker) before initiating treatment with Entresto*

AND

3.6 Patient is not concomitantly on aliskiren therapy

AND

3.7 Entresto is prescribed by, or in consultation with, a cardiologist

Notes	*ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto.

Product Name:Entresto, Entresto Sprinkles

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The Entresto dose has been titrated to a dose of 97 mg (milligrams)/103 mg twice daily or the maximum labeled dose for pediatric patients, or to a maximum dose as tolerated by the patient

AND

2 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/31/2024	Updated formularies. No clinical changes.

Entyvio SC

Prior Authorization Guideline

Guideline ID	GL-180216
Guideline Name	Entyvio SC
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Entyvio SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous Entyvio in place of Entyvio administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

3 - ONE of the following:

3.1 Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

3.2 Patient is currently on Entyvio for subcutaneous use therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is NOT receiving Entyvio for subcutaneous use in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Entyvio SC

Diagnosis	Crohn's disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous Entyvio in place of Entyvio administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

3 - ONE of the following:

3.1 Patient has been established on therapy with Entyvio under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active Crohn's disease

OR

3.2 Patient is currently on Entyvio for subcutaneous use therapy as confirmed by claims history or submission of medical records

AND

4 - Patient is NOT receiving Entyvio in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Entyvio SC	
Diagnosis	Ulcerative Colitis (UC), Crohn’s disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Entyvio for subcutaneous use therapy

AND

2 - Patient is not receiving Entyvio in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]

2 . Revision History

Date	Notes
2/20/2025	Updated formularies. Replaced Stelara with ustekinumab throughout program. Updated bypass language for current users

Eohilia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150994
Guideline Name	Eohilia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/6/2024

1 . Criteria

Product Name:Eohilia	
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of eosinophilic esophagitis (EoE)

AND

2 - Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high power field (HPF)

AND

4 - Secondary causes of esophageal eosinophilia have been ruled out

AND

5 - One of the following:

5.1 Failure to an 8 week trial of both of the following as confirmed by claims history or submission of medical records:

- Proton pump inhibitor (e.g., pantoprazole, omeprazole)
- Inhalational corticosteroid administered orally [e.g., budesonide inhalation suspension (generic Pulmicort Respules), Fluticasone HFA (Flovent HFA authorized generic)]

OR

5.2 History of contraindication or intolerance to both of the following (please specify intolerance or contraindication):

- Proton pump inhibitor (e.g., pantoprazole, omeprazole)
- Inhalational corticosteroid administered orally [e.g., budesonide inhalation suspension (generic Pulmicort Respules), Fluticasone HFA (Flovent HFA authorized generic)]

AND

6 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Gastroenterologist

2 . Revision History

Date	Notes
8/6/2024	New Guideline

Epaned

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134132
Guideline Name	Epaned
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:generic enalapril oral soln, Brand Epaned	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient is less than 8 years of age

OR

2 - BOTH of the following:

2.1 ONE of the following diagnoses:

- Hypertension
- Heart failure
- Asymptomatic left ventricular dysfunction, defined as left ventricular ejection fraction less than or equal to 35%

AND

2.2 ONE of the following:

2.2.1 Failure to TWO formulary oral anti-hypertensives [e.g., angiotensin-converting enzyme (ACE) inhibitor, ACE inhibitor combination, angiotensin-receptor blocker (ARB), ARB combination, thiazide diuretic] as confirmed by claims history or submission of medical records

OR

2.2.2 History of contraindication or intolerance to ALL formulary oral anti-hypertensives (e.g., ACE inhibitor, ACE inhibitor combination, ARB, ARB combination, thiazide diuretic) (please specify contraindication or intolerance)

OR

2.2.3 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to ONE of the following:

- Oral/motor difficulties
- Dysphagia

2 . Revision History

Date	Notes
10/2/2023	Removed RMHP formulary

Erivedge

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117353
Guideline Name	Erivedge
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic basal cell carcinoma

OR

2 - BOTH of the following:

2.1 Diagnosis of locally advanced basal cell carcinoma

AND

2.2 ONE of the following:

- Cancer has recurred following surgery
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name:Erivedge	
Diagnosis	Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medulloblastoma

AND

2 - Patient has mutations in the sonic hedgehog pathway

AND

3 - Patient has failed prior chemotherapy

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma, Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erivedge therapy

Product Name:Erivedge	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Erivedge	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Erivedge therapy

2 . Revision History

Date	Notes
12/1/2022	Updated formularies, cleaned up criteria.

Erivedge

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117353
Guideline Name	Erivedge
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic basal cell carcinoma

OR

2 - BOTH of the following:

2.1 Diagnosis of locally advanced basal cell carcinoma

AND

2.2 ONE of the following:

- Cancer has recurred following surgery
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name:Erivedge	
Diagnosis	Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medulloblastoma

AND

2 - Patient has mutations in the sonic hedgehog pathway

AND

3 - Patient has failed prior chemotherapy

Product Name:Erivedge	
Diagnosis	Basal Cell Carcinoma, Medulloblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erivedge therapy

Product Name:Erivedge	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Erivedge	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Erivedge therapy

2 . Revision History

Date	Notes
12/1/2022	Updated formularies, cleaned up criteria.

Erleada

Prior Authorization Guideline

Guideline ID	GL-138262
Guideline Name	Erleada
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Disease is castration-resistant or recurrent
- Disease is non-metastatic

OR

2.2 BOTH of the following:

- Disease is castration-sensitive or naïve
- Disease is metastatic

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name:Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erleada therapy

Product Name:Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erleada therapy

2 . Revision History

Date	Notes

12/28/2023	Updated GPI list.

Erleada

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138262
Guideline Name	Erleada
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Disease is castration-resistant or recurrent
- Disease is non-metastatic

OR

2.2 BOTH of the following:

- Disease is castration-sensitive or naïve
- Disease is metastatic

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name:Erleada	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Erleada therapy

Product Name:Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Erleada	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Erleada therapy

2 . Revision History

Date	Notes

12/28/2023	Updated GPI list.

Erythropoietic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145867
Guideline Name	Erythropoietic Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Hematocrit is less than 30 percent at initiation of therapy

AND

3 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

AND

4 - ONE of the following:

4.1 Patient is on dialysis

OR

4.2 ALL of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion-related risks

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is on dialysis

AND

2.1.2 Hematocrit remains less than 33 percent

OR

2.2 ALL of the following:

2.2.1 Patient is NOT on dialysis

AND

2.2.2 Hematocrit remains less than 30 percent

AND

2.2.3 Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

2 - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than 30 percent at initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

3 - Endogenous serum erythropoietin level less than or equal to 500 milliunits per milliliter

AND

4 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit less than or equal to 30 percent at initiation of therapy

AND

2 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency) and there is documentation of normal iron stores

AND

3 - One of the following:

3.1 Patient has moderate to severe chronic kidney disease (CKD)

OR

3.2 Undergoing palliative treatment

OR

3.3 Receiving myelosuppressive chemotherapy not given with curative intent

OR

3.4 Both of the following:

- Receiving myelosuppressive chemotherapy with curative intent
- Patient is refusing blood transfusion(s)

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Chemotherapy is given as palliative treatment

AND

3 - Hematocrit remains less than 30 percent for continuation of therapy

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Perioperative hematocrit is greater than 30 percent and less than or equal to 39 percent

AND

2 - Patient is expected to require at least 2 units of blood during the surgical procedure

AND

3 - Patient is at high risk for blood loss during surgery

AND

4 - Patient is unable or unwilling to donate autologous blood

AND

5 - Surgery procedure is elective, non-cardiac, and non-vascular

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome (MDS)

AND

2 - Serum erythropoietin level less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than or equal to 30 percent at the initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

AND

5 - Treatment of lower risk [defined as IPSS-R (Very Low, Low, Intermediate)] disease with symptomatic anemia

AND

6 - One of the following:

6.1 Patient is with del(5q) chromosomal abnormality

OR

6.2 Both of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts less than 15% (or ring sideroblasts less than 5% with an SF3B1 mutation)

OR

6.3 All of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts greater than or equal to15% (or ring sideroblasts greater than or equal to 5% with an SF3B1 mutation)
- Following no response to Reblozyl (luspatercept-aamt)

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

AND

2 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

3 - Serum erythropoietin level less than or equal to 500 milliunits per milliliter

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Serum erythropoietin level less than or equal to 500 mUnits/mL

AND

2 - Hematocrit is less than or equal to 30 percent at the initiation of therapy

AND

3 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Serum erythropoietin level less than or equal to 500 mUnits/mL

AND

3 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C virus (HCV) infection

AND

2 - Patient is receiving ribavirin and interferon therapy

AND

3 - Hematocrit is less than or equal to 30 percent at initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit remains less than or equal to 36 percent for continuation of care

AND

2 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

3 - Patient is receiving ribavirin and interferon therapy

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Erythropoietin Stimulating Agents -Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

AND

2 - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30 percent will not be approved

2 . Revision History

Date	Notes
4/18/2024	Removed step therapy criteria for Epogen, Procrit. Updated criteria f or Anemia Due to Chemo & MDS. New criteria for Myeloproliferative Neoplasms. Updated GPIs

Erythropoietic Agents

Prior Authorization Guideline

Guideline ID	GL-145867
Guideline Name	Erythropoietic Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Hematocrit is less than 30 percent at initiation of therapy

AND

3 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

AND

4 - ONE of the following:

4.1 Patient is on dialysis

OR

4.2 ALL of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hematocrit decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion-related risks

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient is on dialysis

AND

2.1.2 Hematocrit remains less than 33 percent

OR

2.2 ALL of the following:

2.2.1 Patient is NOT on dialysis

AND

2.2.2 Hematocrit remains less than 30 percent

AND

2.2.3 Therapeutic goal is reducing the risk of alloimmunization and/or other RBC transfusion

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

2 - Endogenous serum erythropoietin level is less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than 30 percent at initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Zidovudine Treatment in HIV-Infected Patients

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Patient is receiving zidovudine administered at less than or equal to 4200 milligrams per week

AND

3 - Endogenous serum erythropoietin level less than or equal to 500 milliunits per milliliter

AND

4 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit less than or equal to 30 percent at initiation of therapy

AND

2 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency) and there is documentation of normal iron stores

AND

3 - One of the following:

3.1 Patient has moderate to severe chronic kidney disease (CKD)

OR

3.2 Undergoing palliative treatment

OR

3.3 Receiving myelosuppressive chemotherapy not given with curative intent

OR

3.4 Both of the following:

- Receiving myelosuppressive chemotherapy with curative intent
- Patient is refusing blood transfusion(s)

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Due to Cancer Chemotherapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Chemotherapy is given as palliative treatment

AND

3 - Hematocrit remains less than 30 percent for continuation of therapy

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Preoperative Use for Reduction of Allogeneic Blood Transfusions in Surgery Patients
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Perioperative hematocrit is greater than 30 percent and less than or equal to 39 percent

AND

2 - Patient is expected to require at least 2 units of blood during the surgical procedure

AND

3 - Patient is at high risk for blood loss during surgery

AND

4 - Patient is unable or unwilling to donate autologous blood

AND

5 - Surgery procedure is elective, non-cardiac, and non-vascular

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome (MDS)

AND

2 - Serum erythropoietin level less than or equal to 500 milliunits per milliliter

AND

3 - Hematocrit is less than or equal to 30 percent at the initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

AND

5 - Treatment of lower risk [defined as IPSS-R (Very Low, Low, Intermediate)] disease with symptomatic anemia

AND

6 - One of the following:

6.1 Patient is with del(5q) chromosomal abnormality

OR

6.2 Both of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts less than 15% (or ring sideroblasts less than 5% with an SF3B1 mutation)

OR

6.3 All of the following:

- Patient is without del(5q) chromosomal abnormality
- Ring sideroblasts greater than or equal to15% (or ring sideroblasts greater than or equal to 5% with an SF3B1 mutation)
- Following no response to Reblozyl (luspatercept-aamt)

Product Name:Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Associated with Myelodysplastic syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

AND

2 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

3 - Serum erythropoietin level less than or equal to 500 milliunits per milliliter

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Serum erythropoietin level less than or equal to 500 mUnits/mL

AND

2 - Hematocrit is less than or equal to 30 percent at the initiation of therapy

AND

3 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Anemia associated with Myeloproliferative Neoplasms – Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

2 - Serum erythropoietin level less than or equal to 500 mUnits/mL

AND

3 - Hematocrit remains less than or equal to 36 percent for continuation of therapy

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C virus (HCV) infection

AND

2 - Patient is receiving ribavirin and interferon therapy

AND

3 - Hematocrit is less than or equal to 30 percent at initiation of therapy

AND

4 - Patient does not have evidence of other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency)

Product Name:Epogen, Procrit, Retacrit	
Diagnosis	Anemia in Patients with Hepatitis C with Ribavirin and Interferon Therapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Hematocrit remains less than or equal to 36 percent for continuation of care

AND

2 - Documentation of positive clinical response to erythropoietin stimulating agent (ESA) therapy

AND

3 - Patient is receiving ribavirin and interferon therapy

Product Name:Aranesp, Epogen, Procrit, Retacrit	
Diagnosis	Erythropoietin Stimulating Agents -Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist

AND

2 - Requests for coverage in patients with hemoglobin (Hgb) greater than 10 grams per deciliter or hematocrit (Hct) greater than 30 percent will not be approved

2 . Revision History

Date	Notes
4/18/2024	Removed step therapy criteria for Epogen, Procrit. Updated criteria f or Anemia Due to Chemo & MDS. New criteria for Myeloproliferative Neoplasms. Updated GPIs

Esbriet, Ofev

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124639
Guideline Name	Esbriet, Ofev
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Brand Esbriet, generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by ALL of the following:

1.1 Exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by an ICD-10 Code of J84.112 (idiopathic pulmonary fibrosis)

AND

1.2 ONE of the following:

1.2.1 If the patient was NOT subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

OR

1.2.2 If the patient was subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF

AND

2 - ONE of the following:

2.1 If the request is for Esbriet (pirfenidone), it is not being used in combination with Ofev

OR

2.2 If the request is for Ofev, it is not being used in combination with Esbriet (pirfenidone)

AND

3 - The prescriber is a pulmonologist

Product Name:Brand Esbriet, generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

AND

2 - ONE of the following:

2.1 If the request is for Esbriet (pirfenidone), it is not being used in combination with Ofev

OR

2.2 If the request is for Ofev, it is not being used in combination with Esbriet (pirfenidone)

AND

3 - The prescriber is a pulmonologist

Product Name:Ofev	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 At least TWO of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies [e.g., anticentromere, anti-topoisomerase I, anti-RNA (ribonucleic acid) polymerase III]

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on high-resolution computed tomography (HRCT), involving at least 10% of the lungs

AND

2 - Ofev is not being used in combination with Esbriet (pirfenidone)

AND

3 - The prescriber is a pulmonologist

Product Name:Ofev	
Diagnosis	Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by BOTH of the following:

1.1 Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

AND

1.2 Patient is presenting with clinical signs of progression as defined by ONE of the following in the previous 24 months:

1.2.1 Forced vital capacity (FVC) decline of greater than 10%

OR

1.2.2 TWO of the following:

- FVC decline of greater than or equal to 5%, but less than 10%
- Patient is experiencing worsening respiratory symptoms
- Patient is exhibiting increasing extent of fibrotic changes on chest imaging

AND

2 - Ofev is not being used in combination with Esbriet (pirfenidone)

AND

3 - The prescriber is a pulmonologist

Product Name:Ofev

Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease, Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ofev therapy

AND

2 - Ofev is not being used in combination with Esbriet (pirfenidone)

AND

3 - The prescriber is a pulmonologist

2 . Revision History

Date	Notes
4/13/2023	Added GPI for generic pirfenidone. Updated Esbriet language throug h out criteria to include generic pirfenidone.

Eucrisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138360
Guideline Name	Eucrisa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Eucrisa	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide] as confirmed by claims history or submission of medical records

OR

1.1.2 History of contraindication or intolerance ONE topical corticosteroid [e.g., mometasone furoate, fluocinolone acetonide (generic Synalar), fluocinonide] (please specify contraindication or intolerance)

AND

1.2 ONE of the following:

1.2.1 Patient is less than 2 years of age

OR

1.2.2 Patient is greater than or equal to 2 years of age and ONE of the following:

- Failure to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)] as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to ONE topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)] (Please specify contraindication or intolerance)

OR

2 - Patient is currently on Eucrisa therapy as confirmed by claims history or submission of medical records

2 . Revision History

Date	Notes
12/29/2023	Removed "Medicaid - Community & State Colorado (RMHCAID, RM HCHP, RMHWRP)" from benefit coverage section.

Evrysdi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164400
Guideline Name	Evrysdi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Evrysdi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in ONE of the following:

2.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.2 Compound heterozygous mutation of SMN1 gene [e.g., deletion of SMN1 exon 7 (allele 1) and mutation of SMN1 (allele 2)]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

5 - Patient is not receiving concomitant chronic survival motor neuron (SMN)-modifying therapy [e.g., Spinraza (nusinersen)]

AND

6 - One of the following:

6.1 Patient has not previously received gene replacement therapy for the treatment of SMA [e.g., Zolgensma (onasemnogene abeparvovec-xioi)]

OR

6.2 Both of the following:

6.2.1 Patient has previously received gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] for the treatment of SMA

AND

6.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a decline from pretreatment baseline status following gene replacement therapy [e.g., Zolgensma (onasemnogene abeparvovec-xioi)] as demonstrated by a decline in one of the following exams:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

7 - Submission of medical records (e.g., chart notes, laboratory values) documenting the baseline assessment of at least ONE of the following exams (based on patient age and motor ability) to establish baseline motor ability (baseline motor function analysis could include assessments evaluated prior to receipt of previous chronic SMN-modifying therapy if transitioning therapy)*:

- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) Test
- Motor Function Measure 32 (MFM-32) Scale

AND

8 - Prescribed by or in consultation with a neurologist with expertise in the treatment of SMA

Notes	*Baseline assessments for patients less than 2 months of age request ing Evrysdi are not necessary in order not to delay access to initial the rapy in recently diagnosed infants. Initial assessments shortly post-the rapy can serve as baseline with respect to efficacy reauthorization ass essment.

Product Name:Evrysdi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) with the most recent results documenting a positive clinical response to Evrysdi compared to pretreatment baseline status [inclusive of baseline assessments prior to receipt of previous chronic survival motor neuron (SMN)-modifying therapy] as demonstrated by at least ONE of the following exams:

1.1 Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.2 Hammersmith Infant Neurological Exam Part 2 (HINE-2) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 2-point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- The patient exhibited improvement, or maintenance of previous improvement, in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so

OR

1.3 Hammersmith Functional Motor Scale Expanded (HFMSE) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.4 Revised Upper Limb Module (RULM) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

OR

1.5 Motor Function Measure 32 (MFM-32) with ONE of the following:

- Improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

AND

3 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep

AND

4 - Patient is not receiving concomitant chronic SMN-modifying therapy [e.g., Spinraza (nusinersen)] **AND** **5** - Prescribed by or in consultation with a neurologist with expertise in the treatment of spinal muscular atrophy (SMA)

2 . Revision History

Date	Notes
1/28/2025	Added criteria for patients that have documented decline from pretre atment baseline status following administration of gene replacement t herapy

Exkivity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118602
Guideline Name	Exkivity
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name:Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

AND

4 - Subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

Product Name:Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Exkivity therapy

Product Name:Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Exkivity therapy	

2 . Revision History

Date	Notes
12/20/2022	Updated formularies, cleaned up criteria.

Exkivity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118602
Guideline Name	Exkivity
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name:Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is locally advanced or metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

AND

4 - Subsequent therapy for disease that has progressed on or after platinum-based chemotherapy

Product Name:Exkivity	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Exkivity therapy

Product Name:Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Exkivity	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Exkivity therapy	

2 . Revision History

Date	Notes
12/20/2022	Updated formularies, cleaned up criteria.

Fabhalta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160509
Guideline Name	Fabhalta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Fabhalta	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient will not be prescribed Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, Soliris, Ultomiris)

OR

2.2 Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, Soliris, Ultomiris) which will be discontinued and Fabhalta will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Fabhalta

Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

AND

2 - Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, Soliris, Ultomiris)

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Fabhalta	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

AND

6 - ONE of the following:

6.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally

tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)] as confirmed by claims history or submission of medical records

OR

6.2 Patient has an allergy, contraindication, or intolerance to SGLT2 inhibitors (please specify allergy, contraindication, or intolerance)

AND

7 - ONE of the following:

7.1 Failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) as confirmed by claims history or submission of medical records

OR

7.2 History of intolerance or contraindication to a glucocorticoid (please specify intolerance or contraindication)

AND

8 - Prescribed by or in consultation with a nephrologist

Product Name:Fabhalta	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

2 . Revision History

Date	Notes
11/12/2024	Added criteria for IgAN. Updated examples for combination use requirement for PNH.

Fabhalta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160509
Guideline Name	Fabhalta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Fabhalta	
Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by BOTH of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - ONE of the following:

2.1 Patient will not be prescribed Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, Soliris, Ultomiris)

OR

2.2 Patient is currently receiving another complement inhibitor (e.g., Empaveli, PiaSky, Soliris, Ultomiris) which will be discontinued and Fabhalta will be initiated in accordance with the United States Food and Drug Administration approved labeling

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Fabhalta

Diagnosis	Paroxysmal nocturnal hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy (e.g., increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.)

AND

2 - Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, PiaSky, Soliris, Ultomiris)

AND

3 - Prescribed by, or in consultation with, ONE of the following:

- Hematologist
- Oncologist

Product Name:Fabhalta	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

AND

6 - ONE of the following:

6.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally

tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)] as confirmed by claims history or submission of medical records

OR

6.2 Patient has an allergy, contraindication, or intolerance to SGLT2 inhibitors (please specify allergy, contraindication, or intolerance)

AND

7 - ONE of the following:

7.1 Failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) as confirmed by claims history or submission of medical records

OR

7.2 History of intolerance or contraindication to a glucocorticoid (please specify intolerance or contraindication)

AND

8 - Prescribed by or in consultation with a nephrologist

Product Name:Fabhalta	
Diagnosis	Primary immunoglobulin A nephropathy (IgAN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fabhalta therapy demonstrated by a reduction in proteinuria

2 . Revision History

Date	Notes
11/12/2024	Added criteria for IgAN. Updated examples for combination use requirement for PNH.

Fasenra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154987
Guideline Name	Fasenra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

2 - Documentation of positive clinical response to Fasenra therapy as demonstrated by ONE of the following:

2.1 Reduction in the frequency of exacerbations

OR

2.2 Decreased utilization of rescue medications

OR

2.3 Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline

OR

2.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

OR

2.5 Reduction in oral corticosteroid requirements

AND

3 - Fasenra is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone

furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

4 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter

AND

4 - Fasenra will be used in combination with ONE of the following:

4.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., fluticasone/salmeterol (authorized generic of AirDuo), fluticasone propionate/salmeterol diskus (generic for Advair Diskus), Wixela Inhub

(generic for Advair Diskus), Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Dulera (mometasone/formoterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR), Arnuity Ellipta (fluticasone furoate)]

AND

4.2.2 ONE additional asthma controller medication [e.g., LABA - Striverdi (olodaterol) or Arcapta (indacaterol); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

5 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

6 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

2 . Revision History

Date	Notes
9/16/2024	Modified criteria for existing prior authorization for under the medical benefit.

Fasenra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154987
Guideline Name	Fasenra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

2 - Documentation of positive clinical response to Fasenra therapy as demonstrated by ONE of the following:

2.1 Reduction in the frequency of exacerbations

OR

2.2 Decreased utilization of rescue medications

OR

2.3 Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline

OR

2.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

OR

2.5 Reduction in oral corticosteroid requirements

AND

3 - Fasenra is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone

furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

4 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by ONE of the following:

2.1 Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter

AND

4 - Fasenra will be used in combination with ONE of the following:

4.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., fluticasone/salmeterol (authorized generic of AirDuo), fluticasone propionate/salmeterol diskus (generic for Advair Diskus), Wixela Inhub

(generic for Advair Diskus), Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Dulera (mometasone/formoterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR), Arnuity Ellipta (fluticasone furoate)]

AND

4.2.2 ONE additional asthma controller medication [e.g., LABA - Striverdi (olodaterol) or Arcapta (indacaterol); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

5 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

6 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Fasenra Pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by at least ONE of the following:

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

2 - Used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is NOT receiving Fasenra in combination with any of the following:

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

2 . Revision History

Date	Notes
9/16/2024	Modified criteria for existing prior authorization for under the medical benefit.

Febuxostat

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128908
Guideline Name	Febuxostat
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:generic febuxostat	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to allopurinol (generic Zyloprim) as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to allopurinol (generic Zyloprim) (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
7/25/2023	Updated guideline name from Uloric to febuxostat, updated GPI and product name lists to remove Uloric.

Fentanyl IR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155728
Guideline Name	Fentanyl IR
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Fentanyl citrate lozenges (generic Actiq)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Oral morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oral oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- Oral hydrocodone at a dose of greater than or equal to 60 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative

transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

Product Name:Brand Actiq, Brand Fentora, fentanyl citrate buccal tablet (authorized generic of Fentora)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records demonstrating use is for the management of breakthrough pain associated with a cancer diagnosis (cancer diagnosis must be documented)

AND

2 - Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids (Document drug and date of trial):

- Oral morphine sulfate at a doses of greater than or equal to 60 milligrams per day
- Fentanyl transdermal patch at a dose of greater than or equal to 25 micrograms per hour
- Oral oxycodone at a dose of greater than or equal to 30 milligrams per day
- Oral hydromorphone at a dose of greater than or equal to 8 milligrams per day
- Oral oxymorphone at a dose of greater than or equal to 25 milligrams per day
- Oral hydrocodone at a dose of greater than or equal to 60 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 milligrams per day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain (Document drug)

AND

4 - ONE of the following:

4.1 The patient is not concurrently receiving an alternative fentanyl transmucosal product

OR

4.2 BOTH of the following:

4.2.1 The patient is currently receiving an alternative transmucosal fentanyl product

AND

4.2.2 The prescriber is requesting the termination of all current authorizations for alternative transmucosal fentanyl products in order to begin treatment with the requested medication (Only one transmucosal fentanyl product will be approved at a time. If previous authorizations cannot be terminated, the PA request will be denied)

AND

5 - One of the following:

- Failure to fentanyl citrate lozenges (generic Actiq) confirmed by claims history or submission of medical records
- History of intolerance or contraindication to fentanyl citrate lozenges (generic Actiq) (document intolerance or contraindication)

2 . Revision History

Date	Notes
9/23/2024	Removed Lazanda and Subsys as they are no longer on the market.

Filspari

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206573
Guideline Name	Filspari
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Filspari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk of disease progression

AND

3 - Used to slow kidney function decline

AND

4 - Used to reduce proteinuria

AND

5 - Estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2

AND

6 - BOTH of the following:

6.1 Patient is on a maximized stable dose with ONE of the following prior to initiating therapy confirmed by claims history or submitted medical records

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

AND

6.2 Use of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE inhibitors, ARBs), endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer)], and Tekturna will be discontinued prior to initiating treatment

AND

7 - ONE of the following:

7.1 Failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) confirmed by claims history or submitted medical records.

OR

7.2 History of contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) (please specify intolerance or contraindication)

AND

8 - Prescribed by or in consultation with a nephrologist

Product Name:Filspari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response demonstrated by a reduction in proteinuria

2 . Revision History

Date	Notes
3/4/2025	Updated formularies

Filsuvez

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147169
Guideline Name	Filsuvez
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Filsuvez	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is at least 6 months of age or older

AND

2 - One of the following diagnoses:

- Dystrophic epidermolysis bullosa (DEB)
- Junctional epidermolysis bullosa (JEB)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) confirming a genetic mutation associated with DEB or JEB (i.e., COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3)

AND

4 - Patient has at least one partial thickness wound that meets ALL of the following criteria:

- 10-50 cm2 in size
- Present for at least 3 weeks
- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection
- No evidence or history of basal or squamous cell carcinomas (SCC)

AND

5 - Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

AND

6 - Patient is NOT receiving Filsuvez in combination with Vyjuvek on the same wound(s)

Product Name:Filsuvez	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Filsuvez therapy (e.g., complete wound closure, reduction in wound size, decrease in procedural pain, less frequent dressing changes, decreased total body wound burden)

AND

2 - Wound(s) being treated meets ALL of the following criteria:

- Adequate granulation tissue
- Excellent vascularization
- No evidence of active wound infection
- No evidence or history of basal or squamous cell carcinomas (SCC)

AND

3 - Filsuvez is prescribed by, or in consultation with, a dermatologist with expertise in the treatment of epidermolysis bullosa (EB)

AND

4 - Patient is not receiving Filsuvez in combination with Vyjuvek on the same wound(s)

2 . Revision History

Date	Notes
5/13/2024	New

Firazyr, Sajazir

Prior Authorization Guideline

Guideline ID	GL-148033
Guideline Name	Firazyr, Sajazir
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Sajazir, Brand Firazyr, generic icatibant	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Kalbitor, or Ruconest)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name:Sajazir, Brand Firazyr, generic icatibant	
Diagnosis	Hereditary angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed for the acute treatment of hereditary angioedema (HAE) attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Kalbitor, or Ruconest)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes

6/3/2024	Update to types of genetic variant(s) and diagnostic criteria with normal C1 inhibitor levels in initial auth section and minor language update in reauth section.

Firdapse

Prior Authorization Guideline

Guideline ID	GL-164742
Guideline Name	Firdapse
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Nebraska • Medicaid - Community & State New Mexico • Medicaid - Community & State Indiana • Medicaid - Community & State Pennsylvania

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Firdapse	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Prescribed by or in consultation with a specialist in the treatment of LEMS (e.g., neurologist or oncologist)

AND

3 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]

Product Name:Firdapse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Firdapse therapy

AND

2 - Patient is not receiving Firdapse in combination with similar potassium channel blockers [e.g., Ampyra (dalfampridine)]

2 . Revision History

Date	Notes
2/5/2025	Added Indiana and PA Medicaid formularies. No changes to clinical c riteria.

Fortamet, Glumetza

Prior Authorization Guideline

Guideline ID	GL-123851
Guideline Name	Fortamet, Glumetza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:generic metformin extended-release (generic Fortamet)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - History of greater than or equal to 12-week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records

AND

2 - One of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name:Brand Glumetza, generic metformin extended-release (generic Glumetza)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records

AND

2 - One of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

3 - History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet) as confirmed by claims history or submission of medical records

AND

4 - One of the following:

4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

5 - Submission of article(s) published in the peer-reviewed medical literature showing that the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR AND generic Fortamet)

2 . Revision History

Date	Notes

3/28/2023	Added brand Glumetza

Fortamet, Glumetza

Prior Authorization Guideline

Guideline ID	GL-123851
Guideline Name	Fortamet, Glumetza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:generic metformin extended-release (generic Fortamet)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - History of greater than or equal to 12-week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records

AND

2 - One of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

Product Name:Brand Glumetza, generic metformin extended-release (generic Glumetza)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) as confirmed by claims history or submission of medical records

AND

2 - One of the following:

2.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

2.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

3 - History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet) as confirmed by claims history or submission of medical records

AND

4 - One of the following:

4.1 Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet) as evidenced by the hemoglobin A1c level being above the patient's goal

OR

4.2 Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction)

AND

5 - Submission of article(s) published in the peer-reviewed medical literature showing that the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR AND generic Fortamet)

2 . Revision History

Date	Notes

3/28/2023	Added brand Glumetza

Forteo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161181
Guideline Name	Forteo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Forteo, generic teriparatide, brand Teriparatide	
Diagnosis	Osteoporosis
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Patient is female
- Diagnosis of postmenopausal osteoporosis

OR

1.2 BOTH of the following:

- Patient is male
- Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

OR

2.2 Patient has a history of failure to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) as confirmed by claims history or submission of medical records

OR

2.3 Patient has contraindication or intolerance to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., teriparatide injection, Forteo, Tymlos) during the patient's lifetime

OR

3.2 BOTH of the following:

3.2.1 Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., teriparatide injection, Forteo, Tymlos)

AND

3.2.2 The prescriber attests that the patient remains at or has returned to having a high risk for fracture

AND

4 - ONE of the following:

- Failure to Tymlos as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Tymlos (please specify contraindication or intolerance)

Product Name:Brand Forteo, generic teriparatide, brand Teriparatide	
Diagnosis	Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg (milligrams)/day as confirmed by claims history or submission of medical records

AND

3 - ONE of the following:

3.1 Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

OR

3.2 Patient has a history of failure to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) as confirmed by claims history or submission of medical records

OR

3.3 Patient has contraindication or intolerance to at least one other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate) (please specify contraindication or intolerance)

AND

4 - ONE of the following:

4.1 Treatment duration has not exceeded a total of 24 months of cumulative use of parathyroid hormone analogs (e.g., teriparatide injection, Forteo, Tymlos)

OR

4.2 BOTH of the following:

4.2.1 Patient is currently or has previously been treated with parathyroid hormone analogs (e.g., teriparatide injection, Forteo, Tymlos)

AND

4.2.2 The prescriber attests that the patient remains at or has returned to having a high risk for fracture

Product Name:Brand Forteo, generic teriparatide, brand Teriparatide	
Diagnosis	Osteoporosis, Osteoporosis Associated with Sustained Systemic Glucocorticoid Therapy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment duration of parathyroid hormones (e.g., teriparatide injection, Forteo, Tymlos) has not exceeded a total of 24 months during the patient's lifetime

OR

2 - The patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide injection, Forteo, Tymlos)

2 . Revision History

Date	Notes
11/22/2024	Added generic Teriparatide

Fotivda

Prior Authorization Guideline

Guideline ID	GL-127460
Guideline Name	Fotivda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is refractory

AND

3 - Patient has received two or more prior systemic therapies

Product Name:Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fotivda therapy

Product Name:Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fotivda therapy

2 . Revision History

Date	Notes
7/3/2023	Updated GPI

Fotivda

Prior Authorization Guideline

Guideline ID	GL-127460
Guideline Name	Fotivda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is refractory

AND

3 - Patient has received two or more prior systemic therapies

Product Name:Fotivda	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fotivda therapy

Product Name:Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Fotivda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fotivda therapy

2 . Revision History

Date	Notes
7/3/2023	Updated GPI

Fruzaqla

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147172
Guideline Name	Fruzaqla
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/8/2024

1 . Criteria

Product Name:Fruzaqla	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease of ONE of the following:

- Advanced
- Metastatic

AND

3 - Patient has been previously treated with ALL of the following:

- Fluoropyrimidine-based chemotherapy (e.g., capecitabine, 5-FU)
- Oxaliplatin-based chemotherapy (e.g., CAPEOX, FOLFOX)
- Irinotecan-based chemotherapy (e.g., FOLFIRI, FOLFIRINOX)
- Anti-VEGF therapy (e.g., aflibercept, bevacizumab, ramucirumab)

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Disease is RAS wild-type

AND

4.1.2 Patient has been previously treated with an anti-EGFR therapy (e.g., cetuximab, panitumumab)

OR

4.2 Disease is not RAS wild-type

Product Name:Fruzaqla	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fruzaqla therapy

Product Name:Fruzaqla	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Fruzaqla	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fruzaqla therapy

2 . Revision History

Date	Notes
5/8/2024	Updated PA formulary to CHIP

Fruzaqla

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147172
Guideline Name	Fruzaqla
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/8/2024

1 . Criteria

Product Name:Fruzaqla	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease of ONE of the following:

- Advanced
- Metastatic

AND

3 - Patient has been previously treated with ALL of the following:

- Fluoropyrimidine-based chemotherapy (e.g., capecitabine, 5-FU)
- Oxaliplatin-based chemotherapy (e.g., CAPEOX, FOLFOX)
- Irinotecan-based chemotherapy (e.g., FOLFIRI, FOLFIRINOX)
- Anti-VEGF therapy (e.g., aflibercept, bevacizumab, ramucirumab)

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Disease is RAS wild-type

AND

4.1.2 Patient has been previously treated with an anti-EGFR therapy (e.g., cetuximab, panitumumab)

OR

4.2 Disease is not RAS wild-type

Product Name:Fruzaqla	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Fruzaqla therapy

Product Name:Fruzaqla	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Fruzaqla	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Fruzaqla therapy

2 . Revision History

Date	Notes
5/8/2024	Updated PA formulary to CHIP

Furoscix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160537
Guideline Name	Furoscix
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Furoscix	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic heart failure

AND

2 - Patient has signs or symptoms of congestion due to fluid overload

AND

3 - Patient is established on background loop diuretic therapy (e.g., bumetanide, furosemide, torsemide)

AND

4 - Both of the following:

4.1 Patient does not require ongoing emergency care or hospitalization for heart failure, acute pulmonary edema, or other conditions

AND

4.2 Patient is currently a candidate for parenteral diuresis outside of the hospital

AND

5 - Patient has an estimated creatine clearance greater than 30ml/min

AND

6 - Furoscix is prescribed by or in consultation with a cardiologist

2 . Revision History

Date	Notes
11/12/2024	Removed criteria requiring NYHA Class II or III HF

Galafold

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135467
Guideline Name	Galafold
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Galafold	
Diagnosis	Fabry Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)

Product Name:Galafold	
Diagnosis	Fabry Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)

2 . Revision History

Date	Notes
10/26/2023	Added Elfabrio as a drug to not be used in combination

Galafold

Prior Authorization Guideline

Guideline ID	GL-135467
Guideline Name	Galafold
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Galafold	
Diagnosis	Fabry Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

AND

3 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)

Product Name:Galafold	
Diagnosis	Fabry Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Galafold therapy

AND

2 - Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta) or Elfabrio (pegunigalsidase alfa-iwxj)

2 . Revision History

Date	Notes
10/26/2023	Added Elfabrio as a drug to not be used in combination

Gattex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134510
Guideline Name	Gattex
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Gattex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome (SBS)

AND

2 - Dependent on parenteral support

Product Name:Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gattex therapy

2 . Revision History

Date	Notes
10/9/2023	Updated formularies and cleaned up criteria.

Gavreto

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163845
Guideline Name	Gavreto
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - There is presence of RET rearrangement positive tumors

Product Name:Gavreto	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 Disease is RET gene fusion positive

AND

1.4 Disease is not amenable to radioactive iodine therapy

OR

2 - ALL of the following:

2.1 Diagnosis of medullary carcinoma

AND

2.2 ONE of the following:

- Disease is recurrent, persistent, or progressive
- Disease is symptomatic with distant metastases

AND

2.3 Disease is RET-mutation positive

OR

3 - ALL of the following:

3.1 Diagnosis of anaplastic carcinoma

AND

3.2 ONE of the following:

- Disease is stage IVA or IVB (locoregional)
- Disease is metastatic

AND

3.3 Disease is RET gene fusion positive

Product Name:Gavreto	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of gallbladder cancer

AND

1.1.2 Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of cholangiocarcinoma

AND

1.2.2 Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic
- Resectable locoregionally advanced

AND

2 - Disease is positive for RET gene fusion mutation

Product Name:Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Carcinoma, Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gavreto therapy

Product Name:Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gavreto therapy

2 . Revision History

Date	Notes
1/15/2025	Updated criteria for hepatobiliary cancers

Gavreto

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163845
Guideline Name	Gavreto
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - There is presence of RET rearrangement positive tumors

Product Name:Gavreto	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 Disease is RET gene fusion positive

AND

1.4 Disease is not amenable to radioactive iodine therapy

OR

2 - ALL of the following:

2.1 Diagnosis of medullary carcinoma

AND

2.2 ONE of the following:

- Disease is recurrent, persistent, or progressive
- Disease is symptomatic with distant metastases

AND

2.3 Disease is RET-mutation positive

OR

3 - ALL of the following:

3.1 Diagnosis of anaplastic carcinoma

AND

3.2 ONE of the following:

- Disease is stage IVA or IVB (locoregional)
- Disease is metastatic

AND

3.3 Disease is RET gene fusion positive

Product Name:Gavreto	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of gallbladder cancer

AND

1.1.2 Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of cholangiocarcinoma

AND

1.2.2 Disease is one of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic
- Resectable locoregionally advanced

AND

2 - Disease is positive for RET gene fusion mutation

Product Name:Gavreto	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Carcinoma, Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gavreto therapy

Product Name:Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Gavreto	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Gavreto therapy

2 . Revision History

Date	Notes
1/15/2025	Updated criteria for hepatobiliary cancers

Gilotrif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159291
Guideline Name	Gilotrif
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New York • Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Squamous disease progressing after previous platinum-based chemotherapy
- Tumors are positive for non-resistant epidermal growth factor receptor (EGFR) mutations

Product Name:Gilotrif	
Diagnosis	Advanced Non-Nasopharyngeal Head and Neck Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, non-nasopharyngeal head and neck cancer

AND

2 - Disease has progressed on or after platinum-containing chemotherapy

Product Name:Gilotrif	
Diagnosis	Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastasis due to EGFR (epidermal growth factor receptor)-sensitizing mutation positive non-small cell lung cancer

Product Name:Gilotrif	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Advanced Non-Nasopharyngeal Head and Neck Cancer, Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gilotrif therapy

Product Name:Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Gilotrif will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Gilotrif	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Gilotrif therapy	

2 . Revision History

Date	Notes
11/5/2024	Combined all CAG's into one. No GPI or clinical changes

Gleevec

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135659
Guideline Name	Gleevec
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelogenous/myeloid leukemia (CML)

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Platelet-derived growth factor receptor (PDGFR) gene re-arrangements

Product Name:Brand Gleevec, generic imatinib

Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - ONE of the following:

- Kit D816V mutation negative or unknown
- Well-differentiated SM [WDSM]
- Eosinophilia is present with FIP1L1-PDGFRA fusion gene

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES)/Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least ONE of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

Product Name:Brand Gleevec, generic imatinib

Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dermatofibrosarcoma protuberans (DFSP)

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gastrointestinal stromal tumors (GIST)
- Desmoid tumors/aggressive fibromatosis
- Pigmented villonodular synovitis (PVNS)/tenosynovial giant cell tumor (TGCT)

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of melanoma

AND

2 - Patient has C-KIT (gene) mutation

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	AIDS-Related Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2 - Not used as first line therapy

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Steroid-Refractory Chronic Graft-Versus-Host Disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is being treated with systemic corticosteroids

AND

3 - Patient had no response to first-line therapy options

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

- FIP1L1-PDGFRA rearrangement
- PDGFRB rearrangement
- ABL1 rearrangement

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	All Indications except NCCN
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Gleevec therapy

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Gleevec, generic imatinib	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Gleevec therapy

2 . Revision History

Date	Notes
11/2/2023	Updated formularies, updated diagnoses, updated MDS/MPD, ASM, and AIDS-Related Kaposi Sarcoma criteria sections, cleaned up crite ria.

Prior Authorization Guideline

Guideline ID	GL-197206
Guideline Name	GLP-1 and Dual GIP, GLP-1 Receptor Agonists
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Victoza 1.2mg per day (2 Pen Pack), liraglutide 1.2mg per day (2 Pen Pack), Mounjaro, Ozempic, Rybelsus	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

OR

1.2 For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

2.1 Suboptimal response (i.e., suboptimal glycemic control) to one product, or a combination thereof, from ONE of the following drugs/classes for 90 days in the past 365 days, as confirmed by claims history or submission of medical records

- Metformin
- Metformin combinations
- DPP-4 inhibitors
- DPP-4 inhibitor combinations
- SGLT2 inhibitors
- SGLT2 inhibitor combinations
- Sulfonylureas

OR

2.2 History of contraindication or intolerance to ONE product from any of the following drugs/classes: (please specify contraindication or intolerance)

- Metformin
- Metformin combinations
- DPP-4 inhibitors
- DPP-4 inhibitor combinations
- SGLT2 inhibitors
- SGLT2 inhibitor combinations
- Sulfonylureas

Product Name:Victoza 1.2mg per day (2 Pen Pack), liraglutide 1.2mg per day (2 Pen Pack), Mounjaro, Ozempic, Rybelsus	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

Product Name:Victoza 1.8mg per day (3 Pen Pack), liraglutide 1.8mg per day (3 Pen Pack)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

OR

1.2 For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

- Suboptimal response to metformin (i.e., suboptimal glycemic control) at a minimum dose of 1500mg daily for 90 days, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to metformin (please specify contraindication or intolerance)

AND

3 - History of failure to achieve acceptable glycemic control with Victoza 1.2mg per day for 90 days (2 Pen Pack), as confirmed by claims history or submission of medical records

Product Name:Victoza 1.8mg per day (3 Pen Pack), liraglutide 1.8mg per day (3 Pen Pack)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

Product Name:Bydureon BCise, Byetta, Trulicity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by ONE of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
- Random plasma glucose greater than or equal to 200 mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

OR

1.2 For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

- Suboptimal response to metformin (i.e., suboptimal glycemic control) at a minimum dose of 1500mg daily for 90 days, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to metformin (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Suboptimal response (i.e., suboptimal glycemic control) to both of the following, each for a minimum of 90 days, as confirmed by claims history or submission of medical records:

- A commercially available semaglutide product indicated for type 2 diabetes mellitus (e.g., Ozempic, Rybelsus)
- Mounjaro

OR

3.2 History of contraindication or intolerance to both of the following (please specify contraindication or intolerance)

- A commercially available semaglutide product indicated for type 2 diabetes mellitus (e.g., Ozempic, Rybelsus)
- Mounjaro

Product Name:Bydureon BCise, Byetta, Trulicity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improved A1C)

2 . Revision History

Date	Notes
2/26/2025	Rhode Island market specific version to maintain step thru criteria. A dded reauthorization criteria throughout

Gonadotropin-Releasing Hormone Agonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161316
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:leuprolide acetate inj kit 5 mg/mL, Lupron Depot-Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Onset of secondary sexual characteristics in ONE of the following:

2.1 Females less than or equal to 8 years of age

OR

2.2 Males less than or equal to 9 years of age

AND

3 - Confirmation of diagnosis as defined by ONE of the following:

3.1 Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)

OR

3.2 A pubertal luteinizing hormone response to a gonadotropin releasing hormone (GnRH) stimulation test

OR

3.3 Bone age advanced one year beyond the chronological age

AND

4 - If the request is for Triptodur or Lupron-Depot Ped (6-month), ONE of the following:

4.1 Failure to Fensolvi as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to Fensolvi (please specify intolerance or contraindication)

Product Name:leuprolide acetate inj kit 5 mg/mL, Lupron Depot-Ped, Triptodur, Fensolvi	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving therapy for central precocious puberty

AND

2 - Documentation of positive clinical response to therapy (e.g., decrease in height velocity, cessation of menses, arrest pubertal progression, reduction in bone age advancement)

AND

3 - Patient is currently younger than the appropriate time point for the onset of puberty, as ONE of the following:

3.1 Female younger than 11 years of age

OR

3.2 Male younger than 12 years of age

Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following classes as confirmed by claims history or submission of medical records:

- Oral contraceptives or depot medroxyprogesterone (e.g., Depo-Provera)
- Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.2 History of intolerance or contraindication to BOTH of the following classes (please specify intolerance or contraindication):

- Oral contraceptives or depot medroxyprogesterone (e.g., Depo-Provera)
- Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.3 Patient has had surgical ablation to prevent recurrence

Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Endometriosis
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis or endometriosis is suspected

AND

2 - Recurrence of symptoms following an initial course of therapy

AND

3 - Concurrently to be used with add-back therapy (e.g., progestin, estrogen, or bone sparing agents)

AND

4 - Treatment duration has not exceeded a total of 12 months, as confirmed by claims history or submission of medical records

Notes	Approval Length - Authorization will be issued for 6 months. Duration of both the initial and recurrent course of therapies is no longer than 1 2 months total.

Product Name:Lupron Depot 3.75 mg and 3-month 11.25 mg	
Diagnosis	Uterine Leiomyomata (Fibroids)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 For the treatment of uterine leiomyomata-related anemia

AND

1.2 Patient did not respond to iron therapy of 1 month duration

AND

1.3 For use prior to surgery

OR

2 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy)

Product Name:Lupron Depot 7.5 mg, 22.5 mg, 30 mg, and 45 mg, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Prostate Cancer
Guideline Type	Prior Authorization

Approval Criteria

1 - For a diagnosis of advanced or metastatic prostate cancer, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender Dysphoria in Adolescents*
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient has experienced puberty development to at least Tanner stage 2

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following laboratory tests, based upon the laboratory reference range, confirming:

- Pubertal levels of estradiol in a female
- Pubertal levels of testosterone in a male
- Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
- A pubertal luteinizing hormone response to a gonadotropin-releasing hormone (GnRH) stimulation test

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

5.1 Patient has experienced pubertal changes that have resulted in an increase of their gender dysphoria that has significantly impaired psychological or social functioning

AND

5.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

5.3 BOTH of the following:

5.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

5.3.2 Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

AND

5.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Notes	*Please verify gender dysphoria is a coverable benefit for the patient.

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Gender Dysphoria in Adolescents*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following within the last 6 months:

- LH (luteinizing hormone) suppression assessing for appropriate suppression
- Change in dosing

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of

Mental Disorders (i.e., DSM-5) criteria, by a mental health professional with expertise in child and adolescent psychiatry

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

4.1 Patient continues to meet their individual goals of therapy for gender dysphoria

AND

4.2 Patient continues to have a strong affinity for the desired (opposite of natal) gender

AND

4.3 Discontinuation of treatment and subsequent pubertal development would interfere with or impair psychological functioning and well-being

AND

4.4 Coexisting psychiatric and medical comorbidities or social problems that may interfere with treatment continue to be addressed or removed

AND

4.5 BOTH of the following:

4.5.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

4.5.2 Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

AND

4.6 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Notes	*Please verify gender dysphoria is a coverable benefit for the patient.

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults*
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting the medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting the gonads (i.e., testes, ovaries) have not been removed and are functional (e.g., hormone producing)

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

6.1 Transgender patient has identified goals of gender-affirming hormone therapy

AND

6.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed

AND

6.3 BOTH of the following:

6.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

6.3.2 Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

AND

6.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Notes	*Please verify gender dysphoria is a coverable benefit for the patient

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Adjunct for Gender-Affirming Hormonal Therapy for Transgender Adults*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following within the last 6 months:

- Luteinizing hormone (LH) suppression assessing for appropriate suppression
- Change in dosing

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of gender dysphoria, according to the current Diagnostic and Statistical Manual of Mental Disorders (i.e., DSM-5) criteria, by a mental health professional

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting the

medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in transgender hormone therapy

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting the gonads (i.e., testes, ovaries) are intact

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is currently receiving hormonal therapy (e.g., testosterone, estrogens, progesterones) to achieve the desired (e.g., non-natal) gender

AND

6 - Submission of medical records (e.g., chart notes, laboratory values) documenting inability of cross sex hormone therapy to inhibit natal secondary sex characteristics, luteinizing hormone (LH), or gonadotropins (e.g., menses, testosterone)

AND

7 - Submission of medical records (e.g., chart notes, laboratory values) documenting a letter from the prescriber and/or formal documentation stating ALL of the following:

7.1 Transgender patient continues to meet goals of gender-affirming hormone therapy

AND

7.2 Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment continue to be addressed or removed

AND

7.3 BOTH of the following:

7.3.1 Current enrollment, attendance, and active participation in psychological and social support treatment program

AND

7.3.2 Patient will continue enrollment, attendance, and active participation in psychological and social support throughout the course of treatment

AND

7.4 Patient demonstrates knowledge and understanding of the expected outcomes of treatment and related transgender therapies

Notes	*Please verify gender dysphoria is a coverable benefit for the patient

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj	
Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in pre-menopausal women

AND

2 - Patient is receiving a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name:Lupron Depot, Lupron Depot-Ped, Fensolvi, Triptodur, leuprolide acetate inj kit 5 mg/mL, leuprolide acetate (3 month) 22.5 mg inj

Diagnosis	Fertility Preservation
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently receiving gonadotropin-releasing hormone (GnRH) analog therapy for the purpose of fertility preservation

AND

2 - Patient continues to receive a cytotoxic agent that is associated with causing primary ovarian insufficiency (premature ovarian failure) [e.g., Cytoxan (cyclophosphamide), procarbazine, vinblastine, cisplatin]

Product Name:leuprolide acetate inj kit 5 mg/mL	
Diagnosis	Salivary Gland Tumors
Guideline Type	Prior Authorization

Approval Criteria

1 - For a diagnosis of salivary gland tumors, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit

Product Name:leuprolide acetate inj kit 5 mg/mL	
Diagnosis	Uterine Sarcoma
Guideline Type	Prior Authorization

Approval Criteria

1 - For a diagnosis of uterine sarcoma, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit

Product Name:Lupron Depot, Lupron Depot-Ped, leuprolide acetate inj kit 5 mg/mL	
Diagnosis	NCCN Recommended Regimens
Guideline Type	Prior Authorization
Approval Criteria **1** - For uses supported by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, the requested medication is not delegated to OptumRx for review and should be processed as a medical benefit	

2 . Revision History

Date	Notes
11/26/2024	Updated GPIs. Updated step therapy in CPP section as Fensolvi was moved to preferred and Lupron Depot Ped was moved to NP

Growth Hormone, Growth Stimulating Agents - Managed Medicaid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161787
Guideline Name	Growth Hormone, Growth Stimulating Agents - Managed Medicaid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)*
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 All of the following:

- Infant is less than 4 months of age
- Infant has growth deficiency
- Prescribed by an endocrinologist

OR

1.1.1.2 BOTH of the following:

- History of neonatal hypoglycemia associated with pituitary disease
- Prescribed by an endocrinologist

OR

1.1.1.3 BOTH of the following:

- Diagnosis of panhypopituitarism
- Prescribed by an endocrinologist

AND

1.1.2 If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric growth hormone (GH) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

1.2.2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.2.3.1 BOTH of the following:

1.2.3.1.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

AND

1.2.3.1.2 BOTH GH response values are less than 10 micrograms per liter

OR

1.2.3.2 BOTH of the following:

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 ONE of the following is below the age and gender adjusted normal range as provided by the physician's lab:

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

1.2.4 ONE of the following:

1.2.4.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

1.2.4.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

1.2.5 Prescribed by an endocrinologist

AND

1.2.6 If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:**

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:**

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 Patient is a male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

4.2 Patient is a female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

5 - ONE of the following:

5.1 Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

OR

5.2 BOTH of the following:

- Tanner Stage 3 or greater
- Request does not exceed a maximum supply limit of 0.7 milligrams per kilogram per week

AND

6 - Prescribed by an endocrinologist

Notes	*Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH de ficiency, utilize criteria for Transition Phase Adolescent or Adult GH D eficiency. **Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 ONE of the following:

- History of neonatal hypoglycemia associated with pituitary disease
- Diagnosis of panhypopituitarism

AND

1.1.2 Prescribed by an endocrinologist

AND

1.1.3 ONE of the following:

1.1.3.1 Failure to ONE of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

1.1.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric GH (growth hormone) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

1.2.2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:

1.2.3.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

- Growth hormone releasing hormone

AND

1.2.3.2 Both GH response values are less than 10 micrograms per liter

AND

1.2.4 One of the following:

1.2.4.1 Failure to ONE of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

1.2.4.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

AND

1.2.5 Prescribed by an endocrinologist

Product Name:Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:*

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 Patient is a male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

4.2 Patient is a female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

5 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Sogroya, Ngenla	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of panhypopituitarism

AND

1.1.2 Prescribed by an endocrinologist

AND

1.1.3 ONE of the following:

1.1.3.1 Failure to ONE of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

1.1.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)

- Somatropin (Omnitrope)

OR

1.2 ALL of the following:

1.2.1 Diagnosis of pediatric GH (growth hormone) deficiency as confirmed by ONE of the following:

1.2.1.1 Projected height (as determined by extrapolating pre-treatment growth trajectory along current channel to 18-20 year mark) is greater than 2.0 standard deviations [SD] below midparental height utilizing age and gender growth charts related to height

OR

1.2.1.2 Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) utilizing age and gender growth charts related to height

OR

1.2.1.3 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.4 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 ONE of the following:

1.2.2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

1.2.2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

1.2.3 Submission of medical records (e.g., chart notes, laboratory values) documenting BOTH of the following:

1.2.3.1 Patient has undergone TWO of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa
- Growth hormone releasing hormone

AND

1.2.3.2 Both GH response values are less than 10 micrograms per liter

AND

1.2.4 ONE of the following:

1.2.4.1 If the request is for Sogroya, the patient is 2.5 years of age or older

OR

1.2.4.2 If the request is for Ngenla, the patient is 3 years of age or older

AND

1.2.5 ONE of the following:

1.2.5.1 Failure to ONE of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

1.2.5.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

AND

1.2.6 Prescribed by an endocrinologist

Product Name:Sogroya, Ngenla	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - BOTH of the following:*

- Expected adult height not attained
- Documentation of expected adult height goal (e.g. genetic potential)

AND

3 - Calculated height (growth) velocity over the past 12 months

AND

4 - ONE of the following:

4.1 Patient is a male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

4.2 Patient is a female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

5 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome

AND

2 - Prescribed by an endocrinologist

AND

3 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 BOTH of the following:

1.1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

AND

1.1.2 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 BOTH of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

1.2.3 Prescribed by an endocrinologist

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA (small for gestational age) based on demonstration of catch up growth failure in the first 24 months of life using a birth to 36 month growth chart as confirmed by BOTH of the following:

1.1 Documentation that ONE of the following is below the third percentile for gestational age (greater than or equal to 2 standard deviations [SD] below population mean):

- Birth weight
- Birth length

AND

1.2 Patient has demonstrated failure of catch up growth in the first 24 months of life

AND

2 - Documentation that height remains less than or equal to third percentile (greater than or equal to 2 SD below population mean)

AND

3 - Prescribed by an endocrinologist

AND

4 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with ONE of the following:

1.1 BOTH of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

OR

1.2 BOTH of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 ONE of the following:

1.2.2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

1.2.2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

2 - Height is below the fifth percentile on growth charts for age and gender

AND

3 - Prescribed by an endocrinologist

AND

4 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short-stature homeobox (SHOX) gene deficiency as confirmed by genetic testing

AND

2 - ONE of the following:

2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

3 - Prescribed by an endocrinologist

AND

4 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency

AND

2 - ONE of the following:

2.1 Patient is male and ONE of the following:

- Tanner stage less than 4
- Bone age less than 16 years measured in the past 12 months

OR

2.2 Patient is female and ONE of the following:

- Tanner stage less than 4
- Bone age less than 14 years measured in the past 12 months

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

AND

4 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim

Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not attained
- Expected adult height goal

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 BOTH of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has undergone ONE of the following GH (growth hormone) stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- Glucagon
- ARG
- Macrilen (macimorelin)

AND

2.1.2 ONE of the following peak GH values:

2.1.2.1 ITT less than or equal to 5 micrograms per liter

OR

2.1.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

2.1.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

2.1.2.4 ARG less than or equal to 0.4 micrograms per liter

OR

2.1.2.5 Macimorelin less than 2.8 nanograms per milliliter 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 BOTH of the following:

2.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of THREE of the following anterior pituitary hormones:

- Prolactin
- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

2.2.2 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole),Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Prescribed by an endocrinologist

AND

5 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of Insulin-like Growth Factor 1 (IGF-1)/Somatomedin C level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Prescribed by an endocrinologist

Product Name:Sogroya	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult growth hormone deficiency (GHD) as a result of ONE of the following:

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 BOTH of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

2.1 BOTH of the following:

2.1.1 Patient has undergone ONE of the following GH (growth hormone) stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- Glucagon
- ARG
- Macrilen (macimorelin)

AND

2.1.2 ONE of the following peak GH values:

2.1.2.1 ITT less than or equal to 5 micrograms per liter

OR

2.1.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

2.1.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

2.1.2.4 ARG less than or equal to 0.4 micrograms per liter

OR

2.1.2.5 Macimorelin less than 2.8 nanograms per milliliter 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 BOTH of the following:

2.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting deficiency of THREE of the following anterior pituitary hormones:

- Prolactin
- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

2.2.2 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - ONE of the following:

3.1 Diagnosis of panhypopituitarism

OR

3.2 Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole),Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

4 - Prescribed by an endocrinologist

AND

5 - ONE of the following:

5.1 Failure to ONE of the following, confirmed by claims history or submission of medical records:

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

OR

5.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Somatropin (Norditropin)
- Somatropin (Omnitrope)

Product Name:Sogroya	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of Insulin-like Growth Factor 1 (IGF-1)/Somatomedin C level within the past 12 months

AND

2 - ONE of the following:

2.1 Diagnosis of panhypopituitarism

OR

2.2 Other diagnosis and not used in combination with the following:

- Aromatase inhibitors [e.g., Arimidex (anastrazole), Femara (letrazole)]
- Androgens [e.g., Delatestryl (testosterone enanthate), Depo-Testosterone (testosterone cypionate)]

AND

3 - Prescribed by an endocrinologist

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

2 - Documentation of ONE of the following:

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

3.1 BOTH of the following:

3.1.1 Documentation of high risk of growth hormone (GH) deficiency due to GH deficiency in childhood from ONE of the following:

3.1.1.1 Embryopathic/congenital defects

OR

3.1.1.2 Genetic mutations

OR

3.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

3.1.1.4 Panhypopituitarism

OR

3.1.1.5 Deficiency of THREE of the following anterior pituitary hormones:

- ACTH (adrenocorticotropic hormone)
- TSH (thyroid stimulating hormone)
- Prolactin
- FSH/LH (follicle-stimulating hormone/luteinizing hormone)

AND

3.1.2 ONE of the following:

3.1.2.1 Insulin-like Growth Factor 1 (IGF-1)/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

3.1.2.2 ALL of the following:

3.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

3.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

3.1.2.2.3 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- Insulin tolerance test (ITT)
- ARG (Arginine) and GHRH (growth hormone releasing hormone)
- ARG
- Glucagon

AND

3.1.2.2.4 ONE of the following peak GH values:

3.1.2.2.4.1 ITT less than or equal to 5 micrograms per liter

OR

3.1.2.2.4.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.1.2.2.4.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.1.2.2.4.4 ARG less than or equal to 0.4 micrograms per liter

OR

3.2 ALL of the following:

3.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

3.2.2 Discontinued GH therapy for at least 1 month

AND

3.2.3 BOTH of the following:

3.2.3.1 Patient has undergone ONE of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- GHRH and ARG
- ARG
- Glucagon

AND

3.2.3.2 ONE of the following peak GH values:

3.2.3.2.1 ITT less than or equal to 5 micrograms per liter

OR

3.2.3.2.2 GHRH and ARG of ONE of the following:

- Less than or equal to 11 micrograms per liter if body mass index [BMI] is less than 25 kilograms per meter squared
- Less than or equal to 8 micrograms per liter if BMI is greater than or equal to 25 and less than 30 kilograms per meter squared
- Less than or equal to 4 micrograms per liter if BMI is greater than or equal to 30 kilograms per meter squared

OR

3.2.3.2.3 Glucagon less than or equal to 3 micrograms per liter

OR

3.2.3.2.4 ARG less than or equal to 0.4 micrograms per liter

AND

4 - Prescribed by an endocrinologist

AND

5 - If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (document reason or special circumstance) (See Table 1 in Background section for non-preferred products)

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, Zomacton, Zorbtive, Serostim	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 [Insulin-like Growth Factor 1] and IGFBP-3 [Insulin-like growth factor binding protein 3] levels)

AND

2 - Request does not exceed a maximum supply limit of 0.3 milligrams per kilogram per week

AND

3 - Prescribed by an endocrinologist

Product Name:Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human immunodeficiency virus (HIV)-associated wasting syndrome or cachexia

AND

2 - Documentation of ONE of the following:

2.1 Unintentional weight loss of greater than 10 percent over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5 percent over the last 6 months

OR

2.3 Loss of 5 percent body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kilograms per meter squared

OR

2.5 ONE of the following:

2.5.1 ALL of the following:

- Patient is male
- BCM less than 35 percent of total body weight
- BMI less than 27 kilograms per meter squared

OR

2.5.2 ALL of the following:

- Patient is female
- BCM less than 23 percent of total body weight
- BMI less than 27 kilograms per meter squared

AND

3 - A nutritional evaluation has been completed since onset of wasting first occurred

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes)

AND

5 - Patient's anti-retroviral therapy has been optimized to decrease the viral load

Product Name:Serostim

Diagnosis	Human Immunodeficiency Virus (HIV)-associated wasting syndrome or cachexia
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2 percent increase in body weight and/or body cell mass [BCM])

AND

2 - ONE of the following targets or goals has not been achieved:

- Weight
- BCM
- Body Mass Index (BMI)

Product Name:Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	*4 weeks
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements)

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive*

Notes	*Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

Product Name:Increlex	
Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following criteria:

1.1 Documentation of ALL of the following:

1.1.1 Diagnosis of severe primary Insulin-like Growth Factor 1 (IGF-1) deficiency

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone levels

AND

1.1.5 Documentation of open epiphyses on last bone radiograph

AND

1.1.6 The patient will not be treated with concurrent growth hormone therapy

AND

1.1.7 Prescribed by an endocrinologist

OR

1.2 ALL of the following:

1.2.1 Diagnosis of growth hormone gene deletion and has developed neutralizing antibodies to growth hormone

AND

1.2.2 Documentation of open epiphyses on last bone radiograph

AND

1.2.3 The patient will not be treated with concurrent growth hormone therapy

AND

1.2.4 Prescribed by an endocrinologist

Product Name:Increlex

Diagnosis	Severe Primary IGF-1 Deficiency / Growth Hormone Gene Deletion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 centimeters per year over the previous year of treatment as documented by BOTH of the following:*

- Previous height and date obtained
- Current height and date obtained

AND

2 - Documentation of BOTH of the following:*

- Expected adult height not obtained
- Expected adult height goal

AND

3 - Patient is not treated with concurrent growth hormone therapy

AND

4 - Prescribed by an endocrinologist

Notes	*Documentation of previous height, current height and goal expected adult height will be required for renewal.

2 . Background

Benefit/Coverage/Program Information

Table 1: Human Growth Hormone:

Preferred Agents:

Somatropin (Norditropin®), Somatropin (Omnitrope®)

Nonpreferred Agents:

Somatropin (Genotropin®, Humatrope®, NordiFlex®, Nutropin AQ® NuSpin™, Saizen®, Zorbtive®, Serostim®, and Zomacton®), Skytrofa™ (lonapegsomatropin-tcgd), Ngenla (somatrogon), Sogroya (somapacitan)

Growth Stimulating Products : Mecasermin (Increlex®)

3 . Revision History

Date	Notes
12/9/2024	Removed Nutropin from step thru agents

Haegarda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147189
Guideline Name	Haegarda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Haegarda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

1.2.1 Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6

OR

1.2.2 Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

OR

1.2.3 Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for the prophylaxis of HAE attacks

AND

3 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Orladeyo, Takhzyro)

AND

4 - Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Haegarda

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name:Haegarda	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Haegarda therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Haegarda therapy

AND

3 - Prescribed for the prophylaxis of HAE attacks

AND

4 - Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Orladeyo, Takhzyro)

AND

5 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes
5/13/2024	Updated HAE diagnostic criteria with normal C1 inhibitor levels. Upd ated reauthorization criteria.

HCG

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145852
Guideline Name	HCG
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Novarel, Chorionic Gonadotropin, Ovidrel, Pregnyl	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction

2 . Revision History

Date	Notes
4/17/2024	Removed MD formulary

Hemangeol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164950
Guideline Name	Hemangeol
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Hemangeol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of proliferating infantile hemangioma **AND** **2** - Prescriber provides a reason or special circumstance the patient cannot use generic propranolol oral solution

2 . Revision History

Date	Notes
2/10/2025	Updated formularies

Hemlibra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158182
Guideline Name	Hemlibra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Hemlibra	
Diagnosis	Hemophilia A with Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Patient has developed high-titer factor VIII inhibitors [greater than 5 Bethesda units (BU)]

AND

3 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Hemlibra	
Diagnosis	Hemophilia A with Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

Product Name:Hemlibra	
Diagnosis	Hemophilia A without Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of severe hemophilia A

AND

1.1.2 Documentation of endogenous factor VIII levels less than 1% of normal factor VIII [less than 0.01 international units/milliliter (IU/mL)]

OR

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 BOTH of the following:

1.2.1.1.1 Diagnosis of moderate hemophilia A

AND

1.2.1.1.2 Documentation of endogenous factor VIII level greater than or equal to 1% and less than 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

OR

1.2.1.2 BOTH of the following:

1.2.1.2.1 Diagnosis of mild hemophilia A

AND

1.2.1.2.2 Documentation of endogenous factor VIII level greater than or equal to 5% (greater than or equal to 0.05 IU/mL)

AND

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

OR

1.3 BOTH of the following:

1.3.1 Patient is currently on Hemlibra therapy as confirmed by claims history or submission of medical records

AND

1.3.2 Diagnosis of hemophilia A

AND

2 - Hemlibra is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

AND

3 - Prescriber attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Adynovate, Afstyla, Altuviio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes

Product Name:Hemlibra	
Diagnosis	Hemophilia A without Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Hemlibra in combination with an extended half-life factor VIII replacement product (e.g., Adynovate, Afstyla, Altuviio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes (Prescription claim history that does not show any concomitant extended half-life factor VIII replacement product claim within 60 days of reauthorization request may be used as documentation)

2 . Revision History

Date	Notes
10/29/2024	Added new Hemlibra strengths. Updated list of examples of extende d half-life factor VIII replacement products.

Hemlibra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158182
Guideline Name	Hemlibra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Hemlibra	
Diagnosis	Hemophilia A with Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hemophilia A

AND

2 - Patient has developed high-titer factor VIII inhibitors [greater than 5 Bethesda units (BU)]

AND

3 - Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Product Name:Hemlibra	
Diagnosis	Hemophilia A with Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

Product Name:Hemlibra	
Diagnosis	Hemophilia A without Inhibitors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of severe hemophilia A

AND

1.1.2 Documentation of endogenous factor VIII levels less than 1% of normal factor VIII [less than 0.01 international units/milliliter (IU/mL)]

OR

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 BOTH of the following:

1.2.1.1.1 Diagnosis of moderate hemophilia A

AND

1.2.1.1.2 Documentation of endogenous factor VIII level greater than or equal to 1% and less than 5% (greater than or equal to 0.01 IU/mL to less than 0.05 IU/mL)

OR

1.2.1.2 BOTH of the following:

1.2.1.2.1 Diagnosis of mild hemophilia A

AND

1.2.1.2.2 Documentation of endogenous factor VIII level greater than or equal to 5% (greater than or equal to 0.05 IU/mL)

AND

1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of prophylactic factor VIII replacement products

OR

1.3 BOTH of the following:

1.3.1 Patient is currently on Hemlibra therapy as confirmed by claims history or submission of medical records

AND

1.3.2 Diagnosis of hemophilia A

AND

2 - Hemlibra is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

AND

3 - Prescriber attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Adynovate, Afstyla, Altuviio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes

Product Name:Hemlibra	
Diagnosis	Hemophilia A without Inhibitors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hemlibra therapy

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Hemlibra in combination with an extended half-life factor VIII replacement product (e.g., Adynovate, Afstyla, Altuviio, Eloctate, Jivi) for the treatment of breakthrough bleeding episodes (Prescription claim history that does not show any concomitant extended half-life factor VIII replacement product claim within 60 days of reauthorization request may be used as documentation)

2 . Revision History

Date	Notes
10/29/2024	Added new Hemlibra strengths. Updated list of examples of extende d half-life factor VIII replacement products.

Hepatitis C Criteria

Prior Authorization Guideline

Guideline ID	GL-145777
Guideline Name	Hepatitis C Criteria
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Brand Epclusa, generic sofosbuvir/velpatasvir, Brand Harvoni, generic ledipasvir/sofosbuvir, Sovaldi, Viekira Pak, Zepatier	
Guideline Type	Prior Authorization
Approval Criteria **1** - ALL of the following: **1.1** Prescribers must be enrolled as a billing provider, or an ordering prescribing or referring (OPR) provider with Rhode Island Medicaid*	

AND

1.2 Documentation of ALL of the following:

1.2.1 Chronic hepatitis C stage 0 through 4

AND

1.2.2 Hepatitis C genotyping

AND

1.2.3 History of prior hepatitis C treatment, if relevant

AND

1.2.4 Treatment plan which includes:

1.2.4.1 Medication name, dose, and duration

AND

1.2.4.2 Agreement to submit post-treatment viral load data, if requested

AND

1.3 The request includes clinical documentation of need for an alternative, non-preferred** agent

OR

2 - The request is for continuity of treatment when transitioning between publicly funded delivery systems (e.g., between Fee for Service Medicaid and Managed Care Medicaid,

between Managed Care Medicaid and Fee for Service Medicaid, or between the Department of Corrections and the Medicaid program)*** **OR** **3** - The patient is completing a cycle of therapy which was initiated prior to current policy implementation date	
Notes	*Provider attestation is not accepted as verification of RI PAR status **Requests for non-preferred medications will be reviewed on a case by case basis. Approval will be for the full course of treatment. ***Any medication approval by the prior delivery system will be honored for the portion of the treatment that remains after the transition.

Product Name:Vosevi	
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Prescribers must be enrolled as a billing provider or an ordering prescribing or referring (OPR) provider with Rhode Island Medicaid*

AND

1.2 ONE of the following:

1.2.1 Used as a salvage medication after prior treatment failure**

OR

1.2.2 Documentation of ALL of the following:

1.2.2.1 Chronic hepatitis C stage 0 through 4

AND

1.2.2.2 History of prior hepatitis C treatment, if relevant

AND

1.2.2.3 Treatment plan which includes ALL of the following:

- Medication name, dose, and duration
- Agreement to submit post-treatment viral load data, if requested

OR

2 - The request is for continuity of treatment when transitioning between publicly funded delivery systems (e.g., between Fee for Service Medicaid and Managed Care Medicaid, between Managed Care Medicaid and Fee for Service Medicaid, or between the Department of Corrections and the Medicaid program)***

Notes	*Provider attestation is not accepted as verification of RI PAR status **Prior authorization is not required for Vosevi when used as a salvage medication after prior treatment failure. See package insert for FDA approved indication and prescribing information. Approval will be for the full course of treatment. ***Any medication approval by the prior delivery system will be honored for the portion of the treatment that remains after the transition.

Product Name:Mavyret	
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribers must be enrolled as a billing provider or an ordering prescribing or referring (OPR) provider with Rhode Island Medicaid*

OR

2 - The request is for continuity of treatment when transitioning between publicly funded delivery systems (e.g., between Fee for Service Medicaid and Managed Care Medicaid, between Managed Care Medicaid and Fee for Service Medicaid, or between the Department of Corrections and the Medicaid program)**

Notes	Approval will be for the full course of treatment. *Provider attestation is not accepted as verification of RI PAR status **Any medication approval by the prior delivery system will be honore d for the portion of the treatment that remains after the transition.

2 . Revision History

Date	Notes
4/15/2024	Note added per state request, attestation is not acceptable verificatio n of RI participating provider status

Hetlioz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144636
Guideline Name	Hetlioz
Formulary	• Medicaid - Community & State New York • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Brand Hetlioz, generic tasimelteon, Hetlioz LQ	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of non-24-hour sleep wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome)

AND

1.1.2 Patient is totally blind (has no light perception)

OR

1.2 Diagnosis of nighttime sleep disturbances in Smith-Magenis-Syndrome (SMS)

AND

2 - ONE of the following:

2.1 History of contraindication or intolerance to melatonin therapy (please specify contraindication or intolerance)

OR

2.2 BOTH of the following:

2.2.1 Failure of at least 6 months of continuous therapy (i.e., uninterrupted daily treatment) with melatonin, as confirmed by claims history or submission of medical records

AND

2.2.2 Continuous trial of melatonin was done under the guidance of a specialist in sleep disorders

AND

3 - Prescribed by or in consultation with a specialist in sleep disorders

Product Name:Brand Hetlioz, generic tasimelteon, Hetlioz LQ	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
3/19/2024	Added generic tasimelteon capsules as a target to the guideline; Min or cosmetic updates; No changes to criteria.

Hycamtin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138234
Guideline Name	Hycamtin
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma

AND

2 - Disease is M1 disseminated

AND

3 - Patient has a contraindication to or disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC), Merkel Cell Carcinoma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin (topotecan) therapy

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hycamtin (topotecan) therapy

2 . Revision History

Date	Notes
12/27/2023	Updated Merkel cell carcinoma criteria based on current NCCN recommendations.

Hycamtin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138234
Guideline Name	Hycamtin
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel cell carcinoma

AND

2 - Disease is M1 disseminated

AND

3 - Patient has a contraindication to or disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	Small Cell Lung Cancer (SCLC), Merkel Cell Carcinoma
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Hycamtin (topotecan) therapy

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Hycamtin, generic topotecan	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Hycamtin (topotecan) therapy

2 . Revision History

Date	Notes
12/27/2023	Updated Merkel cell carcinoma criteria based on current NCCN recommendations.

Hyftor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135121
Guideline Name	Hyftor
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Hyftor	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tuberous sclerosis

AND

2 - One of the following:

2.1 One or more of the following major features:

- Hypomelanotic macules (At least 3; at least 5 mm diameter)
- Angiofibroma (At least 3) or fibrous cephalic plaque
- Ungual fibromas (At least 2)
- Shagreen patch
- Multiple retinal hamartomas
- Multiple cortical tubers and/or radial migration lines
- Subependymal nodule (At least 2)
- Subependymal giant cell astrocytoma
- Cardiac rhabdomyoma
- Lymphangiomyomatosis (LAM)
- Angiomyolipomas (At least 2)

OR

2.2 Two or more of the following minor features:

- “Confetti” skin lesions
- Dental enamel pits (At least 3)
- Intraoral fibromas (At least 2)
- Retinal achromic patch
- Multiple renal cysts
- Nonrenal hamartomas
- Sclerotic bone lesions

OR

2.3 Confirmed presence of a mutation in the TSC1 or TSC2 gene

AND

3 - Patient has facial angiofibroma associated with tuberous sclerosis

AND

4 - Patient is not receiving Hyftor in combination with a systemic mTOR (mechanistic target of rapamycin) inhibitor [e.g., Rapamune (sirolimus), Afinitor (everolimus)]

AND

5 - Hyftor is being prescribed by, or in consultation, with a dermatologist, neurologist, or oncologist

Product Name:Hyftor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in skin lesions)

AND

2 - Patient is not receiving Hyftor in combination with a systemic mTOR inhibitor [e.g., Rapamune (sirolimus), Afinitor (everolimus)]

AND

3 - Hyftor is being prescribed by, or in consultation, with a dermatologist, neurologist, or oncologist

2 . Revision History

Date	Notes
10/17/2023	Removed RMHCO formulary

Ibrance

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144875
Guideline Name	Ibrance
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Ibrance	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, or metastatic breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

- Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Used in combination with Faslodex (fulvestrant)

Product Name:Ibrance	
Diagnosis	Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable retroperitoneal WD-DDLS (well-differentiated/dedifferentiated liposarcoma)

Product Name:Ibrance	
Diagnosis	Breast Cancer, Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ibrance therapy

Product Name:Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ibrance will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ibrance	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ibrance therapy

2 . Revision History

Date	Notes
3/29/2024	Specified type of unresectable WD-DDLS to be retroperitoneal

Iclusig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138211
Guideline Name	Iclusig
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Iclusig	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelogenous/ myeloid leukemia (CML)

AND

2 - One of the following:

2.1 BOTH of the following:

- Disease is in the chronic phase
- Patient has resistance or intolerance to two or more tyrosine kinase inhibitor (TKI) therapies [e.g., imatinib mesylate, Sprycel (dasatinib), or Tasigna (nilotinib)]

OR

2.2 Confirmed documentation of T315I mutation

OR

2.3 BOTH of the following:

- Disease is in the accelerated or blast phase
- No other kinase inhibitors are indicated

Product Name:Iclusig	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL)

Product Name:Iclusig	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - One of the following:

2.1 Patient has a FGFR1 (fibroblast growth factor receptor 1) rearrangement

OR

2.2 Patient has an ABL1 (gene) rearrangement

Product Name:Iclusig	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/metastatic disease after progression on approved therapies (e.g. imatinib, sunitinib, regorafenib, and standard dose ripretinib)

Product Name:Iclusig	
Diagnosis	Chronic Myelogenous / Myeloid Leukemia (CML), Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL), Myeloid/Lymphoid Neoplasms, Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iclusig therapy

Product Name:Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Iclusig	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Iclusig therapy	

2 . Revision History

Date	Notes
1/8/2024	Updated Ph+ ALL criteria based on NCCN recommendations. Added criteria for GIST based on NCCN recommendations.

ICS.LABA Combination Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158100
Guideline Name	ICS.LABA Combination Products
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:generic budesonide/formoterol, generic Breyna	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 BOTH of the following:

1.1.1 Diagnosis of COPD

AND

1.1.2 ONE of the following:

1.1.2.1 Failure of ONE of the following confirmed by claims history or submitted medical records

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

1.1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of asthma

AND

1.2.2 ONE of the following:

1.2.2.1 Patient is less than 12 years of age

OR

1.2.2.2 ONE of the following:

1.2.2.2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

1.2.2.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

Product Name:fluticasone/vilanterol (authorized generic of Breo Ellipta)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of asthma

AND

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)

- Wixela Inhub (generic Advair Diskus)

OR

1.2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

1.2.2 ONE of the following:

1.2.2.1 Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

OR

1.2.2.2 History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

OR

2 - ALL of the following:

2.1 Diagnosis of COPD

AND

2.2 ONE of the following:

2.2.1 Failure of ONE of the following confirmed by claims history or submitted medical records

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

2.3 ONE of the following:

2.3.1 Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

OR

2.3.2 History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

Product Name:Advair HFA, fluticasone-salmeterol (authorized generic of Advair HFA), Dulera, AirDuo Digihaler, AirDuo Respiclick *	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - ONE of the following:

2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

3 - ONE of the following:

3.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

Notes	*Policy applies to Brand Necessary requests

Product Name:Brand Symbicort, Brand Advair Diskus*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of asthma

AND

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient is less than 12 years of age

AND

1.2.1.2 ONE of the following:

1.2.1.2.1 Failure of Breyna or budesonide/formoterol (generic of Symbicort) confirmed by claims history or submitted medical records

OR

1.2.1.2.2 History of intolerance or contraindication to Breyna or budesonide/formoterol (generic of Symbicort) (please specify intolerance or contraindication)

OR

1.2.2 BOTH of the following:

1.2.2.1 ONE of the following:

1.2.2.1.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

1.2.2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

1.2.2.2 ONE of the following:

1.2.2.2.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

1.2.2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

2 - All of the following:

2.1 Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2.2 ONE of the following:

2.2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)

- Wixela Inhub (generic Advair Diskus)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

2.3 ONE of the following:

2.3.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

Notes	*Policy applies to Brand Necessary requests

Product Name:Breo Ellipta*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of asthma

AND

1.2 BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

1.2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- fluticasone/salmeterol (authorized generic of AirDuo Respiclick)
- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

1.2.2 ONE of the following:

1.2.2.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

1.2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Breyna or budesonide/formoterol (generic of Symbicort))

- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

2 - ALL of the following:

2.1 Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2.2 ONE of the following:

2.2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- fluticasone propionate/salmeterol diskus (generic Advair Diskus)
- Wixela Inhub (generic Advair Diskus)

AND

2.3 ONE of the following:

2.3.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Breyna or budesonide/formoterol (generic of Symbicort)
- fluticasone/vilanterol (authorized generic of Breo Ellipta)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication): • Breyna or budesonide/formoterol (generic of Symbicort) • fluticasone/vilanterol (authorized generic of Breo Ellipta)

Notes	*Policy applies to Brand Necessary requests

2 . Revision History

Date	Notes
10/28/2024	Added new Breo Ellipta strength. Clarified preferred Respiclick product in T/F language.

Idhifa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157989
Guideline Name	Idhifa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH2 (isocitrate dehydrogenase 2) mutation-positive

AND

3 - ONE of the following:

3.1 Disease is relapsed or refractory

OR

3.2 Used as low-intensity treatment induction when not a candidate for intensive induction therapy

OR

3.3 Used for consolidation therapy as continuation of low-intensity regimen used for induction

OR

3.4 Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen

Product Name:Idhifa	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Idhifa therapy

Product Name:Idhifa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Idhifa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Idhifa therapy

2 . Revision History

Date	Notes

10/24/2024	Updated initial auth criteria for AML based on NCCN recommendatio ns; Minor cosmetic updates.

Ilaris

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164637
Guideline Name	Ilaris
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FCAS and MWS

Product Name:Ilaris	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Familial cold autoinflammatory syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)

AND

2 - Documentation of positive clinical response to Ilaris therapy

Product Name:Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS

Product Name:Ilaris	
Diagnosis	Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name:Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)
- Mevalonate Kinase Deficiency (MKD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of HIDS or MKD

Product Name:Ilaris	
Diagnosis	Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for ONE of the following:

- Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)
- Mevalonate Kinase Deficiency (MKD)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Product Name:Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Familial Mediterranean Fever (FMF)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF

AND

3 - ONE of the following:

3.1 Failure to colchicine as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to colchicine (please specify contraindication or intolerance)

Product Name:Ilaris	
Diagnosis	Familial Mediterranean Fever (FMF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Familial Mediterranean Fever (FMF)

AND

2 - Documentation of positive clinical response to Ilaris therapy, defined by a decrease in index disease flare or normalization of CRP (C-reactive protein)

Product Name:Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA

AND

3 - Patient is NOT receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

Product Name:Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

Product Name:Ilaris	
Diagnosis	Still's Disease [Adult-Onset Still's Disease (AOSD)]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Adult Onset Still's Disease (AOSD)

AND

2 - Diagnosis is made by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of Still's Disease

AND

3 - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

Product Name:Ilaris	
Diagnosis	Still's Disease [Adult-Onset Still's Disease (AOSD)]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently on Ilaris therapy for Adult Onset Still's Disease (AOSD)

AND

2 - Documentation of positive clinical response to Ilaris therapy

AND

3 - Patient is not receiving Ilaris in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz (tofacitinib)]

Product Name:Ilaris	
Diagnosis	Gout Flare
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a gout flare

AND

2 - ONE of the following:

2.1 History of failure to BOTH of the following confirmed by claims history or submission of medical records:

- Colchicine
- Non-steroidal anti-inflammatory drugs (NSAIDs)

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Colchicine
- Non-steroidal anti-inflammatory drugs (NSAIDs)

AND

3 - Provider attests that the patient is not an appropriate candidate for systemic corticosteroids

AND

4 - Prescribed by one of the following:

- Rheumatologist
- Nephrologist

AND

5 - The patient has not received Ilaris in the past 12 weeks

2 . Revision History

Date	Notes
2/3/2025	Updated formularies. Updated concurrent use criteria

Ilumya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-182195
Guideline Name	Ilumya
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Ilumya	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic moderate to severe plaque psoriasis

AND

2 - Patient is NOT receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by, or in consultation with, a dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Ilumya therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab), Enbrel (etanercept)]

OR

4.2.1.2 ALL of the following:

4.2.1.2.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

AND

4.2.1.2.2 ONE of the following:

- Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

AND

4.2.1.2.3 ONE of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

AND

4.2.2 ONE of the following:

4.2.2.1 Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

• One of the preferred adalimumab products* • Enbrel (etanercept) • One of the preferred ustekinumab products*

Notes	*See PDL links in Background

Product Name:Ilumya	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ilumya therapy

AND

2 - Patient is NOT receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
2/21/2025	Updated formularies. Updated criteria to add ST through two preferred targeted immunomodulators. Updated safety check language. Removed reference to brand Stelara - replaced with generic

Imbruvica

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161243
Guideline Name	Imbruvica
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Imbruvica	
Diagnosis	B-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of mantle cell lymphoma (MCL)

AND

1.2 ONE of the following:

1.2.1 Patient has received at least one prior therapy for MCL

OR

1.2.2 Used in pre-treatment therapy in combination with Rituxan (rituximab) to limit the number of cycles with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen

OR

2 - Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

OR

3 - BOTH of the following:

3.1 Diagnosis of ONE of the following:

- Diffuse large B-cell lymphoma [non-GCB DLBCL (non-germinal center B-cell diffuse large B-cell) and non-candidate for transplant]
- Human Immunodeficiency Virus (HIV)-related B-cell lymphoma
- Post-transplant lymphoproliferative disorders
- Histologic transformation to diffuse large B-cell lymphoma
- Hairy cell leukemia
- Nodal or splenic marginal zone lymphoma (MZL)

- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Extranodal marginal zone lymphoma (EMZL) of nongastric sites (noncutaneous)
- High grade B-cell lymphoma

AND

3.2 Used as second-line or a subsequent therapy

Product Name:Imbruvica	
Diagnosis	Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Product Name:Imbruvica	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - ONE of the following:

2.1 Used as second-line or a subsequent therapy

OR

2.2 Used as induction therapy if the patient is unsuitable or intolerant to high-dose methotrexate

Product Name:Imbruvica	
Diagnosis	B-Cell Lymphoma, Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Imbruvica therapy

Product Name:Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft versus host disease

AND

2 - History of failure of at least one other systemic therapy [e.g., corticosteroids, mycophenolate, etc.] as confirmed by claims history or submission of medical records

Product Name:Imbruvica	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response while on Imbruvica therapy

Product Name:Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Imbruvica	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Imbruvica therapy

2 . Revision History

Date	Notes
11/25/2024	Added rituximab to RHyperCVAD and minor formatting changes

Impavido

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124418
Guideline Name	Impavido
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Impavido	
Approval Length	28 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has a diagnosis of ONE of the following:

- Visceral leishmaniasis due to Leishmania donovani
- Cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis
- Mucosal leishmaniasis due to Leishmania braziliensis
- Primary Amebic Meningoencephalitis (PAM)
- Keratitis due to Acanthamoeba
- Amebic encephalitis due to Balamuthia mandrillaris

2 . Revision History

Date	Notes
4/10/2023	Updated formularies.

Inbrija

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144882
Guideline Name	Inbrija
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Inbrija	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Inbrija will be used as intermittent treatment for OFF episodes

AND

3 - Prescribed by, or in consultation with, a neurologist or specialist in the treatment of Parkinson's disease

AND

4 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

5 - Patient continues to experience greater than or equal to 2 hours of OFF time per day despite optimal management of carbidopa/levodopa therapy including BOTH of the following:

- Taking carbidopa/levodopa on an empty stomach or at least one half-hour or more before or one hour after a meal or avoidance of high protein diet
- Dose and dosing interval optimization

AND

6 - ONE of the following:

6.1 Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes confirmed by claims history or submission of medical records (trial must be from two different classes):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

OR

6.2 History of contraindication or intolerance to ALL anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

Product Name:Inbrija	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inbrija therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
3/29/2024	Updated initial authorization to 12 months.

Ingrezza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164976
Guideline Name	Ingrezza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Ingrezza	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe tardive dyskinesia

AND

2 - ONE of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Product Name:Ingrezza	
Diagnosis	Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea associated with Huntington's disease

AND

2 - Prescribed by or in consultation with ONE of the following:

- Neurologist
- Psychiatrist

Product Name:Ingrezza	
Diagnosis	Tardive Dyskinesia, Chorea associated with Huntington's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ingrezza therapy

2 . Revision History

Date	Notes
2/11/2025	Updated formularies. Updated GPIs

Inhaled Corticosteroids

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123923
Guideline Name	Inhaled Corticosteroids
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Asmanex HFA, Asmanex Twisthaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of asthma	

AND

2 - ONE of the following:

2.1 Failure of Brand Fluticasone propionate HFA confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to Brand Fluticasone propionate HFA (please specify intolerance or contraindication)

Product Name:Alvesco, ArmonAir Digihaler, Arnuity Ellipta, Flovent Diskus, Brand Flovent HFA, Pulmicort Flexhaler, Qvar RediHaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - ONE of the following:

2.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

- Brand Fluticasone propionate HFA
- Asmanex HFA or Asmanex Twisthaler

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Brand Fluticasone propionate HFA
- Asmanex HFA or Asmanex Twisthaler

2 . Revision History

Date	Notes
3/29/2023	Removed Fluticasone propionate (Flovent HFA AG) from product details

Inlyta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158204
Guideline Name	Inlyta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Inlyta	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of advanced renal cell carcinoma

AND

1.2 ONE of the following:

- Patient has failed one prior systemic therapy
- The requested medication will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)

OR

2 - Diagnosis of relapsed or stage IV renal cell carcinoma

Product Name:Inlyta	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Persistent
- Metastatic

AND

3 - Disease is not amenable to radioactive iodine treatment

Product Name:Inlyta	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

Product Name:Inlyta	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of alveolar soft part sarcoma (ASPS)

AND

2 - The requested medication will be used in combination with Keytruda (pembrolizumab)

Product Name:Inlyta	
Diagnosis	Renal Cell Carcinoma, Thyroid Carcinoma, Salivary Gland Tumor, Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Product Name:Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inlyta therapy

2 . Revision History

Date	Notes
10/29/2024	Updated initial auth criteria for RCC. Updated diagnosis header for R CC in reauth section. Minor update to initial auth criteria for NCCN R ecommended Regimens with no changes to clinical intent; Minor cos metic updates.

Inlyta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158204
Guideline Name	Inlyta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Inlyta	
Diagnosis	Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of advanced renal cell carcinoma

AND

1.2 ONE of the following:

- Patient has failed one prior systemic therapy
- The requested medication will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)

OR

2 - Diagnosis of relapsed or stage IV renal cell carcinoma

Product Name:Inlyta	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Persistent
- Metastatic

AND

3 - Disease is not amenable to radioactive iodine treatment

Product Name:Inlyta	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

Product Name:Inlyta	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of alveolar soft part sarcoma (ASPS)

AND

2 - The requested medication will be used in combination with Keytruda (pembrolizumab)

Product Name:Inlyta	
Diagnosis	Renal Cell Carcinoma, Thyroid Carcinoma, Salivary Gland Tumor, Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inlyta therapy

Product Name:Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Inlyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inlyta therapy

2 . Revision History

Date	Notes
10/29/2024	Updated initial auth criteria for RCC. Updated diagnosis header for R CC in reauth section. Minor update to initial auth criteria for NCCN R ecommended Regimens with no changes to clinical intent; Minor cos metic updates.

Inqovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123558
Guideline Name	Inqovi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of myelodysplastic syndrome (MDS)

AND

1.2 Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

OR

2 - Diagnosis of chronic myelomonocytic leukemia (CMML)

Product Name:Inqovi	
Diagnosis	Myelodysplastic Syndrome (MDS), Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inqovi therapy

Product Name:Inqovi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Inqovi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Inqovi therapy	

2 . Revision History

Date	Notes
3/21/2023	Combined formularies, cleaned up criteria.

Inrebic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135140
Guideline Name	Inrebic
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis

AND

2 - One of the following:

2.1 Failure to Jakafi (ruxolitinib) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to Jakafi (ruxolitinib) (please specify intolerance or contraindication)

OR

2.3 Patient is currently on Inrebic therapy

Product Name:Inrebic	
Diagnosis	Myelofibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has evidence of symptom improvement or reduction in spleen volume while on Inrebic

Product Name:Inrebic

Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 (Janus kinase 2) rearrangement

AND

3 - ONE of the following:

3.1 Failure to Jakafi (ruxolitinib) confirmed by claims history or submitted medical records

OR

3.2 History of intolerance or contraindication to Jakafi (ruxolitinib) (please specify intolerance or contraindication)

OR

3.3 Patient is currently on Inrebic therapy

Product Name:Inrebic	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Inrebic therapy

Product Name:Inrebic	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Inrebic	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Inrebic therapy

2 . Revision History

Date	Notes
10/18/2023	Removed RMHCO formulary

Insulin Pen Needles and Syringes

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158113
Guideline Name	Insulin Pen Needles and Syringes
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Non-preferred insulin pen needles and insulin syringes	
Diagnosis	Non-Preferred
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - If the request is non-preferred*, history of failure to a preferred* BD (Becton Dickinson) insulin pen needle or syringe as confirmed by claims history or submission of medical records **OR** **2** - If the request is non-preferred*, physician has provided documentation as to why the patient is unable to use a preferred* BD product (document rationale)	
Notes	*PDL links are listed in Background.

Product Name:All insulin pen needles and insulin syringes	
Diagnosis	Requests exceeding 6 pen needles or syringes per day*
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Physician confirmation that the patient requires a greater quantity because of more frequent delivery of insulin	
Notes	*The quantity limit for both pen needles and syringes is 6 of each per day.

2 . Background

Benefit/Coverage/Program Information
PDL links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
10/28/2024	Updated GPIs

Insulins

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145635
Guideline Name	Insulins
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Admelog vial, Apidra vial, Humalog 100U/ml vial, Insulin Aspart vial, Lyumjev vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Failure to insulin lispro vial confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)

Product Name:Novolog vial, Fiasp vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- insulin lispro vial
- Insulin Aspart vial

OR

1.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- insulin lispro vial
- Insulin Aspart vial

Product Name:Novolog Mix 70/30 vial, Novolog Mix 70/30 Relion vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to Insulin Aspart mix vial confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to Insulin Aspart mix vial (please specify intolerance or contraindication)

Product Name:Humalog Mix 75/25 vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML (please specify intolerance or contraindication)

Product Name:Humulin R U-500 vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient requires more than 200 units of insulin per day

Product Name:Insulin Lispro Kwikpen, Insulin Lispro Junior Kwikpen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

1.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

1.3 History of failure to insulin lispro vial as demonstrated by poorly controlled diabetes based on hemoglobin A1c

OR

1.4 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Apidra Solostar pen, Humalog cartridge, Humalog Kwikpen, Humalog Junior Kwikpen, Insulin Aspart Penfill, Insulin Aspart Flexpen, Admelog Solostar pen, Lyumjev Kwikpen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 One of the following:

1.1.1 Failure to insulin lispro vial confirmed by claims history or submission of medical records

OR

1.1.2 History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)

OR

1.2 ONE of the following:

1.2.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

1.2.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

1.2.3 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

AND

2 - ONE of the following:

2.1 Failure to insulin lispro Kwikpen confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to insulin lispro Kwikpen (please specify intolerance or contraindication)

Product Name:Humalog Tempo Pen, Lyumjev Tempo Pen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to insulin lispro Kwikpen confirmed by claims history or submission of medical records

OR

1.1.2 History of contraindication or intolerance to insulin lispro Kwikpen (please specify intolerance or contraindication)

AND

1.2 Prescriber provides a reason or special circumstance the patient has to use the Tempo product

Product Name:Novolog Penfill, Novolog Flexpen, Fiasp Penfill, Fiasp Pumpcart, Fiasp FlexTouch	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following:

1.1.1 Failure to insulin lispro vial confirmed by claims history or submission of medical records

OR

1.1.2 History of contraindication or intolerance to insulin lispro vial (please specify intolerance or contraindication)

OR

1.2 ONE of the following:

- A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin
- A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin
- The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

AND

2 - One of the following:

2.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Insulin lispro Kwikpen

- Insulin aspart pen or cartridge

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Insulin lispro Kwikpen
- Insulin aspart pen or cartridge

Product Name:Novolin R Flexpen, Novolin R Flexpen Relion	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Humulin R U-100 vial
- Novolin R U-100 vial

OR

1.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Humulin R U-100 vial
- Novolin R U-100 vial

OR

2 - ONE of the following:

2.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

2.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

2.3 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Humulin R U-500 Kwikpen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient requires more than 200 units of insulin per day

AND

1.2 ONE of the following:

1.2.1 Failure to Humulin R U-500 vial confirmed by claims history or submission of medical records

OR

1.2.2 History of contraindication or intolerance to Humulin R U-500 vial (please specify intolerance or contraindication)

OR

2 - BOTH of the following:

2.1 Patient requires more than 200 units of insulin per day

AND

2.2 ONE of the following:

2.2.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

2.2.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

2.2.3 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Humulin N Kwikpen, Novolin N Flexpen, Novolin N Flexpen Relion	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Humulin N U-100 vial
- Novolin N U-100 vial

OR

1.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication):

- Humulin N U-100 vial
- Novolin N U-100 vial

OR

2 - ONE of the following:

2.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

2.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

2.3 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Humalog Mix Kwikpen 50/50, Insulin Aspart Flexpen 70/30, Humulin Kwikpen 70/30, Novolin Flexpen 70/30, Novolin Flexpen Relion 70/30	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)

OR

2 - ONE of the following:

2.1 A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin

OR

2.2 A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

OR

2.3 The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

Product Name:Novolog Mix 70/30 Flexpen, Novolog Mix 70/30 Flexpen Relion	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following:

- Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records
- History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)

OR

1.2 ONE of the following:

- A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin
- A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin
- The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

AND

2 - ONE of the following:

- Failure to Insulin Aspart Flexpen 70/30 100U/ML confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Insulin Aspart Flexpen 70/30 100U/ML (please specify intolerance or contraindication)

Product Name:Humalog Mix Kwikpen 72/25	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 ONE of the following:

- Failure to the corresponding preferred insulin mix vial confirmed by claims history or submission of medical records
- History of contraindication or intolerance to the corresponding preferred insulin mix vial (please specify intolerance or contraindication)

OR

1.2 ONE of the following:

- A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin
- A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin
- The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on hemoglobin A1c

AND

2 - One of the following:

- Failure to insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Insulin lispro protamine/insulin lispro Kwikpen 75/25 100U/ML (please specify intolerance or contraindication)

Product Name:Basaglar Kwikpen, Insulin Glargine Solostar 100U/ml, Insulin glargine-yfgn Pen, Semglee yfgn Pen Injector	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

AND

1.2 The provider has given clinical justification why the patient is unable to use the preferred insulin glargine products

Product Name:Basaglar Tempo Pen	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

AND

1.2 Prescriber provides a reason or special circumstance the patient has to use the Tempo product

Product Name:Toujeo Solostar, Insulin Glargine Solostar 300U/ml, Toujeo Max Solostar, Insulin Glargine Max Solostar 300U/ml	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.1.3 The provider has given clinical justification why the patient needs a concentrated glargine formulation

AND

1.2 If the request is for Toujeo Solostar or Toujeo Solostar Max, ONE of the following:

1.2.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Insulin glargine Solostar 300U/ml
- Insulin glargine Max Solostar 300U/ml

OR

1.2.2 History of intolerance or contraindication to ONE of the following (please specify intolerance or contraindication):

- Insulin glargine Solostar 300U/ml
- Insulin glargine Max Solostar 300U/ml

Product Name:Levemir Flexpen, Insulin Degludec Flextouch 100U/mL	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

2 - History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

Product Name:Tresiba Flextouch 100U/mL	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

AND

2 - The provider has given clinical justification why the patient is unable to use the insulin degludec flextouch product

Product Name:Insulin Degludec Flextouch 200U/mL	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

2 - History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

3 - The provider has given clinical justification why the patient needs a concentrated formulation

Product Name:Tresiba Flextouch 200U/mL	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.3 The provider has given clinical justification why the patient needs a concentrated formulation

AND

2 - The provider has given clinical justification why the patient is unable to use the insulin degludec flextouch product

Product Name:Insulin Glargine vial, Insulin glargine-yfgn vial, Semglee yfgn vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Failure to BOTH of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

AND

1.2 The provider has given clinical justification why the patient is unable to use the preferred insulin glargine products

Product Name:Levemir vial, Insulin Degludec vial	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

Product Name:Tresiba vial	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Failure to ONE of the following confirmed by claims history or submission of medical records:

- Rezvoglar Kwikpen
- Lantus (pens or vials)

OR

1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Rezvoglar Kwikpen
- Lantus (pens or vials)

AND

2 - The provider has given clinical justification why the patient is unable to use the insulin degludec product

Product Name:Admelog Solostar, Apidra, Insulin Aspart vial, Insulin Lispro vial, Humalog vial, Novolog vial, Novolog Relion vial, Fiasp vial, Lyumjev vial, Novolog Mix 70/30 vial, Novolog Mix 70/30 Relion vial, Humulin R U-500 vial, Apidra Solostar, Insulin Aspart Flexpen, Insulin Aspart Penfill, Insulin Lispro Junior Kwikpen, Insulin Lispro Kwikpen, Humalog Junior Kwikpen, Humalog Kwikpen, Humalog Tempo Pen, Novolog Flexpen, Novolog Flexpen Relion, Novolog Penfill, Fiasp Flextouch, Fiasp Penfill, Fiasp Pumpcart, Lyumjev Kwikpen, Lyumjev Tempo Pen, Novolin R Flexpen Relion, Novolin R Flexpen, Humulin R U-500 Kwikpen, Humulin N Kwikpen, Novolin N Flexpen Relion, Novolin N Flexpen, Humalog Mix 75/25 Kwikpen, Insulin Lispro Mix Kwikpen 72/25, Humalog Mix 50/50 Kwikpen, Insulin Aspart Protamine/Insulin Aspart 70/30 Flexpen, Humulin 70/30 Kwikpen, Novolin 70/30 Flexpen, Novolin 70/30 Flexpen Relion, Novolog Mix 70/30 Flexpen, Novolog Mix 70/30 Flexpen Relion, Lantus Solostar, Basaglar Tempo Pen, Toujeo Solostar, Insulin Glargine Solostar 300U/ml, Toujeo Max Solostar, Insulin Glargine Max Solostar 300U/ml, Semglee yfgn Pen Injector, Semglee yfgn vial Levemir Flexpen, Tresiba Flextouch, Insulin Degludec Flextouch, Semglee vial, Lantus vial, Levemir vial, Tresiba vial, Insulin Degludec vial, Basaglar Kwikpen, Insulin Glargine vial, Insulin Glargine-YFGN pen and vial, Insulin Glargine Solostar 100U/ml,

Humulin R vial, Novolin R vial, Novolin R Relion vial, Humulin N vial, Novolin N Relion vial, Novolin N vial, Insulin Aspart Protamine/Insulin Aspart 70/30 vial, Humalog Mix 75/25 vial, Humalog Mix 50/50 vial, Humulin 70/30 vial, Novolin 70/30 Relion vial, Novolin 70/30 vial, Admelog vial, Humalog Cartridge, Rezvoglar Kwikpen	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Quantity requests exceeding the limited amount will be approved based on physician confirmation that the patient requires a greater quantity due to poorly controlled diabetes based on blood glucose and/or hemoglobin A1c

2 . Background

Benefit/Coverage/Program Information

Table 1. PDL Links

Colorado	https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html
Hawaii	https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html
Maryland	https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html
New Jersey	https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html
New York/ New York EPP	https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html
Rhode Island	https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

	Pennsylvania CHIP	https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

3 . Revision History

Date	Notes
4/11/2024	Updated current Insulin glargine Solostar product names to specify 100U/ml. Added Insulin glargine Solostar 300U/ml and Insulin glargine max Solostar 300U/ml GPIs and updated Toujeo/Toujeo Max criteria. Added new Insulin glargine Solostar 300U/ml and Insulin glargine max Solostar 300U/ml GPIs to QL section.

Iqirvo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158115
Guideline Name	Iqirvo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Iqirvo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)

AND

3.1.2 Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) [please specify contraindication or intolerance]

AND

4 - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

AND

5 - Prescribed by one of the following:

- Hepatologist

- Gastroenterologist

Product Name:Iqirvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Iqirvo therapy)

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - Patient is not receiving Iqirvo in combination with Livdelzi (seladelpar) or Ocaliva (obeticholic acid)

AND

4 - Prescribed by one of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes

10/28/2024	New

Iressa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136146
Guideline Name	Iressa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

2.1 Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions

OR

2.2 Tumors are positive for exon 21 (L858R) substitution mutations

OR

2.3 Tumors are positive for a known sensitizing EGFR mutation (e.g, exon 20 S7681 mutation, exon 18 G719X mutation, exon 21 L861Q mutation)

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iressa therapy

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	Central Nervous System (CNS) Cancers

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central nervous system (CNS) cancer with metastatic lesions

AND

2 - Iressa is active against primary (NSCLC) tumor with a known epidermal growth factor receptor (EGFR) sensitizing mutation

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iressa therapy

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Iressa, generic gefitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Iressa therapy	

2 . Revision History

Date	Notes
11/14/2023	Updated list of examples of sensitizing EGFR mutations in NSCLC cr iteria, added generic gefitinib to GPI and product name lists.

Iron Chelators

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127981
Guideline Name	Iron Chelators
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias

AND

1.2 Ferriprox (deferiprone) will not be used for the treatment of transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia

Product Name:Brand Ferriprox, generic deferiprone	
Diagnosis	Chronic Iron Overload due to Blood Transfusion
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndrome

AND

1.2 Patient has liver iron (Fe) concentration (LIC) levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade (deferasirox) or Jadenu (deferasirox)

AND **1.3** Patient has serum ferritin levels consistently greater than 300 micrograms per liter prior to initiation of treatment with Exjade (deferasirox) or Jadenu (deferasirox)

Product Name:Brand Exjade, Brand Jadenu, generic deferasirox	
Diagnosis	Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
7/14/2023	Removed RMH and ACUAZ formularies.

Irritable Bowel Syndrome - Diarrhea

Prior Authorization Guideline

Guideline ID	GL-208216
Guideline Name	Irritable Bowel Syndrome - Diarrhea
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:generic alosetron, Brand Lotronex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms for at least six months

AND

2 - Patient was female at birth

AND

3 - ONE of the following:

3.1 Failure to a tricyclic antidepressant (e.g., amitriptyline) as confirmed by claims history or submitted medical records

OR

3.2 History of intolerance or contraindication to a tricyclic antidepressant (e.g., amitriptyline) (please specify intolerance or contraindication)

AND

4 - Anatomic or biochemical abnormalities of the GI (gastrointestinal) tract have been excluded

Product Name:generic alosetron, Brand Lotronex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

Product Name:Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - ONE of the following:

2.1 Failure to a tricyclic antidepressant (e.g., amitriptyline) as confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to a tricyclic antidepressant (e.g., amitriptyline) (please specify intolerance or contraindication)

Product Name:Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Viberzi therapy

2 . Revision History

Date	Notes
3/5/2025	Updated formularies

Isotretinoin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145385
Guideline Name	Isotretinoin
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Accutane, Myorisan, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD	
Diagnosis	Oncology Uses (Off Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN)

OR

2 - Use is supported by ONE of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

Product Name:Accutane, Myorisan, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD	
Diagnosis	Acne
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

OR

1.2 Diagnosis of treatment resistant acne

AND

2 - ONE of the following:

2.1 Failure to an adequate trial on TWO of the following conventional therapy regimens confirmed by claims history or submission of medical records:

- Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [e.g., Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)]
- Oral antibiotic [e.g., Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]
- Topical antibiotic with or without benzoyl peroxide [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)]

AND

3 - If the request is non-preferred*, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication (please specify reason or special circumstance)

Notes	*PDL links are listed in Background.

Product Name:Accutane, Myorisan, generic isotretinoin, Claravis, Amnesteem, Zenatane, Brand Absorica, Absorica LD	
Diagnosis	Acne
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - After greater than or equal to 2 months OFF therapy, persistent or recurring severe recalcitrant nodular acne is still present

OR

2 - Total cumulative dose for total duration of therapy is less than 150 milligrams/kilogram (mg/kg) (will be approved up to a total of 150 mg/kg)

2 . Background

Benefit/Coverage/Program Information

PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
4/4/2024	Updated CO PDL Link

Isturisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127865
Guideline Name	Isturisa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Isturisa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cushing's disease

AND

2 - ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name:Isturisa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

2 . Revision History

Date	Notes
7/11/2023	Updated formularies, removed indications.

Isturisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127865
Guideline Name	Isturisa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Isturisa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cushing's disease

AND

2 - ONE of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative

Product Name:Isturisa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to Isturisa therapy

2 . Revision History

Date	Notes
7/11/2023	Updated formularies, removed indications.

Itovebi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164670
Guideline Name	Itovebi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Itovebi	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Disease is PIK3CA-mutation positive

AND

6 - Used following recurrence on or after completing adjuvant endocrine therapy

AND

7 - Used in combination with both of the following:

- Ibrance (palbociclib)

- Fulvestrant

Product Name:Itovebi	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Itovebi therapy

Product Name:Itovebi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Itovebi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to Itovebi therapy

2 . Revision History

Date	Notes
2/4/2025	New guideline

Iwilfin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143217
Guideline Name	Iwilfin
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Iwilfin	
Diagnosis	High-Risk Neuroblastoma (HRNB)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high-risk neuroblastoma (HRNB)

AND

2 - Patient has shown at least a partial response to prior multiagent, multimodality therapy

AND

3 - Prior therapy included anti-GD2 immunotherapy (e.g., Danyelza (naxitamab-gqgk), Unituxin (dinutuximab))

Product Name:Iwilfin	
Diagnosis	High-Risk Neuroblastoma (HRNB)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Iwilfin therapy

Product Name:Iwilfin	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Iwilfin	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Iwilfin therapy

2 . Revision History

Date	Notes
4/16/2024	New guideline

Jakafi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163749
Guideline Name	Jakafi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Symptomatic lower-risk myelofibrosis

OR

1.2 Intermediate or higher-risk myelofibrosis

OR

1.3 Post-polycythemia vera myelofibrosis

OR

1.4 Post-essential thrombocythemia myelofibrosis

OR

1.5 Both of the following:

- Myelofibrosis-associated anemia
- Presence of symptomatic splenomegaly and/or constitutional symptoms

Product Name:Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of low-risk polycythemia vera

AND

1.2 One of the following:

1.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

OR

1.2.2 History of contraindication or intolerance to both of the following (please specify contraindication or intolerance):

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

OR

2 - Diagnosis of high-risk polycythemia vera

Product Name:Jakafi	
Diagnosis	Essential Thrombocythemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of essential thrombocythemia

AND

2 - Inadequate response or loss of response to ONE of the following:

- Hydroxyurea
- Pegasys (peginterferon alfa-2a)
- Agrylin (Anagrelide)

Product Name:Jakafi	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

2 - Used for splenomegaly or other disease-related symptoms

Product Name:Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera, Essential Thrombocythemia, Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi*

Notes	*If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of acute graft versus host disease (GVHD)

AND

1.2 Disease is steroid refractory

OR

2 - BOTH of the following:

2.1 Diagnosis of chronic GVHD

AND

2.2 Failure of one or two lines of systemic therapy

Product Name:Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of symptom improvement while on Jakafi

Product Name:Jakafi	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 rearrangement

Product Name:Jakafi

Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of chronic myelomonocytic leukemia (CMML)-2

AND

1.2 Used in combination with a hypomethylating agent (e.g., azacitidine, decitabine)

OR

2 - BOTH of the following:

2.1 Diagnosis of myelodysplastic/myeloproliferative neoplasm (MDS/MPN) with neutrophilia

AND

2.2 Disease is positive for CSF3R or JAK2 mutation

Product Name:Jakafi	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of one of the following:

- Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- Enteropathy-associated T-cell lymphoma (EATL)
- Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
- Angioimmunoblastic T-cell lymphoma (AITL)
- Nodal peripheral T-cell lymphoma with T-follicular helper phenotype (PTCL, TFH)
- Follicular T-cell lymphoma (FTCL)
- Anaplastic large cell lymphoma (ALCL)

AND

1.2 Used as initial palliative intent therapy or second-line and subsequent therapy for relapsed/refractory disease

OR

2 - Both of the following:

2.1 One of the following diagnoses:

- T-cell large granular lymphocytic leukemia
- T-cell prolymphocytic leukemia

AND

2.2 Used as second-line or subsequent therapy

OR

3 - Both of the following:

3.1 Diagnosis of hepatosplenic T-cell lymphoma

AND

3.2 Used for refractory disease after two first-line therapy regimens

Product Name:Jakafi	
Diagnosis	Myeloid/Lymphoid Neoplasms, Myelodysplastic Syndromes, T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Jakafi therapy	

Product Name:Jakafi	
Diagnosis	Pediatric Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pediatric acute lymphoblastic leukemia **AND** **2** - Used as a component of consolidation therapy	

Product Name:Jakafi	
Diagnosis	Immunotherapy-Related Toxicities
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of CAR-T induced G4 cytokine release syndrome

AND

1.2 Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., Actemra [tocilizumab])

OR

2 - Both of the following:

2.1 Diagnosis of immune checkpoint inhibitor-related toxicities

AND

2.2 Used in combination with Orencia (abatacept) for the management of concomitant myositis and myocarditis

Product Name:Jakafi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Jakafi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy

2 . Revision History

Date	Notes
1/14/2025	Multiple criteria updates, including new criteria for Myeloproliferative Neoplasms. Updated auth length for multiple dx.

Jakafi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163749
Guideline Name	Jakafi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Symptomatic lower-risk myelofibrosis

OR

1.2 Intermediate or higher-risk myelofibrosis

OR

1.3 Post-polycythemia vera myelofibrosis

OR

1.4 Post-essential thrombocythemia myelofibrosis

OR

1.5 Both of the following:

- Myelofibrosis-associated anemia
- Presence of symptomatic splenomegaly and/or constitutional symptoms

Product Name:Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of low-risk polycythemia vera

AND

1.2 One of the following:

1.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

OR

1.2.2 History of contraindication or intolerance to both of the following (please specify contraindication or intolerance):

- Hydroxyurea
- Interferon therapy (e.g., Intron A, Pegasys)

OR

2 - Diagnosis of high-risk polycythemia vera

Product Name:Jakafi	
Diagnosis	Essential Thrombocythemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of essential thrombocythemia

AND

2 - Inadequate response or loss of response to ONE of the following:

- Hydroxyurea
- Pegasys (peginterferon alfa-2a)
- Agrylin (Anagrelide)

Product Name:Jakafi	
Diagnosis	Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

2 - Used for splenomegaly or other disease-related symptoms

Product Name:Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera, Essential Thrombocythemia, Myeloproliferative Neoplasms
Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Jakafi*

Notes	*If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Jakafi, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of acute graft versus host disease (GVHD)

AND

1.2 Disease is steroid refractory

OR

2 - BOTH of the following:

2.1 Diagnosis of chronic GVHD

AND

2.2 Failure of one or two lines of systemic therapy

Product Name:Jakafi	
Diagnosis	Graft versus host disease (GVHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of symptom improvement while on Jakafi

Product Name:Jakafi	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has a JAK2 rearrangement

Product Name:Jakafi

Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of chronic myelomonocytic leukemia (CMML)-2

AND

1.2 Used in combination with a hypomethylating agent (e.g., azacitidine, decitabine)

OR

2 - BOTH of the following:

2.1 Diagnosis of myelodysplastic/myeloproliferative neoplasm (MDS/MPN) with neutrophilia

AND

2.2 Disease is positive for CSF3R or JAK2 mutation

Product Name:Jakafi	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of one of the following:

- Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- Enteropathy-associated T-cell lymphoma (EATL)
- Monomorphic epitheliotropic intestinal T-cell lymphoma (MEITL)
- Angioimmunoblastic T-cell lymphoma (AITL)
- Nodal peripheral T-cell lymphoma with T-follicular helper phenotype (PTCL, TFH)
- Follicular T-cell lymphoma (FTCL)
- Anaplastic large cell lymphoma (ALCL)

AND

1.2 Used as initial palliative intent therapy or second-line and subsequent therapy for relapsed/refractory disease

OR

2 - Both of the following:

2.1 One of the following diagnoses:

- T-cell large granular lymphocytic leukemia
- T-cell prolymphocytic leukemia

AND

2.2 Used as second-line or subsequent therapy

OR

3 - Both of the following:

3.1 Diagnosis of hepatosplenic T-cell lymphoma

AND

3.2 Used for refractory disease after two first-line therapy regimens

Product Name:Jakafi	
Diagnosis	Myeloid/Lymphoid Neoplasms, Myelodysplastic Syndromes, T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jakafi therapy

Product Name:Jakafi	
Diagnosis	Pediatric Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric acute lymphoblastic leukemia

AND

2 - Used as a component of consolidation therapy

Product Name:Jakafi	
Diagnosis	Immunotherapy-Related Toxicities
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of CAR-T induced G4 cytokine release syndrome

AND

1.2 Disease is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., Actemra [tocilizumab])

OR

2 - Both of the following:

2.1 Diagnosis of immune checkpoint inhibitor-related toxicities

AND

2.2 Used in combination with Orencia (abatacept) for the management of concomitant myositis and myocarditis

Product Name:Jakafi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Jakafi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy

2 . Revision History

Date	Notes
1/14/2025	Multiple criteria updates, including new criteria for Myeloproliferative Neoplasms. Updated auth length for multiple dx.

Jaypirca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144886
Guideline Name	Jaypirca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Jaypirca	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Disease is relapsed or refractory

AND

3 - Both of the following:

3.1 Patient has received at least two prior systemic therapies for MCL [e.g., Rituxan (rituximab)]

AND

3.2 Patient has received at least one Bruton Tyrosine Kinase (BTK) inhibitor therapy for MCL [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]

Product Name:Jaypirca	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma

AND

2 - Patient has been previously treated with both of the following:

2.1 Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Imbruvica (ibrutinib), Calquence (acalabrutinib), Brukinsa (zanubrutinib)]

AND

2.2 B-cell lymphoma 2 (BCL-2) inhibitor therapy [e.g., Venclexta (venetoclax)]

Product Name:Jaypirca	
Diagnosis	Mantle Cell Lymphoma (MCL), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Jaypirca therapy

Product Name:Jaypirca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Jaypirca

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jaypirca therapy

2 . Revision History

Date	Notes
3/28/2024	Added criteria for CLL/SLL.

Jesduvroq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143172
Guideline Name	Jesduvroq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least four months

AND

3 - BOTH of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level is less than 11 g/dL (grams per deciliter)

AND

5 - ONE of the following:

5.1 Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records

OR

5.2 History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) (please specify contraindication or intolerance)

AND

6 - Prescribed by or in consultation with ONE of the following:

- Hematologist

- Nephrologist

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jesduvroq therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by both of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 12 g/dL (grams per deciliter)

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Hematologist

• Nephrologist

2 . Revision History

Date	Notes
2/20/2024	New guideline

Jesduvroq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143172
Guideline Name	Jesduvroq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least four months

AND

3 - BOTH of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level is less than 11 g/dL (grams per deciliter)

AND

5 - ONE of the following:

5.1 Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records

OR

5.2 History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) (please specify contraindication or intolerance)

AND

6 - Prescribed by or in consultation with ONE of the following:

- Hematologist

- Nephrologist

Product Name:Jesduvroq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jesduvroq therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by both of the following:

- Ferritin greater than 100 mcg/L (micrograms per liter)
- Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 12 g/dL (grams per deciliter)

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with ONE of the following:

- Hematologist

• Nephrologist

2 . Revision History

Date	Notes
2/20/2024	New guideline

Joenja

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150140
Guideline Name	Joenja
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Joenja	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

AND

2 - Diagnosis has been confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1

AND

3 - Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia)

AND

4 - ONE of the following:

4.1 Failure to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) (please specify intolerance or contraindication)

AND

5 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

6 - BOTH of the following:

- Patient is 12 years of age or older
- Patient weighs greater than or equal to 45 kg (kilograms)

Product Name:Joenja	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Joenja therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations)

AND

2 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

3 - Patient weighs greater than or equal to 45 kg

2 . Revision History

Date	Notes
7/23/2024	Updated initial authorization duration to 12 months.

Joenja

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150140
Guideline Name	Joenja
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Joenja	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)

AND

2 - Diagnosis has been confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1

AND

3 - Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia)

AND

4 - ONE of the following:

4.1 Failure to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to one current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy) (please specify intolerance or contraindication)

AND

5 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

6 - BOTH of the following:

- Patient is 12 years of age or older
- Patient weighs greater than or equal to 45 kg (kilograms)

Product Name:Joenja	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Joenja therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations)

AND

2 - Prescribed by ONE of the following:

- Hematologist
- Immunologist

AND

3 - Patient weighs greater than or equal to 45 kg

2 . Revision History

Date	Notes
7/23/2024	Updated initial authorization duration to 12 months.

Juxtapid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144905
Guideline Name	Juxtapid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 BOTH of the following:

1.2.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) greater than 400 mg/dL (milligrams per deciliter)

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Patient has received comprehensive counseling regarding appropriate diet

AND

3 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid specialist

AND

5 - ONE of the following:

5.1 Failure to Repatha (evolocumab) as confirmed by claims history or submission of medical records

OR

5.2 History of intolerance or contraindication to Repatha (evolocumab) (please specify intolerance or contraindication)

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

Product Name:Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to receive comprehensive counseling regarding appropriate diet

AND

2 - Patient continues to receive other lipid-lowering therapy (e.g., statin, low density lipoprotein [LDL] apheresis)

AND

3 - Documentation of a positive clinical response to therapy from pre-treatment baseline

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab), Repatha (evolocumab)]

2 . Revision History

Date	Notes
3/27/2024	Updated diagnostic criteria per European Atherosclerosis Society gui dance.

Jynarque

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134102
Guideline Name	Jynarque
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)

Product Name:Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jynarque therapy	

2 . Revision History

Date	Notes
10/2/2023	Readded NDCs, they are necessary to distinguish between Tolvaptan and Samsca guidelines.

Jynarque

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134102
Guideline Name	Jynarque
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)

Product Name:Jynarque, Jynarque Pak	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Jynarque therapy	

2 . Revision History

Date	Notes
10/2/2023	Readded NDCs, they are necessary to distinguish between Tolvaptan and Samsca guidelines.

Kalydeco

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151778
Guideline Name	Kalydeco
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient has at least ONE of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco, listed in Table 1 (see Background)

AND

3 - Prescribed by, or in consultation with a provider who specializes in the treatment of CF

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kalydeco therapy (e.g., improved lung function, stable lung function)

2 . Background

Benefit/Coverage/Program Information

Table 1. CFTR Gene Mutations

711+3A→G *	F311del	I148T	R75Q	S589N

2789+5G→A *	F311L	I175V	R117C *	S737F
3272-26A→G *	F508C	I807M	R117G	S945L *
3849+10kbC→T *	F508C;S1251N †	I1027T	R117H *	S977F *
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W *	R170H	S1251N *
A455E *	G178R *	L320V	R347H *	S1255P *
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q *	T1053I
D110H	G551D *	L1480P	R553Q	V232D
D192G	G551S *	M152V	R668C	V562I
D579G *	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H *	G1069R	P67L *	R1070Q	W1282R
D1270N	G1244E *	Q237E	R1070W *	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D *	Q359R	R1283M	
E822K	H939R	Q1291R	S549N *	

E831X *	H1375P	R74W	S549R *

* Clinical data exist for these mutations.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
8/14/2024	Annual review. Removed prescriber requirement from reauthorization criteria. Updated reference.

Kalydeco

Prior Authorization Guideline

Guideline ID	GL-151778
Guideline Name	Kalydeco
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient has at least ONE of the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco, listed in Table 1 (see Background)

AND

3 - Prescribed by, or in consultation with a provider who specializes in the treatment of CF

Product Name:Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kalydeco therapy (e.g., improved lung function, stable lung function)

2 . Background

Benefit/Coverage/Program Information

Table 1. CFTR Gene Mutations

711+3A→G *	F311del	I148T	R75Q	S589N

2789+5G→A *	F311L	I175V	R117C *	S737F
3272-26A→G *	F508C	I807M	R117G	S945L *
3849+10kbC→T *	F508C;S1251N †	I1027T	R117H *	S977F *
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W *	R170H	S1251N *
A455E *	G178R *	L320V	R347H *	S1255P *
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q *	T1053I
D110H	G551D *	L1480P	R553Q	V232D
D192G	G551S *	M152V	R668C	V562I
D579G *	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H *	G1069R	P67L *	R1070Q	W1282R
D1270N	G1244E *	Q237E	R1070W *	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D *	Q359R	R1283M	
E822K	H939R	Q1291R	S549N *	

E831X *	H1375P	R74W	S549R *

* Clinical data exist for these mutations.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
8/14/2024	Annual review. Removed prescriber requirement from reauthorization criteria. Updated reference.

Kerendia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160440
Guideline Name	Kerendia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - Both of the following:

2.1 UACR (urinary albumin-to-creatinine ratio) greater than or equal to 30 mg/g

AND

2.2 eGFR (estimated glomerular filtration rate) greater than or equal to 25 mL/min/1.73 m2

AND

3 - Kerendia is being used to reduce the risk of at least ONE of the following:

- Sustained eGFR decline
- End-stage kidney disease
- Cardiovascular death
- Non-fatal myocardial infarction
- Hospitalization for heart failure

AND

4 - Serum potassium level is less than or equal to 5 mEQ/L (milliequivalents/liter) prior to initiating treatment

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following as confirmed by claims history or submission of medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

AND

6 - ONE of the following:

- Patient is on a stabilized dose and receiving concomitant therapy with a SGLT2 inhibitor (e.g., Farxiga)
- Failure to a SGLT2 inhibitor (e.g., Farxiga) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to a SGLT2 inhibitor (e.g., Farxiga) (please specify intolerance or contraindication)

Product Name:Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
11/11/2024	Updated auth durations. Updated diagnosis to CDK associated with T2D

Keveyis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123500
Guideline Name	Keveyis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Brand Keveyis, generic dichlorphenamide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperkalemic periodic paralysis or related variant

OR

2 - Diagnosis of primary hypokalemic periodic paralysis or related variant

Product Name:Brand Keveyis, generic dichlorphenamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
3/20/2023	Added generic dichlorphenamide to GPI and product name list, clean ed up criteria.

Kevzara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156338
Guideline Name	Kevzara
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Kevzara	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - One of the following:

2.1 All of the following:

2.1.1 One of the following:

2.1.1.1 Failure to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submitted medical records

OR

2.1.1.2 History of intolerance or contraindication to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

2.1.1.3 Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

2.1.2 One of the following:

2.1.2.1 Failure of one preferred adalimumab product* confirmed by claims history or submitted medical records

OR

2.1.2.2 History of intolerance or contraindication to all preferred adalimumab products* (please specify intolerance or contraindication)

AND

2.1.3 One of the following:

2.1.3.1 Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records

OR

2.1.3.2 History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

OR

2.2 Patient is currently on Kevzara therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*See Table 1 for PDL Links

Product Name:Kevzara	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kevzara therapy

AND

2 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Product Name:Kevzara	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polymyalgia rheumatica (PMR)

AND

2 - Patient has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper

AND

3 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

Product Name:Kevzara	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kevzara therapy

AND

2 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

Product Name:Kevzara	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

3 - One of the following:

- Failure of one preferred adalimumab product* confirmed by claims history or submitted medical records
- History of intolerance or contraindication to all preferred adalimumab products* (please specify intolerance or contraindication)

AND

4 - One of the following:

- Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*See Table 1 for PDL Links

Product Name:Kevzara	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kevzara therapy

AND

2 - Patient is not receiving Kevzara in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

2 . Background

Benefit/Coverage/Program Information

Table 1: PDL Links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
9/26/2024	Added criteria for pJIA. Updated safety language

Kineret

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160482
Guideline Name	Kineret
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - One of the following:

4.1 Patient is currently on Kineret therapy as confirmed by claims history or submission of medical records

OR

4.2 Both of the following:

4.2.1 One of the following:

4.2.1.1 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

OR

4.2.1.2 Failure to a 3 month trial of one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses confirmed by claims history or submission of medical records

OR

4.2.1.3 History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

AND

4.2.2 One of the following:

4.2.2.1 Failure of THREE of the following confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

Notes	* For a list of preferred adalimumab products please reference drug c overage tools.

Product Name:Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA) (formerly Still's Disease)

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - One of the following:

4.1 Patient is currently on Kineret therapy as confirmed by claims history or submission of medical records

OR

4.2 One of the following:

4.2.1 Failure of Tyenne (tocilizumab-aazg) confirmed by claims history or submitted medical records

OR

4.2.2 History of intolerance or contraindication to Tyenne (tocilizumab-aazg) (please specify intolerance or contraindication)

Product Name:Kineret	
Diagnosis	Adult Onset Still's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult onset Still's Disease

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator

[e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA)

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name:Kineret	
Diagnosis	Rheumatoid Arthritis (RA), Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Systemic Juvenile Idiopathic Arthritis (SJIA), Adult Onset Still's Disease, Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Kineret therapy

AND

2 - Patient is NOT receiving Kineret in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

2 . Revision History

Date	Notes
11/12/2024	Removed Cimzia as an alternative in RA section

Kisqali

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163686
Guideline Name	Kisqali
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Kisqali	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following types of breast cancer

- Early stage (II or III) at high-risk of recurrence
- Advanced
- Recurrent
- Metastatic

AND

2 - BOTH of the following:

- Disease is hormone receptor (HR)-positive
- Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3 - ONE of the following:

- Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Used in combination with Faslodex (fulvestrant)

AND

4 - ONE of the following:

4.1 One of the following:

4.1.1 Failure to Verzenio (abemaciclib) confirmed by claims history or submission of medical records

OR

4.1.2 History of contraindication or intolerance to Verzenio (abemaciclib) (please specify intolerance or contraindication)

OR

4.2 Patient is currently on Kisqali therapy

Product Name:Kisqali	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic endometrial cancer

AND

2 - Tumor is estrogen receptor (ER)-positive

AND

3 - Used in combination with letrozole

Product Name:Kisqali	
Diagnosis	Breast Cancer, Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali therapy

Product Name:Kisqali	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Kisqali	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Kisqali therapy	

2 . Revision History

Date	Notes
1/13/2025	Updated criteria for new indication.

Kisqali Femara Co-Pack

Prior Authorization Guideline

Guideline ID	GL-163699
Guideline Name	Kisqali Femara Co-Pack
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following types of breast cancer:

- Early stage (II or III) at high-risk of recurrence
- Advanced
- Recurrent
- Metastatic

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 Failure to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole) confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole) (please specify intolerance or contraindication)

OR

4.3 Patient is currently on Kisqali Femara Co-Pack therapy

Product Name:Kisqali Femara Co-Pack

Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic endometrial cancer

AND

2 - Tumor is estrogen receptor (ER)-positive

Product Name:Kisqali Femara Co-Pack	
Diagnosis	Breast Cancer, Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Product Name:Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Kisqali Femara Co-Pack	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Kisqali Femara Co-Pack therapy	

2 . Revision History

Date	Notes
1/13/2025	Updated criteria for new indication

Korlym

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147198
Guideline Name	Korlym
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Brand Korlym, generic mifepristone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

2 - ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name:Brand Korlym, generic mifepristone	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response while on the requested therapy

2 . Revision History

Date	Notes
5/13/2024	Updated reauthorization criteria and added generic mifepristone as a target. Updated product name lists and GPI tables accordingly.

Korlym

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147198
Guideline Name	Korlym
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Brand Korlym, generic mifepristone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

2 - ONE of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - ONE of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

Product Name:Brand Korlym, generic mifepristone	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response while on the requested therapy

2 . Revision History

Date	Notes
5/13/2024	Updated reauthorization criteria and added generic mifepristone as a target. Updated product name lists and GPI tables accordingly.

Koselugo

Prior Authorization Guideline

Guideline ID	GL-158103
Guideline Name	Koselugo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are BOTH of the following:

- Inoperable
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment, bladder/bowel dysfunction)

Product Name:Koselugo	
Diagnosis	Glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Circumscribed glioma with presence of BRAF fusion or BRAF V600E activating mutations

OR

1.2 NF-1 mutated glioma

AND

2 - Disease is recurrent or progressive

AND

3 - Used as monotherapy

Product Name:Koselugo	
Diagnosis	Langerhans Cell Histiocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans cell histiocytosis

AND

2 - ONE of the following:

- Presence of MAP kinase pathway mutation
- No detectable mutation
- Genetic testing not available

AND

3 - Used as monotherapy

Product Name:Koselugo	
Diagnosis	Neurofibromatosis Type 1, Glioma, Langerhans Cell Histiocytosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Koselugo therapy

Product Name:Koselugo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Koselugo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Koselugo therapy

2 . Revision History

Date	Notes

10/28/2024	Updated diagnosis header in reauth section to remove reference to p ilocytic astrocytoma and added glioma.

Krazati

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156444
Guideline Name	Krazati
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Krazati	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Presence of KRAS G12C mutation

AND

3 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

Product Name:Krazati	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Presence of KRAS G12C mutation

AND

3 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

Product Name:Krazati	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ampullary adenocarcinoma

AND

2 - Presence of KRAS G12C mutation

AND

3 - Disease is ONE of the following:

- Recurrent

- Advanced
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

Product Name:Krazati	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Presence of KRAS G12C mutation

AND

3 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

Product Name:Krazati	
Diagnosis	Biliary Tract Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder Cancer
- Intrahepatic cholangiocarcinoma
- Extrahepatic cholangiocarcinoma

AND

2 - Presence of KRAS G12C mutation

AND

3 - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

AND

4 - Patient has received at least one prior systemic therapy

Product Name:Krazati	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Colorectal Cancer, Ampullary Adenocarcinoma, Pancreatic Adenocarcinoma, Biliary Tract Cancers
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Krazati therapy

Product Name:Krazati	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Krazati	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Krazati therapy

2 . Revision History

Date	Notes

9/30/2024	Combined criteria for colon and rectal cancer in one section – Colorectal Cancer. Added criteria for NCCN recommended use of Krazati in biliary tract cancer.

Kuvan

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134600
Guideline Name	Kuvan
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:generic sapropterin, Brand Kuvan	
Diagnosis	Phenylketonuria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)

2 . Revision History

Date	Notes
10/11/2023	Updated formularies.

Lampit

Prior Authorization Guideline

Guideline ID	GL-164745
Guideline Name	Lampit
Formulary	• Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) • Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Indiana • Medicaid - Community & State Pennsylvania

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Lampit	
Approval Length	60 Day(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of Chagas disease (American trypanosomiasis) caused by Trypanosoma cruzi

2 . Revision History

Date	Notes
2/5/2025	Added Indiana and PA Medicaid formularies. No changes to clinical c riteria.

Lazcluze

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160558
Guideline Name	Lazcluze
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Colorado • Medicaid - Community & State New York

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Lazcluze	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Disease is positive for ONE of the following:

- Epidermal growth factor receptor (EGFR) exon 19 deletion
- EGFR exon 21 L858R mutation

AND

4 - Used in combination with Rybrevant (amivantamab-vmjw)

Product Name:Lazcluze	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lazcluze therapy

Product Name:Lazcluze	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lazcluze	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lazcluze therapy

2 . Revision History

Date	Notes
11/13/2024	New program

Lenvima

Prior Authorization Guideline

Guideline ID	GL-144981
Guideline Name	Lenvima
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to one prior anti-angiogenic therapy as confirmed by claims history or submission of medical records [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)]

OR

2.1.1.2 History of intolerance or contraindication to one prior anti-angiogenic therapy [e.g., Avastin (bevacizumab), Votrient (pazopanib), Sutent (sunitinib), Nexavar (sorafenib)] (please specify contraindication or intolerance)

AND

2.1.2 Used in combination with Afinitor (everolimus)

OR

2.2 Used in combination with Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	Renal Cell Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Afinitor (everolimus) or Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC)

AND

2 - Disease is locally recurrent, metastatic, progressive, or symptomatic

AND

3 - Disease is radioactive iodine-refractory or ineligible

Product Name:Lenvima	
Diagnosis	Hepatobiliary Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Diagnosis of hepatocellular carcinoma

AND

1.1.2 Disease is ONE of the following:

- Unresectable
- Metastatic

OR

1.2 ALL of the following:

1.2.1 Diagnosis of biliary tract cancer

AND

1.2.2 Disease is ONE of the following:

- Unresectable or resected gross residual (R2) disease
- Metastatic

AND

1.2.3 Disease has progressed on or after systemic treatment

AND

1.2.4 Used in combination with Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	Adenoid Cystic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent adenoid cystic carcinoma

Product Name:Lenvima	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

AND

2 - ONE of the following:

2.1 Used as a single agent for those who cannot tolerate first-line combination regimens

OR

2.2 Used as a second line therapy in unresectable locally advanced disease, solitary metastasis or ipsilateral pleural metastasis, or extrathoracic metastatic disease

Product Name:Lenvima	
Diagnosis	Thyroid Cancer, Hepatobiliary Cancer, Adenoid Cystic Carcinoma, Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

Product Name:Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometrial carcinoma

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous melanoma

AND

2 - Disease is ONE of the following:

- Disease is unresectable
- Disease is metastatic

AND

3 - Used in combination with Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	Endometrial Carcinoma, Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lenvima therapy

AND

2 - Used in combination with Keytruda (pembrolizumab)

Product Name:Lenvima	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Lenvima will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Lenvima	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Lenvima therapy	

2 . Revision History

Date	Notes
3/28/2024	Updated thyroid cancer criteria based on label and NCCN. Updated hepatobiliary and thymic cancer based on NCCN recommendations.

Lidoderm

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154785
Guideline Name	Lidoderm
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:generic lidocaine 5% patch, Brand Lidoderm	
Diagnosis	Post-Herpetic Neuralgia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of post-herpetic neuralgia

Product Name:generic lidocaine 5% patch, Brand Lidoderm	
Diagnosis	Neuropathic Pain
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain

AND

2 - ONE of the following:

2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Tricyclic anti-depressant (e.g., amitriptyline)
- SNRI (serotonin and norepinephrine reuptake inhibitor) anti-depressant (e.g., duloxetine, venlafaxine)
- Anticonvulsant (e.g., gabapentin, pregabalin)

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Tricyclic anti-depressant (e.g., amitriptyline)
- SNRI anti-depressant (e.g., duloxetine, venlafaxine)
- Anticonvulsant (e.g., gabapentin, pregabalin)

Product Name:generic lidocaine 5% patch, Brand Lidoderm	
Diagnosis	Neuropathic Pain

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
9/24/2024	Updated formularies, updated GPI and product name lists

Litfulo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164653
Guideline Name	Litfulo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Litfulo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of severe alopecia areata

AND

2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

AND

3 - Patient has a current episode of alopecia areata with at least 50% scalp hair loss

AND

4 - ONE of the following:

4.1 Patient is less than 18 years of age

OR

4.2 Failure to Olumiant confirmed by claims history or submission of medical records

OR

4.3 History of intolerance or contraindication to Olumiant (please specify intolerance or contraindication)

AND

5 - Patient is not receiving Litfulo in combination with either of the following:

- Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

6 - Prescribed by or in consultation with a dermatologist

Product Name:Litfulo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Litfulo therapy

AND

2 - Patient is not receiving Litfulo in combination with either of the following:

- Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

2 . Revision History

Date	Notes
2/3/2025	Updated safety check language

Livdelzi

Prior Authorization Guideline

Guideline ID	GL-164659
Guideline Name	Livdelzi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Livdelzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - One of the following:

3.1 Both of the following:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)

AND

4 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

5 - Prescribed by one of the following:

- Hepatologist

- Gastroenterologist

Product Name:Livdelzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Livdelzi therapy)

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

4 - Prescribed by one of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes

2/4/2025	New program

Livdelzi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164659
Guideline Name	Livdelzi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Livdelzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - One of the following:

3.1 Both of the following:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)

AND

4 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

5 - Prescribed by one of the following:

- Hepatologist

- Gastroenterologist

Product Name:Livdelzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Livdelzi therapy)

AND

2 - Patient does not have decompensated cirrhosis

AND

3 - Patient is not receiving Livdelzi in combination with Iqirvo (elafibranor) or Ocaliva (obeticholic acid)

AND

4 - Prescribed by one of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes

2/4/2025	New program

Livmarli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158233
Guideline Name	Livmarli
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Livmarli	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive familial intrahepatic cholestasis (PFIC)

AND

2 - Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein

AND

3 - Patient is experiencing moderate to severe pruritus associated with PFIC.

AND

4 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

AND

5 - Patient has had an inadequate response to at least two conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline)

AND

6 - Prescribed by a gastroenterologist or hepatologist.

Product Name:Livmarli	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritis and less sleep disturbance)

AND

2 - Prescribed by a gastroenterologist or hepatologist

Product Name:Livmarli	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Alagille syndrome (ALGS)

AND

2 - Confirmation of diagnosis by presence of the JAG1 or Notch2 gene mutation

AND

3 - Patient has a serum bile acid concentration above the upper limit of the normal reference range for the reporting laboratory.

AND

4 - Patient is experiencing moderate to severe pruritis associated with ALGS

AND

5 - Patient has had an inadequate response to at least two conventional treatments for the symptomatic relief of pruritus (e.g., ursodeoxycholic acid, diphenhydramine, cholestyramine, rifampin, naltrexone, and sertraline)

AND

6 - Prescribed by a gastroenterologist or hepatologist.

Product Name:Livmarli	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Livmarli therapy (e.g., reduced serum bile acids, improved pruritis)

AND

2 - Prescribed by a gastroenterologist or hepatologist.

2 . Revision History

Date	Notes

10/30/2024	Updated examples of conventional treatment within initial authorizati on criteria for both PFIC and ALGS. Corrected spelling of pruritus.

Livtencity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123295
Guideline Name	Livtencity
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Livtencity	
Approval Length	2 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of post-transplant cytomegalovirus (CMV) infection or CMV disease

AND

2 - CMV infection or disease is refractory to treatment (with or without genotypic resistance) to ONE of the following:

- Ganciclovir
- Valganciclovir
- Cidofovir
- Foscarnet

AND

3 - Patient will not use the requested medication in combination with ganciclovir or valganciclovir

2 . Revision History

Date	Notes
3/15/2023	Updated formulary list, cleaned up criteria.

Lokelma, Veltassa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154634
Guideline Name	Lokelma, Veltassa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Lokelma, Veltassa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-life threatening hyperkalemia

AND

2 - Where clinically appropriate, loop or thiazide diuretic therapy for potassium removal has failed

AND

3 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

Product Name:Lokelma, Veltassa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a positive clinical response to Lokelma or Veltassa therapy

AND

2 - Patient continues to require treatment for hyperkalemia

AND

3 - Patient follows a low potassium diet (less than or equal to 3 grams per day)

2 . Revision History

Date	Notes
9/9/2024	Removed requirement to adjust medications.

Long-Acting Opioid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161932
Guideline Name	Long-Acting Opioid Products
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches	
Diagnosis	Cancer/Hospice/End of Life Related Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

OR

2 - Patient is in hospice or is receiving end of life care

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name:hydrocodone bitartrate ER caps, oxymorphone ER	
Diagnosis	Cancer/Hospice/End of Life Related Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

OR

1.2 Patient is in hospice or is receiving end of life care

AND

2 - ONE of the following:

2.1 The patient has failed a trial of at least ONE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)

• preferred fentanyl transdermal **OR** **2.2** The patient has a history of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance): • morphine sulfate controlled release tablets (generic MS Contin) • preferred fentanyl transdermal **OR** **2.3** BOTH of the following: **2.3.1** Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, or end of life care related pain **AND** **2.3.2** The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, or end of life care pain (document date regimen was started)	
Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the request is for oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER) and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.

Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone tabs/soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER	
Diagnosis	Cancer/Hospice/End of Life Related Pain*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

OR

1.2 Patient is in hospice or is receiving end of life care

AND

2 - ONE of the following:

2.1 The patient has failed a trial of at least THREE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

OR

2.2 The patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

<table>
<tr><td colspan="2">

- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

OR

2.3 BOTH of the following:

2.3.1 Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, or end of life care related pain

AND

2.3.2 The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, or end of life care pain (document date regimen was started)

</td></tr>
<tr><td>Notes</td><td>*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.
If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 12 month authorization should be entered for preferred products, depending on what the patient has already tried:
• If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for oxymorphone ER-non crush resistant (generic) and hydrocodone extended-release capsules (generic Zohydro ER).
• If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER)], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.</td></tr>
</table>

Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to BOTH of the following:

1.1 Patient has been screened for substance abuse/opioid dependence

AND

1.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - BOTH of the following:

3.1 Patient has been screened for underlying depression and/or anxiety

AND

3.2 If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

OR

4.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

4.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

OR

4.4 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

5 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), ONE of the following:

5.1 BOTH of the following:

5.1.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

AND

5.1.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

OR

5.2 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name:hydrocodone bitartrate ER caps, oxymorphone ER	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to BOTH of the following:

1.1 Patient has been screened for substance abuse/opioid dependence

AND

1.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - BOTH of the following:

3.1 Patient has been screened for underlying depression and/or anxiety

AND

3.2 If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

OR

4.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

4.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

OR

4.4 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

5 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), ONE of the following:

5.1 BOTH of the following:

5.1.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

AND

5.1.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

OR

5.2 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

6 - ONE of the following:

6.1 Patient has failed a trial of at least ONE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

OR

6.2 Patient has a history of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the request is for oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER) and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.

Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone tabs/soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to BOTH of the following:

1.1 Patient has been screened for substance abuse/opioid dependence

AND

1.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - BOTH of the following:

3.1 Patient has been screened for underlying depression and/or anxiety

AND

3.2 If applicable, any underlying conditions have been or will be addressed

AND

4 - ONE of the following:

4.1 Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days [document drug(s) and date of trial]

OR

4.2 The patient is already receiving chronic opioid therapy prior to surgery for postoperative pain

OR

4.3 Postoperative pain is expected to be moderate to severe and persist for an extended period of time

OR

4.4 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

5 - If the request is for neuropathic pain (examples of neuropathic pain include neuralgias and neuropathies), ONE of the following:

5.1 BOTH of the following:

5.1.1 Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (document date of trial) (if contraindicated, document contraindication)

AND

5.1.2 Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose (document drug and date of trial) (if contraindicated, document contraindication)

OR

5.2 Patient is new to plan and currently established on long-acting opioid therapy for at least the past 30 days

AND

6 - ONE of the following:

6.1 Patient has failed a trial of at least THREE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

OR

6.2 Patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried: • If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for oxymorphone ER-non crush resistant (generic) and hydrocodone extended-release capsules (generic Zohydro ER). • If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER)], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.

Product Name:generic morphine sulfate ER/CR tabs, fentanyl 12, 25, 50, 75, 100 mcg/hr patches	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

AND

2 - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attests to BOTH of the following:

3.1 Patient has been screened for substance abuse/opioid dependence

AND

3.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name:hydrocodone bitartrate ER caps, oxymorphone ER	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

AND

2 - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attests to BOTH of the following:

3.1 Patient has been screened for substance abuse/opioid dependence

AND

3.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

4 - ONE of the following:

4.1 Patient has failed a trial of at least ONE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

OR

4.2 Patient has a history of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be i

	ssued and a maximum 60-day authorization may be authorized one ti me for the requested drug/strength combination up to the requested q uantity for transition to an alternative treatment. If the request is for oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER) and th e patient is currently taking the requested long-acting opioid for at leas t 30 days and has met the medical necessity authorization criteria req uirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authori zation may be authorized one time for the requested drug/strength co mbination up to the requested quantity for transition to an alternative tr eatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and pr eferred fentanyl transdermal.

Product Name:morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, fentanyl 37.5, 62.5, 87.5 mcg/hr patches, methadone tabs/soln, generic methadone conc, Brand Methadose conc, Brand Zohydro ER	
Diagnosis	Non-cancer/Non-hospice/Non-end of life care related pain*
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

AND

2 - Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

3 - Prescriber attests to BOTH of the following:

3.1 Patient has been screened for substance abuse/opioid dependence

AND

3.2 Pain is moderate to severe and expected to persist for an extended period of time (chronic)

AND

4 - ONE of the following:

4.1 Patient has failed a trial of at least THREE of the following, as confirmed by claims history or submission of medical records (document drugs and date of trials):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

OR

4.2 Patient has a history of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- morphine sulfate controlled release tablets (generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release capsules (generic Zohydro ER)

Notes	*If the patient is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. If the request is for a non-preferred product and the patient is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried:

	• If the patient has tried morphine sulfate controlled release tablets (generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for oxymorphone ER-non crush resistant (generic) and hydrocodone extended-release capsules (generic Zohydro ER). • If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (generic MS Contin), preferred fentanyl transdermal, oxymorphone ER-non crush resistant (generic) or hydrocodone extended-release capsules (generic Zohydro ER)], an authorization should be entered for morphine sulfate controlled release tablets (generic MS Contin) and preferred fentanyl transdermal.

Product Name:tramadol ER, Conzip	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The patient has failed a trial of tramadol IR (immediate release) as confirmed by claims history or submission of medical records

OR

1.2 The patient has a history of contraindication or intolerance to tramadol IR (please specify contraindication or intolerance)

OR

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 Patient is being treated for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)

OR

2.1.2 Patient is in hospice or is receiving end of life care

AND

2.2 BOTH of the following:

2.2.1 Patient is established on pain therapy with the requested medication for cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice related pain, or end of life care related pain

AND

2.2.2 The medication is not a new regimen for treatment of cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice, or end of life care pain (document date regimen was started)

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, methadone tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER	
Guideline Type	Quantity Limit
Approval Criteria **1** - The requested dose cannot be achieved by moving to a higher strength of the product **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists (see Table 1 in Background)	
Notes	Authorization will be issued for: • 12 months for cancer/hospice/end of life related pain. • 12 months for all Tramadol ER requests. • 6 months for non-cancer/non-hospice/non-end of life related pain.

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, methadone tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER	
Diagnosis	Cancer/Hospice/End of Life Related Pain
Approval Length	12 Months*
Guideline Type	Morphine Milligram Equivalent (MME)
Approval Criteria **1** - Doses exceeding the cumulative morphine milligram equivalent (MME) of 90 milligrams (mg) will be approved up to the requested amount for ALL opioid products if the patient has cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance), hospice pain, or an end of life diagnosis	
Notes	*Authorization will be issued for 12 months for cancer/hospice/end of life related pain. The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, methadone tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER	
Diagnosis	Non-cancer/non-hospice/non-end of life related pain
Approval Length	6 Months*
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalent (MME)
Approval Criteria **1** - If the dose exceeds the maximum cumulative morphine milligram equivalent (MME) of 90 mg, ALL of the following:	

1.1 Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

1.2 Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

1.3 BOTH of the following:

1.3.1 Patient has been screened for underlying depression and/or anxiety

AND

1.3.2 If applicable, any underlying conditions have been or will be addressed

AND

1.4 ONE of the following:

1.4.1 Opioid medication doses of less than 90 MME have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

OR

1.4.2 Patient is new to plan and currently established on the requested MME for at least the past 30 days

Notes	*Authorization will be issued for 6 months for non-cancer/non-hospice/ non-end of life related pain up to the current requested MME plus 90 MME. If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization c riteria requirements, a denial should be issued and a maximum 60-da y authorization may be authorized one time for the requested MME do se.

Product Name:generic morphine sulfate ER/CR tabs, fentanyl patches, hydrocodone bitartrate ER caps, oxymorphone ER, morphine sulfate ER caps, hydromorphone ER, generic hydrocodone bitartrate ER tabs, Brand Hysingla ER, Brand MS Contin, Nucynta ER, oxycodone ER, Oxycontin, Xtampza ER, methadone tabs/soln, generic methadone conc, Brand Methadose conc, tramadol ER, Conzip, Brand Zohydro ER	
Diagnosis	Non-cancer/non-hospice/non-end of life related pain
Approval Length	6 Months*
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalent (MME)

Approval Criteria

1 - If the dose exceeds the maximum cumulative morphine milligram equivalent (MME) of 90 milligrams, ALL of the following:

1.1 Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

1.2 Document rationale for not tapering or discontinuing opioid if treatment goals are not being met

AND

1.3 Documented meaningful improvement in pain and function when assessed against treatment goals (document improvement in function or pain score improvement)

Notes	*Authorization will be issued for 6 months for non-cancer/non-hospice/ non-end of life related pain up to the current requested MME plus 90 MME. If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization c riteria requirements, a denial should be issued and a maximum 60-da y authorization may be authorized one time for the requested MME do se.

2 . Revision History

Date	Notes
12/11/2024	Updated Oxycontin GPIs. Updated cancer language.

Lonhala and Yupelri

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121003
Guideline Name	Lonhala and Yupelri
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name:Lonhala Magnair (Starter Kit and Refill Kit), Yupelri	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD)

AND

2 - ONE of the following:

2.1 One of the following:

- Failure of Incruse Ellipta confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Incruse Ellipta (please specify intolerance or contraindication)

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Incruse Ellipta) to control his/her COPD due to ONE of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute)

AND

2.2.2 One of the following:

- Failure of ipratropium nebulized solution (generic Atrovent) confirmed by claims history or submitted medical records
- History of intolerance or contraindication to ipratropium nebulized solution (generic Atrovent) (please specify intolerance or contraindication)

Product Name:Lonhala Magnair (Starter Kit and Refill Kit), Yupelri	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
2/6/2023	Removed TD

Lonsurf

Prior Authorization Guideline

Guideline ID	GL-147684
Guideline Name	Lonsurf
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Lonsurf	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer (mCRC)

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Anti-vascular endothelial growth factor (VEGF) biological therapy

AND

3 - ONE of the following:

3.1 Tumors is RAS mutant-type

OR

3.2 BOTH of the following:

- Tumor is RAS wild-type
- History of failure, contraindication, or intolerance to anti-EGFR (epidermal growth factor receptor) therapy

Product Name:Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Unresectable locally advanced, recurrent, or metastatic gastric cancer
- Unresectable locally advanced, recurrent, or metastatic gastroesophageal junction adenocarcinoma

AND

2 - History of failure, contraindication, or intolerance to treatment with at least TWO prior lines of chemotherapy that consisted of the following agents:

- Fluoropyrimidine (e.g., fluorouracil)
- Platinum (e.g., carboplatin, cisplatin, oxaliplatin)
- Taxane (e.g., docetaxel, paclitaxel) or irinotecan
- Human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

Product Name:Lonsurf	
Diagnosis	Colorectal Cancer, Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lonsurf therapy

Product Name:Lonsurf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lonsurf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lonsurf therapy

2 . Revision History

Date	Notes
6/6/2024	Updated diagnostic criteria for colorectal cancer. Updated gastric/gas troesophageal junction adenocarcinoma diagnostic criteria.

Lorbrena

Prior Authorization Guideline

Guideline ID	GL-144987
Guideline Name	Lorbrena
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

2.1 Disease is BOTH of the following:

- Recurrent, advanced, or metastatic
- Anaplastic lymphoma kinase (ALK)-positive

OR

2.2 BOTH of the following:

2.2.1 Disease is BOTH of the following:

- Recurrent, advanced, or metastatic
- ROS proto-oncogene 1 (ROS1)-positive

AND

2.2.2 Disease has progressed on at least ONE of the following therapies:

- Rozlytrek (entrectinib)
- Xalkori (crizotinib)
- Zykadia (ceritinib)

Product Name:Lorbrena	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester Disease (ECD)

AND

2 - Disease is BOTH of the following:

- Symptomatic, relapsed, or refractory
- ALK-positive

Product Name:Lorbrena	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation

Product Name:Lorbrena	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - Disease is ONE of the following:

- Advanced
- Recurrent/metastatic
- Inoperable

AND

3 - Disease is ALK - positive

Product Name:Lorbrena	
Diagnosis	Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Anaplastic large cell lymphoma (ALCL)
- Large B-Cell lymphoma

AND

2 - Disease is relapsed or refractory

AND

3 - Disease is ALK - positive

Product Name:Lorbrena	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Histiocytic Neoplasms, Soft Tissue Sarcoma, Uterine Sarcoma, Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lorbrena therapy

Product Name:Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lorbrena	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lorbrena therapy

2 . Revision History

Date	Notes
4/3/2024	Added criteria for NCCN recommended use of Lorbrena in uterine sa rcoma, peripheral T-Cell lymphoma and large B-cell lymphoma.

Lovenox

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120239
Guideline Name	Lovenox
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Continuation of Therapy Upon Hospital Discharge
Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Will be approved as continuation of therapy upon hospital discharge

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Prophylaxis of DVT - Orthopedic Surgery
Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For deep vein thrombosis (DVT) prophylaxis

AND

2 - Patient is undergoing ONE of the following:

- Hip fracture surgery
- Hip replacement surgery
- Knee replacement surgery

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Prophylaxis of DVT - Abdominal Surgery
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For deep vein thrombosis (DVT) prophylaxis following abdominal surgery

AND

2 - Patient is at risk for thromboembolic complications

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Prophylaxis of DVT - Restricted Mobility
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For deep vein thrombosis (DVT) prophylaxis in patients at risk for thromboembolic complications due to severely restricted mobility during acute illness

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	DVT Treatment
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For the treatment of acute deep vein thrombosis (DVT)

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Prophylaxis of Ischemic Complications
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For prophylaxis of ischemic complications in ONE of the following:

- Unstable angina

- Non-Q-Wave myocardial infarction

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Acute ST-Segment Elevation Myocardial Infarction
Approval Length	2 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For the treatment of acute ST-segment elevation myocardial infarction (STEMI)

AND

2 - ONE of the following:

- Managed medically
- Managed with subsequent percutaneous coronary intervention

Product Name:Brand Lovenox, generic enoxaparin	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND **2** - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program	
Notes	Authorization will be issued for the compendia recommended duration of therapy, not to exceed 12 months.

2 . Revision History

Date	Notes
1/18/2023	Updated GPI list, cleaned up note.

Lucemyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123306
Guideline Name	Lucemyra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Lucemyra	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - For symptoms of abrupt opioid withdrawal	

AND

2 - Opioids have been discontinued

AND

3 - ONE of the following:

3.1 ONE of the following:

3.1.1 Failure to clonidine confirmed by claims history or submission of medical records

OR

3.1.2 History of contraindication or intolerance to clonidine (please specify intolerance or contraindication)

OR

3.2 Lucemyra was initiated in the inpatient setting*

Notes	*Authorization will be issued for 14 days of therapy. If Lucemyra was initiated in the inpatient setting, the total course of therapy should not exceed 14 days.

2 . Revision History

Date	Notes
3/16/2023	Updated T/F criteria.

Lumakras

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155012
Guideline Name	Lumakras
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C (gene)-mutated

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutated

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced

- Metastatic

AND

3 - Tumor is KRAS G12C-mutation positive

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Colon Cancer
- Rectal Cancer

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutation positive

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lumakras therapy

Product Name:Lumakras	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lumakras	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lumakras therapy

2 . Revision History

Date	Notes
9/16/2024	Added criteria for ampullary adenocarcinoma, colon cancer, and rect al cancer

Lumakras

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155012
Guideline Name	Lumakras
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C (gene)-mutated

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Pancreatic Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutated

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Ampullary Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced

- Metastatic

AND

3 - Tumor is KRAS G12C-mutation positive

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Colon Cancer
- Rectal Cancer

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutation positive

AND

4 - Patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)

Product Name:Lumakras	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lumakras therapy

Product Name:Lumakras	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lumakras	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lumakras therapy

2 . Revision History

Date	Notes
9/16/2024	Added criteria for ampullary adenocarcinoma, colon cancer, and rect al cancer

Lupkynis

Prior Authorization Guideline

Guideline ID	GL-152711
Guideline Name	Lupkynis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Provider attests to ONE of the following:

- Diagnosis is biopsy proven
- Biopsy is contraindicated in the patient

AND

3 - Provider attests to ONE of the following:

3.1 Clinical progression (e.g., worsening of proteinuria or serum creatinine) after 3 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

OR

3.2 Failure to respond after 6 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

AND

4 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

5 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

6 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lupkynis therapy

AND

2 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

3 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

4 - Prescribed by ONE of the following:

- Nephrologist

- Rheumatologist

AND

5 - ONE of the following:

5.1 Patient has been on Lupkynis therapy for less than 12 months

OR

5.2 BOTH of the following:

5.2.1 Patient has completed 12 or more months of Lupkynis therapy

AND

5.2.2 The provider attests that the benefit of continuation of therapy exceeds the risk in light of the patient's treatment response and risk of worsening nephrotoxicity

2 . Revision History

Date	Notes
8/27/2024	Annual review. Updated authorization lengths to 12 months.

Lupkynis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152711
Guideline Name	Lupkynis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Provider attests to ONE of the following:

- Diagnosis is biopsy proven
- Biopsy is contraindicated in the patient

AND

3 - Provider attests to ONE of the following:

3.1 Clinical progression (e.g., worsening of proteinuria or serum creatinine) after 3 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

OR

3.2 Failure to respond after 6 months of induction therapy with immunosuppressive agents (e.g., mycophenolate, cyclophosphamide, methylprednisolone), as confirmed by claims history or submission of medical records

AND

4 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

5 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

6 - Prescribed by ONE of the following:

- Nephrologist
- Rheumatologist

Product Name:Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lupkynis therapy

AND

2 - Prescribed in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil and corticosteroids)

AND

3 - Patient is NOT receiving Lupkynis in combination with either of the following:

- Cyclophosphamide
- Benlysta (belimumab)

AND

4 - Prescribed by ONE of the following:

- Nephrologist

- Rheumatologist

AND

5 - ONE of the following:

5.1 Patient has been on Lupkynis therapy for less than 12 months

OR

5.2 BOTH of the following:

5.2.1 Patient has completed 12 or more months of Lupkynis therapy

AND

5.2.2 The provider attests that the benefit of continuation of therapy exceeds the risk in light of the patient's treatment response and risk of worsening nephrotoxicity

2 . Revision History

Date	Notes
8/27/2024	Annual review. Updated authorization lengths to 12 months.

Lynparza

Prior Authorization Guideline

Guideline ID	GL-154720
Guideline Name	Lynparza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Lynparza	
Diagnosis	Breast Cancer (High Risk Early)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high risk early breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

3 - Disease is human growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 Patient is hormone receptor (HR) negative

OR

4.2 BOTH of the following:

4.2.1 Patient is hormone receptor (HR) positive

AND

4.2.2 Patient is continuing concurrent treatment with endocrine therapy

AND

5 - Patient has been treated with neoadjuvant or adjuvant chemotherapy

AND

6 - Treatment duration has not exceeded 12 months of therapy

Product Name:Lynparza	
Diagnosis	Breast Cancer (Metastatic or Recurrent)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Metastatic breast cancer

OR

1.2 Recurrent breast cancer

AND

2 - Presence of deleterious or suspected deleterious germline breast cancer (BRCA)-mutations (gBRCAm)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

3.1.2 ONE of the following:

3.1.2.1 Disease is hormone receptor (HR) negative

OR

3.1.2.2 BOTH of the following:

3.1.2.2.1 Disease is hormone receptor (HR) positive

AND

3.1.2.2.2 ONE of the following:

- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate

OR

3.2 Disease is human epidermal growth factor receptor 2 (HER2)-positive

Product Name:Lynparza	
Diagnosis	Ovarian Cancer (Maintenance Therapy)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is one of the following:

- Advanced
- Recurrent

AND

3 - ONE of the following:

3.1 Presence of deleterious or suspected deleterious germline or somatic BRCA-mutations

OR

3.2 Both of the following:

3.2.1 Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability

AND

3.2.2 Used in combination with bevacizumab (e.g., Avastin, Mvasi)

AND

4 - Patient has had a complete or partial response to platinum-based chemotherapy

AND

5 - Request is for maintenance therapy

Product Name:Lynparza	
Diagnosis	Ovarian Cancer (Treatment)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - Disease is ONE of the following:

- Advanced
- Persistent
- Recurrent

AND

3 - Presence of deleterious or suspected deleterious germline BRCA (breast cancer gene)-mutation

AND

4 - Patient has been treated with two or more prior lines of chemotherapy

Product Name:Lynparza	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of deleterious or suspected deleterious germline BRCA1/2 (breast cancer gene)-mutation

AND

4 - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name:Lynparza	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

AND

2.1.2 Disease has progressed following prior treatment with ONE of the following:

- Enzalutamide (Xtandi)
- Abiraterone (e.g., Zytiga, Yonsa)

OR

2.2 ALL of the following:

2.2.1 Presence of deleterious or suspected deleterious BRCA-mutation

AND

2.2.2 Used in combination with abiraterone (e.g., Zytiga, Yonsa)

AND

2.2.3 Used in combination with ONE of the following:

- Prednisone
- Prednisolone

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name:Lynparza	
Diagnosis	Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - The requested medication is NOT used as first-line therapy

Product Name:Lynparza	
Diagnosis	Breast Cancer (Metastatic or Recurrent), Ovarian Cancer (Maintenance or Treatment), Pancreatic Cancer, Prostate Cancer, Uterine Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lynparza therapy

Product Name:Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lynparza	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lynparza therapy

2 . Revision History

Date	Notes
9/10/2024	Updated formatting for ovarian cancer without change in clinical inten t.

Lysteda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159421
Guideline Name	Lysteda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State New York • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Brand Lysteda, generic tranexamic acid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cyclic heavy menstrual bleeding

2 . Revision History

Date	Notes
11/7/2024	Updated Markets in Scope. No changes to clinical criteria

Lytgobi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163892
Guideline Name	Lytgobi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Lytgobi	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma (intrahepatic or extrahepatic)

AND

2 - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

AND

3 - Positive for fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements

AND

4 - Used as second line or subsequent treatment

Product Name:Lytgobi	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lytgobi therapy

Product Name:Lytgobi

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lytgobi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lytgobi therapy

2 . Revision History

Date	Notes
1/16/2025	Updated cholangiocarcinoma initial criteria

Lytgobi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163892
Guideline Name	Lytgobi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Lytgobi	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma (intrahepatic or extrahepatic)

AND

2 - Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

AND

3 - Positive for fibroblast growth factor receptor 2 (FGFR2) fusions or rearrangements

AND

4 - Used as second line or subsequent treatment

Product Name:Lytgobi	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Lytgobi therapy

Product Name:Lytgobi

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Lytgobi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Lytgobi therapy

2 . Revision History

Date	Notes
1/16/2025	Updated cholangiocarcinoma initial criteria

Marinol, Syndros

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161398
Guideline Name	Marinol, Syndros
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - ONE of the following:

2.1 Failure to formulary generic dronabinol as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to formulary generic dronabinol (please specify contraindication or intolerance)

OR

2.3 Patient is unable to swallow capsules

AND

3 - ONE of the following:

3.1 Failure to a 5HT-3 (5-hydroxytryptamine type 3) receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] (please specify contraindication or intolerance)

AND

4 - ONE of the following:

4.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

OR

4.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

Product Name:Brand Marinol, generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - ONE of the following:

2.1 Failure to a 5HT-3 (5-hydroxytryptamine type 3) receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to a 5HT-3 receptor antagonist [e.g., Anzemet (dolasetron), Kytril (granisetron), or Zofran (ondansetron)] (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

OR

3.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lorazepam (generic Ativan)
- Prochlorperazine (generic Compazine)
- Dexamethasone (generic Decadron)
- Haloperidol (generic Haldol)
- Promethazine (generic Phenergan)
- Metoclopramide (generic Reglan)
- Olanzapine (generic Zyprexa)

Product Name:Syndros

Diagnosis	Anorexia in a patient with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in a patient with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

3.2.1 Patient is less than 65 years of age

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to megestrol (generic Megace) as confirmed by claims history or submission of medical records

OR

3.2.2.2 History of intolerance or contraindication to megestrol (generic Megace) (please specify intolerance or contraindication)

AND

4 - ONE of the following:

4.1 Failure to formulary generic dronabinol as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to formulary generic dronabinol (please specify contraindication or intolerance)

OR

4.3 Patient is unable to swallow capsules

Product Name:Brand Marinol, generic dronabinol	
Diagnosis	Anorexia in a patient with AIDS
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in a patient with AIDS (acquired immunodeficiency syndrome)

AND

2 - Patient is on antiretroviral therapy

AND

3 - ONE of the following:

3.1 Patient is 65 years of age or greater

OR

3.2 BOTH of the following:

3.2.1 Patient is less than 65 years of age

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to megestrol (generic Megace) as confirmed by claims history or submission of medical records

OR

3.2.2.2 History of intolerance or contraindication to megestrol (generic Megace) (please specify intolerance or contraindication)

2 . Revision History

Date	Notes
11/27/2024	Added GPIs for Brand Marinol capsules 5mg and 10mg strengths. Minor update to 5HT-3 definition, with no changes to clinical intent.

Mavenclad

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-192187
Guideline Name	Mavenclad
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary progressive MS with relapses)

AND

2 - Prescribed by, or in consultation with, a specialist in the treatment of MS (e.g., neurologist)

AND

3 - ONE of the following:

3.1 Trial and failure (after trial of at least 4 weeks) to TWO of the following disease-modifying therapies for MS (one of which must be a preferred dimethyl fumarate product) as confirmed by claims history or submission of medical records:

- Interferon beta-1a (Avonex*, Rebif*, Plegridy)
- Interferon beta-1b (Betaseron*, Extavia*)
- Glatiramer acetate products (e.g., Copaxone, Glatopa)
- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Teriflunomide (generic Aubagio)
- Fingolimod (generic Gilenya)
- Mayzent (siponimod)
- Tysabri (natalizumab)**
- Ocrevus (ocrelizumab)**
- Lemtrada (alemtuzumab)**
- Zeposia (ozanimod)*
- Kesimpta (ofatumumab)*
- Bafiertam (monomethyl fumarate)*
- Briumvi (ublituximab)**

OR

3.2 History of contraindication or intolerance to TWO of the following disease-modifying therapies for MS (please specify contraindication or intolerance)

- Interferon beta-1a (Avonex*, Rebif*, Plegridy)
- Interferon beta-1b (Betaseron*, Extavia*)
- Glatiramer acetate products (e.g., Copaxone, Glatopa)

- A preferred dimethyl fumarate product (e.g., Tecfidera)
- Teriflunomide (generic Aubagio)
- Fingolimod (generic Gilenya)
- Mayzent (siponimod)
- Tysabri (natalizumab)**
- Ocrevus (ocrelizumab)**
- Lemtrada (alemtuzumab)**
- Zeposia (ozanimod)*
- Kesimpta (ofatumumab)*
- Bafiertam (monomethyl fumarate)*
- Briumvi (ublituximab)**

OR

3.3 Patient is currently on Mavenclad

AND

4 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)]

Notes	*Avonex, Rebif, Betaseron, Bafiertam, Kesimpta, Zeposia, and Extavia are non-preferred and should not be included in denial to provider. **Briumvi, Tysabri, Ocrevus, and Lemtrada are medical benefit and should not be included in denial to provider.

Product Name:Mavenclad	
Approval Length	2 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mavenclad treatment

AND

2 - Patient is NOT receiving Mavenclad in combination with another disease modifying therapy [e.g., interferon beta preparations, glatiramer acetate products, Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Gilenya (fingolimod), Mayzent (siponimod), Ocrevus (ocrelizumab), Lemtrada (alemtuzumab), or Aubagio (teriflunomide)] **AND** **3** - Patient has not exceeded the FDA (Food and Drug Administration)-recommended limit of 2 treatment courses (4 treatment cycles) of Mavenclad	
Notes	Duration of coverage will be limited to 1 reauthorization to allow 2 cum ulative treatment courses (4 treatment cycles) of Mavenclad therapy.

2 . Revision History

Date	Notes
2/24/2025	Updated formularies. Updated step through language to reference ge neric product for Aubagio and Gilenya, added Briumvi as option for st ep

Mekinist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150996
Guideline Name	Mekinist
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Mekinist	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Unresectable melanoma

OR

1.1.1.2 Metastatic melanoma

OR

1.1.1.3 BOTH of the following:

1.1.1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.1.1.3.2 Used in combination with Tafinlar (dabrafenib)

AND

1.1.2 Cancer is positive for BRAF V600 (gene) mutation

OR

1.2 Distant metastatic uveal melanoma

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E (gene) mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.1.2 Cancer is positive for BRAF V600E (gene) mutation

AND

1.1.3 Used in combination with Tafinlar (dabrafenib)

AND

1.1.4 ONE of the following:

1.1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.1.4.2 Prescribed as adjuvant therapy following resection

OR

1.2 ALL of the following:

1.2.1 ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

1.2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.2.4 Disease is refractory to radioactive iodine treatment

AND

1.2.5 Cancer is positive for BRAF V600 mutation

AND

1.2.6 Used in combination with Tafinlar (dabrafenib)

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Mekinist is active against the primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E (gene) mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease

- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E (gene) mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

AND

6 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - ONE of the following:

- Mitogen-activated protein (MAP) kinase pathway mutation
- No detectable mutation
- Testing not available

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E (gene) mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

AND

6 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Pancreatic Cancer, Ambullary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Used in combination with Tafinlar (dabrafenib)

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is one of the following:

- Recurrent and unresectable
- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)

AND

2 - Disease is one of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Melanoma, NSCLC, Thyroid Cancer, CNS Cancers, Epithelial Ovarian /Fallopian Tube /Primary Peritoneal Cancers, Hepatobiliary Cancers, Histiocytic Neoplasms, Solid Tumors, Pancreatic /Ampullary Cancer , Hairy Cell Leukemia, Salivary Gland Tumor, GIST
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Product Name:Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mekinist therapy

2 . Revision History

Date	Notes
8/6/2024	Added criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Mekinist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150996
Guideline Name	Mekinist
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Mekinist	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 ONE of the following:

1.1.1.1 Unresectable melanoma

OR

1.1.1.2 Metastatic melanoma

OR

1.1.1.3 BOTH of the following:

1.1.1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.1.1.3.2 Used in combination with Tafinlar (dabrafenib)

AND

1.1.2 Cancer is positive for BRAF V600 (gene) mutation

OR

1.2 Distant metastatic uveal melanoma

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E (gene) mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following:

1.1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.1.2 Cancer is positive for BRAF V600E (gene) mutation

AND

1.1.3 Used in combination with Tafinlar (dabrafenib)

AND

1.1.4 ONE of the following:

1.1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.1.4.2 Prescribed as adjuvant therapy following resection

OR

1.2 ALL of the following:

1.2.1 ONE of the following diagnoses:

- Follicular Carcinoma
- Oncocytic Carcinoma
- Papillary Carcinoma

AND

1.2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.2.4 Disease is refractory to radioactive iodine treatment

AND

1.2.5 Cancer is positive for BRAF V600 mutation

AND

1.2.6 Used in combination with Tafinlar (dabrafenib)

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Mekinist is active against the primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E (gene) mutation

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease

- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E (gene) mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

AND

6 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease
- Rosai-Dorfman Disease

AND

2 - ONE of the following:

- Mitogen-activated protein (MAP) kinase pathway mutation
- No detectable mutation
- Testing not available

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E (gene) mutation

AND

5 - Used in combination with Tafinlar (dabrafenib)

AND

6 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Pancreatic Cancer, Ambullary Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Used in combination with Tafinlar (dabrafenib)

AND

3 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is one of the following:

- Recurrent and unresectable
- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Tafinlar (dabrafenib)

AND

5 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)

AND

2 - Disease is one of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with Tafinlar (dabrafenib)

AND

4 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	Melanoma, NSCLC, Thyroid Cancer, CNS Cancers, Epithelial Ovarian /Fallopian Tube /Primary Peritoneal Cancers, Hepatobiliary Cancers, Histiocytic Neoplasms, Solid Tumors, Pancreatic /Ampullary Cancer , Hairy Cell Leukemia, Salivary Gland Tumor, GIST
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mekinist therapy

Product Name:Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for Mekinist solution, there is a reason or special circumstance why the patient is unable to use Mekinist tablets (document reason or special circumstance)

Product Name:Mekinist	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mekinist therapy

2 . Revision History

Date	Notes
8/6/2024	Added criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Mektovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164675
Guideline Name	Mektovi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of melanoma

AND

1.2 Disease is one of the following:

- Unresectable
- Metastatic

AND

1.3 Patient is positive for BRAFV600 mutation

AND

1.4 Used in combination with Braftovi (encorafenib)

AND

1.5 ONE of the following:

1.5.1 Patient has a contraindication or history of intolerance to ONE of the following regimens (please specify intolerance or contraindication):

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.5.2 Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.5.3 For continuation of prior Mektovi therapy

OR

2 - ALL of the following:

2.1 Diagnosis of melanoma

AND

2.2 Disease is one of the following:

- Unresectable
- Metastatic

AND

2.3 Patient is positive for NRAS-mutation

AND

2.4 Progression after prior immune checkpoint inhibitor therapy

Product Name:Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

- BRAFV600 mutation positive
- Used in combination with Braftovi (encorafenib)

OR

2.2 NRAS-mutated tumor

Product Name:Mektovi	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Multisystem Langerhans Cell Histiocytosis
- Single-system lung Langerhans Cell Histiocytosis
- Langerhans Cell Histiocytosis with CNS (central nervous system) lesions

AND

2 - ONE of the following:

- Disease is positive for mitogen-activated protein (MAP) kinase pathway mutation
- No other detectable/actionable mutation
- Testing is not available

Product Name:Mektovi	
Diagnosis	Serous Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low-grade serous carcinoma

AND

2 - Disease is recurrent

Product Name:Mektovi	
Diagnosis	Histiocytic Neoplasms, Serous Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

Product Name:Mektovi

Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with imatinib mesylate (generic Gleevec)

Product Name:Mektovi	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with imatinib mesylate (Gleevec)

Product Name:Mektovi	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Patient is positive for BRAFV600 mutation

AND

4 - Used in combination with Braftovi (encorafenib)

AND

5 - ONE of the following:

5.1 Patient has a contraindication or history of intolerance to Tafinlar (dabrafenib) plus Mekinist (trametinib) (please specify intolerance or contraindication)

OR

5.2 Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for Tafinlar (dabrafenib) plus Mekinist (trametinib)

OR

5.3 For continuation of prior Mektovi therapy

Product Name:Mektovi	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with Braftovi (encorafenib)

Product Name:Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mektovi therapy

2 . Revision History

Date	Notes
2/4/2025	Updated formularies. Updated reauth criteria

Mektovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164675
Guideline Name	Mektovi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of melanoma

AND

1.2 Disease is one of the following:

- Unresectable
- Metastatic

AND

1.3 Patient is positive for BRAFV600 mutation

AND

1.4 Used in combination with Braftovi (encorafenib)

AND

1.5 ONE of the following:

1.5.1 Patient has a contraindication or history of intolerance to ONE of the following regimens (please specify intolerance or contraindication):

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.5.2 Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for either of the following regimens:

- Tafinlar (dabrafenib) plus Mekinist (trametinib)
- Zelboraf (vemurafenib) plus Cotellic (cobimetinib)

OR

1.5.3 For continuation of prior Mektovi therapy

OR

2 - ALL of the following:

2.1 Diagnosis of melanoma

AND

2.2 Disease is one of the following:

- Unresectable
- Metastatic

AND

2.3 Patient is positive for NRAS-mutation

AND

2.4 Progression after prior immune checkpoint inhibitor therapy

Product Name:Mektovi	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - ONE of the following:

2.1 BOTH of the following:

- BRAFV600 mutation positive
- Used in combination with Braftovi (encorafenib)

OR

2.2 NRAS-mutated tumor

Product Name:Mektovi	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Multisystem Langerhans Cell Histiocytosis
- Single-system lung Langerhans Cell Histiocytosis
- Langerhans Cell Histiocytosis with CNS (central nervous system) lesions

AND

2 - ONE of the following:

- Disease is positive for mitogen-activated protein (MAP) kinase pathway mutation
- No other detectable/actionable mutation
- Testing is not available

Product Name:Mektovi	
Diagnosis	Serous Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low-grade serous carcinoma

AND

2 - Disease is recurrent

Product Name:Mektovi	
Diagnosis	Histiocytic Neoplasms, Serous Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

Product Name:Mektovi

Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent
- Metastatic

AND

3 - Used in combination with imatinib mesylate (generic Gleevec)

Product Name:Mektovi	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with imatinib mesylate (Gleevec)

Product Name:Mektovi	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Patient is positive for BRAFV600 mutation

AND

4 - Used in combination with Braftovi (encorafenib)

AND

5 - ONE of the following:

5.1 Patient has a contraindication or history of intolerance to Tafinlar (dabrafenib) plus Mekinist (trametinib) (please specify intolerance or contraindication)

OR

5.2 Provider attests that the patient is not an appropriate candidate based on the patient's clinical status or comorbidities for Tafinlar (dabrafenib) plus Mekinist (trametinib)

OR

5.3 For continuation of prior Mektovi therapy

Product Name:Mektovi	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Mektovi therapy

AND

2 - Used in combination with Braftovi (encorafenib)

Product Name:Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Mektovi	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Mektovi therapy

2 . Revision History

Date	Notes
2/4/2025	Updated formularies. Updated reauth criteria

Mepron

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127422
Guideline Name	Mepron
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Brand Mepron, generic atovaquone	
Diagnosis	Pneumocystis Jirovecii Pneumonia (PCP) Prophylaxis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis [e.g., HIV (human immunodeficiency virus)] warranting PCP (pneumocystis jirovecii pneumonia) infection prophylaxis

AND

2 - The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone (please specify intolerance or contraindication)

Product Name:Brand Mepron, generic atovaquone	
Diagnosis	Pneumocystis Jirovecii Pneumonia (PCP) Treatment
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of mild to moderate pneumonia caused by pneumocystis jirovecii

AND

2 - ONE of the following:

2.1 Failure of trimethoprim-sulfamethoxazole (TMP-SMX) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to TMP-SMX (please specify intolerance or contraindication)

2 . Revision History

Date	Notes
6/30/2023	Updated formularies.

Mepron

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127422
Guideline Name	Mepron
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Brand Mepron, generic atovaquone	
Diagnosis	Pneumocystis Jirovecii Pneumonia (PCP) Prophylaxis
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis [e.g., HIV (human immunodeficiency virus)] warranting PCP (pneumocystis jirovecii pneumonia) infection prophylaxis

AND

2 - The patient has a documented intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone (please specify intolerance or contraindication)

Product Name:Brand Mepron, generic atovaquone	
Diagnosis	Pneumocystis Jirovecii Pneumonia (PCP) Treatment
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of mild to moderate pneumonia caused by pneumocystis jirovecii

AND

2 - ONE of the following:

2.1 Failure of trimethoprim-sulfamethoxazole (TMP-SMX) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to TMP-SMX (please specify intolerance or contraindication)

2 . Revision History

Date	Notes
6/30/2023	Updated formularies.

Migranal, Trudhesa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-192189
Guideline Name	Migranal, Trudhesa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Brand Migranal, generic dihydroergotamine mesylate nasal spray, Trudhesa	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of migraine headaches with or without aura

AND

2 - ONE of the following:

2.1 Failure to THREE preferred 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray, confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to THREE preferred 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray (please specify intolerance or contraindication)

Product Name:Brand Migranal, generic dihydroergotamine mesylate nasal spray, Trudhesa	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Prescribed by, or in consultation with, ONE of the following:

- Neurologist
- Pain management specialist

AND

3 - Currently receiving prophylactic therapy with at least ONE of the following:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan (generic Atacand)*
- A calcitonin gene-related peptide receptor*** (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy* (fremanezumab), Emgality (galcanezumab), Qulipta* (atogepant), Vyepti** (eptinezumab-jjmr)]
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA (Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - BOTH of the following:

4.1 ONE of the following:

4.1.1 Higher dose or quantity is supported by the manufacturer's prescribing information

OR

4.1.2 Higher dose or quantity is supported by ONE of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

OR

4.1.3 Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the Food and Drug Administration (FDA) for the diagnosis indicated

AND

4.2 Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	*This is non-preferred and should not be included in denial to provider . **This is a medical benefit and should not be included in denial to provider. ***Requires a prior authorization.

2 . Revision History

Date	Notes
2/24/2025	Updated formularies. Updated step therapy language, naratriptan step therapy removed. Updated list of prophylactic therapy

Miplyffa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-192193
Guideline Name	Miplyffa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Miplyffa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes

AND

3 - Miplyffa is being used to treat neurological manifestations of NPC

AND

4 - Miplyffa is prescribed in combination with miglustat

AND

5 - Patient is NOT receiving Miplyffa in combination with Aqneursa (levacetylleucine)

AND

6 - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

Product Name:Miplyffa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Miplyffa therapy (e.g., slowed disease progression from baseline based on assessment with NPC–specific scales)

AND

2 - Miplyffa continues to be prescribed in combination with miglustat

AND

3 - Patient is NOT receiving Miplyffa in combination with Aqneursa (levacetylleucine)

AND

4 - Miplyffa is prescribed by or in consultation with a provider with expertise in the treatment of NPC

2 . Revision History

Date	Notes
2/24/2025	Updated formularies. Added criteria that Miplyffa not taken in combin ation with Aqneursa

Mozobil

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144753
Guideline Name	Mozobil
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Brand Mozobil, generic plerixafor	
Diagnosis	Hematopoietic Stem Cell Mobilization
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Patients with non-Hodgkin's lymphoma (NHL) who will be undergoing autologous hematopoietic stem cell (HSC) transplantation
- Patients with multiple myeloma (MM) who will be undergoing autologous HSC transplantation

AND

2 - Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Zarxio (filgrastim)]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Brand Mozobil, generic plerixafor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Mozobil, generic plerixafor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
3/21/2024	Updated benefit coverage to combine NY with the other CORE formularies; Added new generic plerixafor as a target to the guideline (updated GPI tables and product name lists accordingly); For NCCN Recommended Regimen (reauth section), updated criterion to remove reference to "Mozobil therapy" and replaced with "the requested therapy". No changes to clinical intent.

MS Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161400
Guideline Name	MS Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic glatiramer, Glatopa, Mayzent, Plegridy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of multiple sclerosis (MS)

Product Name:Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS) **AND** **2** - ONE of the following: **2.1** Failure of at least two of the preferred* alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records **OR** **2.2** History of intolerance or contraindication to all of the preferred* alternatives (please specify intolerance or contraindication) **OR** **2.3** Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records	
Notes	*See table 1 in background for PDL links

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is 10 years of age or older

AND

3 - ONE of the following:

3.1 Failure of fingolimod 0.5mg (generic Gilenya 0.5 mg) confirmed by claims history or submitted medical records

OR

3.2 History of intolerance or contraindication to fingolimod 0.5mg (generic Gilenya 0.5 mg) (please specify intolerance or contraindication)

OR

3.3 Patient is currently on Tascenso ODT therapy as documented by claims history or submission of medical records

Notes	*See table 1 in background for PDL links

Product Name:Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5mg, Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - ONE of the following:

2.1 Failure of at least two of the preferred* alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to all of the preferred* alternatives (please specify intolerance or contraindication)

OR

2.3 Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records

AND

3 - ONE of the following:

3.1 The brand is being requested because of an adverse reaction, allergy or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)

OR

3.2 The brand is being requested due to an incomplete response with a generic/authorized generic equivalent, as documented by submission of medical records

OR

3.3 The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient.

OR **3.4** Special clinical circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the patient (document special clinical circumstances)

Notes	*See table 1 in background for PDL links

Product Name:Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Brand Vumerity, Tascenso ODT, Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5 mg, Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information
Table 1: PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
11/27/2024	Updated GPIs. Removed dimethyl fumarate, teriflunomide and fingolimod

MS Agents

Prior Authorization Guideline

Guideline ID	GL-161400
Guideline Name	MS Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic glatiramer, Glatopa, Mayzent, Plegridy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of multiple sclerosis (MS)

Product Name:Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis (MS) **AND** **2** - ONE of the following: **2.1** Failure of at least two of the preferred* alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records **OR** **2.2** History of intolerance or contraindication to all of the preferred* alternatives (please specify intolerance or contraindication) **OR** **2.3** Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records	
Notes	*See table 1 in background for PDL links

Product Name:Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - Patient is 10 years of age or older

AND

3 - ONE of the following:

3.1 Failure of fingolimod 0.5mg (generic Gilenya 0.5 mg) confirmed by claims history or submitted medical records

OR

3.2 History of intolerance or contraindication to fingolimod 0.5mg (generic Gilenya 0.5 mg) (please specify intolerance or contraindication)

OR

3.3 Patient is currently on Tascenso ODT therapy as documented by claims history or submission of medical records

Notes	*See table 1 in background for PDL links

Product Name:Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5mg, Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - ONE of the following:

2.1 Failure of at least two of the preferred* alternatives (one of which must be a preferred dimethyl fumarate product) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to all of the preferred* alternatives (please specify intolerance or contraindication)

OR

2.3 Patient is currently on the requested drug therapy as confirmed by claims history or submission of medical records

AND

3 - ONE of the following:

3.1 The brand is being requested because of an adverse reaction, allergy or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)

OR

3.2 The brand is being requested due to an incomplete response with a generic/authorized generic equivalent, as documented by submission of medical records

OR

3.3 The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient.

OR **3.4** Special clinical circumstances exist that preclude the use of a generic/authorized generic equivalent of the brand medication for the patient (document special clinical circumstances)

Notes	*See table 1 in background for PDL links

Product Name:Avonex, Bafiertam, Betaseron, Extavia, Kesimpta, Ponvory, Rebif, Brand Vumerity, Tascenso ODT, Brand Aubagio, Brand Copaxone, Brand Gilenya 0.5 mg, Brand Tecfidera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information
Table 1: PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
11/27/2024	Updated GPIs. Removed dimethyl fumarate, teriflunomide and fingolimod

Mulpleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135118
Guideline Name	Mulpleta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Mulpleta	
Diagnosis	Thrombocytopenia
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria
1 - Diagnosis of thrombocytopenia **AND** **2** - Patient has chronic liver disease **AND** **3** - Patient is scheduled to undergo a procedure

2 . Revision History

Date	Notes
10/17/2023	Updated formularies.

Multaq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135119
Guideline Name	Multaq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Multaq	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)
- Persistent AF defined as AF less than 6 months duration

AND

1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.3 Patient does NOT have New York Heart Association (NYHA) Class IV heart failure

AND

1.4 Patient does NOT have symptomatic heart failure with recent decompensation requiring hospitalization

OR

2 - For continuation of current therapy

2 . Revision History

Date	Notes
10/18/2023	Updated formularies, cleaned up criteria.

Myalept

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127850
Guideline Name	Myalept
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

AND

4 - Patient has at least ONE of the following:

4.1 Diabetes mellitus or insulin resistance with persistent hyperglycemia (hemoglobin A1C greater than 7.0%) despite BOTH of the following:

- Dietary intervention
- Optimized insulin therapy at maximum tolerated doses

OR

4.2 Persistent hypertriglyceridemia (triglycerides greater than 250 milligrams per deciliter) despite BOTH of the following:

- Dietary intervention
- Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Product Name:Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Myalept therapy

AND

2 - Used as an adjunct to diet modification

AND

3 - Prescribed by an endocrinologist

2 . Revision History

Date	Notes
7/11/2023	Removed RMH, and ACUAZ formularies.

Mycapssa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-192203
Guideline Name	Mycapssa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of acromegaly by ONE of the following:

- Serum GH (growth hormone) level > 1 ng/mL (nanogram/milliliter) after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis
- Elevated serum IGF-1 (insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 ONE of the following:

1.2.1 Inadequate response to ONE of the following:

- Surgical resection
- Pituitary irradiation
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 Not a candidate for ALL of the following:

- Surgical resection
- Pituitary irradiation
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Patient has responded to and tolerated treatment with ONE of the following somatostatin analogs:

- Sandostatin (octreotide) or Sandostatin LAR
- Somatuline Depot (lanreotide) [Note: Somatuline Depot (lanreotide) might not be covered on your pharmacy prescription drug benefit. Coverage might be available on your medical benefit.]

AND **1.4** The provider has submitted clinical justification why the patient is unable to be maintained on current octreotide or lanreotide therapy* **OR** **2** - Patient is currently on Mycapssa therapy for acromegaly

Notes	*UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity.

Product Name:Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Mycapssa therapy

2 . Revision History

Date	Notes
2/25/2025	Updated formularies. Updated initial auth criteria wording

Mytesi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145891
Guideline Name	Mytesi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Mytesi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) associated diarrhea

2 . Revision History

Date	Notes
4/18/2024	Combined all CORE formularies. No changes to criteria and no other changes to guideline made.

Namzaric

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149855
Guideline Name	Namzaric
Formulary	• Medicaid - Community & State New York • Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Namzaric	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - BOTH of the following:

1.1 History of BOTH of the following as confirmed by claims history or submission of medical records:

1.1.1 Memantine (generic Namenda)

AND

1.1.2 Donepezil (generic Aricept)

AND

1.2 Patient is stabilized on 10mg of donepezil once daily as confirmed by claims history or submission of medical records

2 . Revision History

Date	Notes
7/15/2024	Removed CO Rocky Mountain and Arizona Formularies. No clinical c riteria changes.

Nasonex, Xhance

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155771
Guideline Name	Nasonex, Xhance
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Brand Nasonex, generic mometasone (Rx version only), Allergy nasal spray	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Failure to ONE of the following as confirmed by claims history or submission of medical record

- Prescription fluticasone nasal spray (generic Flonase)
- Flonase allergy relief (fluticasone propionate) OTC brand or generic

OR

2 - History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Prescription fluticasone nasal spray (generic Flonase)
- Flonase allergy relief (fluticasone propionate) OTC brand or generic

Product Name:Xhance	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of chronic rhinosinusitis with nasal polyps

OR

1.2 Diagnosis of chronic rhinosinusitis without nasal polyps

AND

2 - One of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records

- Fluticasone nasal spray (generic Flonase, Flonase Allergy)

- Mometasone nasal spray (generic Nasonex or Nasonex 24H Allergy)

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Fluticasone nasal spray (generic Flonase, Flonase Allergy)
- Mometasone nasal spray (generic Nasonex or Nasonex 24H Allergy)

2 . Revision History

Date	Notes
9/24/2024	New.

Nayzilam and Valtoco

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148354
Guideline Name	Nayzilam and Valtoco
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of epilepsy

AND

2 - Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

Product Name:Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Valtoco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

AND

4 - ONE of the following:

4.1 Patient is less than 12 years of age

OR

4.2 ONE of the following:

4.2.1 Failure of Nayzilam confirmed by claims history or submitted medical records

OR

4.2.2 History of contraindication or intolerance to Nayzilam (please specify contraindication or intolerance)

Product Name:Valtoco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/10/2024	Revised drug table for Valtoco name change.

Nayzilam and Valtoco

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148354
Guideline Name	Nayzilam and Valtoco
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of epilepsy

AND

2 - Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

Product Name:Nayzilam	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Valtoco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epilepsy

AND

2 - Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

AND

3 - The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

AND

4 - ONE of the following:

4.1 Patient is less than 12 years of age

OR

4.2 ONE of the following:

4.2.1 Failure of Nayzilam confirmed by claims history or submitted medical records

OR

4.2.2 History of contraindication or intolerance to Nayzilam (please specify contraindication or intolerance)

Product Name:Valtoco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/10/2024	Revised drug table for Valtoco name change.

Nerlynx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155025
Guideline Name	Nerlynx
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Nerlynx	
Diagnosis	Early-Stage or Node-Positive Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of early-stage breast cancer

AND

1.2 Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

1.3 Used as extended adjuvant therapy following adjuvant trastuzumab containing therapy (e.g., Herceptin, Kanjinti)

AND

1.4 Patient will not have more than 12 months of treatment per occurrence*

OR

2 - ALL of the following:

2.1 Diagnosis of node positive breast cancer

AND

2.2 Disease is hormone receptor (HR)-positive and HER2-positive

AND

2.3 Used as extended adjuvant therapy following adjuvant trastuzumab containing therapy (e.g., Herceptin, Kanjinti)

AND

2.4 Patient has a perceived high risk of recurrence

AND

2.5 Patient will not have more than 12 months of treatment per occurrence*

Notes	*Duration of coverage is limited to 12 months per occurrence.

Product Name:Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of advanced or metastatic breast cancer

AND

1.2 Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

1.3 Patient has received two or more prior anti-HER2 based regimens in metastatic setting

AND

1.4 Will be used in combination with capecitabine (generic Xeloda)

OR

2 - BOTH of the following:

2.1 Diagnosis of stage IV (M1) breast cancer

AND

2.2 ONE of the following:

2.2.1 Both of the following:

- Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease
- Patient has already received a CDK4/6 inhibitor therapy

OR

2.2.2 Triple negative disease

Product Name:Nerlynx	
Diagnosis	Breast Cancer with Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient has brain metastases

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with ONE of the following:

- capecitabine (generic Xeloda)
- Paclitaxel

Product Name:Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer, Breast Cancer with Brain Metastases
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nerlynx therapy

Product Name:Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Nerlynx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Nerlynx therapy	

2 . Revision History

Date	Notes
9/16/2024	Updated formatting, no changes to criteria

Nexavar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158284
Guideline Name	Nexavar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 BOTH of the following:

- Medically or surgically unresectable tumor
- Diagnosis of Stage IV disease

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - ONE of the following:

2.1 Patient has metastatic disease

OR

2.2 Patient has extensive liver tumor burden

OR

2.3 Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only)

OR

2.4 BOTH of the following:

- Patient is not a transplant candidate
- Disease is unresectable

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable recurrent disease
- Persistent locoregional disease
- Metastatic disease

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 Disease is refractory to radioactive iodine treatment

OR

2 - ALL of the following:

2.1 Diagnosis of medullary thyroid carcinoma

AND

2.2 ONE of the following:

- Disease is progressive
- Disease is symptomatic with distant metastases

AND

2.3 ONE of the following:

2.3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Caprelsa (vandetanib)
- Cometriq (cabozantinib)

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of angiosarcoma

OR

2 - Diagnosis of desmoid tumors/aggressive fibromatosis

OR

3 - BOTH of the following:

3.1 Diagnosis of progressive gastrointestinal stromal tumors (GIST)

AND

3.2 ONE of the following:

3.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- imatinib (generic for Gleevec)
- sunitinib (generic for Sutent)
- Stivarga (regorafenib)
- Qinlock (ripretinib)

OR

3.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- imatinib (generic for Gleevec)
- sunitinib (generic for Sutent)
- Stivarga (regorafenib)
- Qinlock (ripretinib)

OR

4 - Diagnosis of solitary fibrous tumor/hemangiopericytoma

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of chordoma

AND

1.2 Disease is recurrent

OR

2 - BOTH of the following:

2.1 ONE of the following:

- Diagnosis of osteosarcoma
- Diagnosis of dedifferentiated chondrosarcoma
- Diagnosis of high-grade undifferentiated pleomorphic sarcoma (UPS)

AND

2.2 Not used as first-line therapy

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has FLT3-ITD mutation-positive disease

AND

3 - ONE of the following:

- Patient has relapsed disease
- Patient has refractory disease

AND

4 - Used in combination with ONE of the following:

- azacytidine (generic for Vidaza)
- decitabine (generic for Dacogen)

AND

5 - Patient is unable to tolerate more aggressive treatment regimens

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - ONE of the following:

- Patient has persistent disease
- Patient has recurrent disease

AND

3 - Disease is platinum-resistant

AND

4 - Used in combination with topotecan

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable
- Metastatic

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and FLT3 rearrangement

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	Renal Cell Carcinoma (RCC), Hepatocellular Carcinoma, Thyroid Cancer, Soft Tissue Sarcoma, Bone Cancer, Acute Myeloid Leukemia, Ovarian Cancer, Salivary Gland Tumor, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Nexavar, generic sorafenib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
10/30/2024	Updated product name lists throughout guideline. Minor update to re auth criteria sections, with no changes to clinical intent. Minor cosmet ic update to diagnosis header for NCCN sections, with no changes to clinical intent.

Nexletol, Nexlizet

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152514
Guideline Name	Nexletol, Nexlizet
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Nexletol, Nexlizet	
Diagnosis	Hyperlipidemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)

OR

1.2 Established cardiovascular disease (CVD) as documented by one of the following:

- coronary artery disease
- symptomatic peripheral arterial disease
- cerebrovascular atherosclerotic disease

OR

1.3 High risk for cardiovascular disease (CVD) as documented by one of the following:

- Diabetes and over 60 years old
- Reynolds risk score greater than 30%
- Coronary artery calcium score greater than 400 Agatston units
- ASCVD risk score greater than or equal to 20% with the American College of Cardiology/American Heart Association (ACC/AHA) risk estimator

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) confirming ONE of the following [prescription claims history may be used in conjunction as confirmation of medication use, dose, and duration]:

2.1 Patient has been receiving at least 12 consecutive weeks of high intensity statin therapy [i.e., atorvastatin 40-80 mg (milligrams), rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without CK (creatine kinase) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin extended-release 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) confirming ONE of the following LDL-C (low-density lipoprotein cholesterol) values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL (milligrams/deciliter) with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) confirming ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) confirming ONE of the following [prescription claims history may be used in conjunction as confirmation of medication use, dose, and duration]:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

Product Name:Nexletol, Nexlizet	
Diagnosis	Hyperlipidemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

AND

2 - Patient continues to receive statin at maximally tolerated dose (unless patient has documented inability to take statins)

2 . Revision History

Date	Notes
8/27/2024	Updated indications to include established and high risk for CVD based on updated labeling. Lowered LDL-C threshold for initiation of therapy. Updated background.

Ninlaro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151693
Guideline Name	Ninlaro
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Ninlaro	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name:Ninlaro	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory systemic light chain amyloidosis

Product Name:Ninlaro	
Diagnosis	Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenström macroglobulinemia/lymphoplasmacytic lymphoma

AND

2 - Used in combination with rituximab and dexamethasone

Product Name:Ninlaro

Diagnosis	Multiple Myeloma, Systemic Light Chain Amyloidosis, Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ninlaro therapy

Product Name:Ninlaro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ninlaro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ninlaro therapy

2 . Revision History

Date	Notes
8/13/2024	Simplified criteria for multiple myeloma to only require diagnosis chec k.

Nityr

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134707
Guideline Name	Nityr
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Nityr	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hereditary tyrosinemia type 1

2 . Revision History

Date	Notes
10/12/2023	Updated formularies.

Nocdurna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144989
Guideline Name	Nocdurna
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria (as defined by nighttime urine production that exceeds one-third of the 24-hour urine production)

AND

2 - Patient wakes at least twice per night on a reoccurring basis to void

AND

3 - Documented serum sodium level is currently within normal limits of the normal laboratory reference range and has been within normal limits over the previous six months

AND

4 - The patient has been evaluated for other medical causes and has either not responded to, tolerated, or has a contraindication to treatments for identifiable medical causes [e.g., overactive bladder, benign prostatic hyperplasia/lower urinary tract symptoms (BPH/LUTS), elevated post-void residual urine, and heart failure]

AND

5 - Prescriber attests that the risks have been assessed and benefits outweigh the risks

Product Name:Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nocdurna therapy

AND **2** - Patient has routine monitoring for serum sodium levels **AND** **3** - Prescriber attests that the risks of hyponatremia have been assessed and benefits outweigh the risks

2 . Revision History

Date	Notes
3/28/2024	Increased initial authorization to 12 months

Non-Preferred Drugs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-108054
Guideline Name	Non-Preferred Drugs
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name:Non-Preferred Medications	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - If the requested medication is a behavioral health medication, ONE of the following:

1.1 The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

OR

1.2 The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

OR

2 - All of the following:

2.1 One of the following:

2.1.1 Both of the following:

2.1.1.1 One of the following:

2.1.1.1.1 The patient had an inadequate response with at least three different generic or preferred medications if available, as confirmed by claims history or submission of medical records. Prior trials of generic or preferred alternatives must sufficiently demonstrate that the generic or preferred alternatives are either ineffective or inappropriate at the time of the request

OR

2.1.1.1.2 In instances where there are fewer than three generic or preferred alternatives, the patient must have ONE of the following:

- History of failure to all of the generic or preferred alternatives, as confirmed by claims history or submission of medical records
- History of, contraindication, or intolerance to all of the generic or preferred alternatives (please specify contraindication or intolerance).

OR

2.1.1.1.3 The patient had a documented side effect and/or intolerance to a trial with at least three different generic or preferred medications, if available. (specify the side effect or intolerance)

OR

2.1.1.1.4 Documentation that all of the generic or preferred alternatives are contraindicated for this patient's specific condition. (specify contraindication)

OR

2.1.1.1.5 Documentation that there is a reason or special circumstance that all of the generic or preferred alternatives are not clinically appropriate for the patient. (document reason or special circumstance)

AND

2.1.1.2 One of the following:

2.1.1.2.1 If the request is for a multi-source brand medication, OR a branded medication with an authorized generic, ONE of the following:

- The brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)
- The brand is being requested due to an incomplete response with a generic/authorized generic equivalent as documented by submission of medical records
- The brand is being requested because transition to a generic/authorized generic equivalent could result in destabilization of the patient
- Special clinical circumstances exist that preclude the use of a generic/authorized equivalent of the multi-source brand medication for the patient (document special clinical circumstances)

OR

2.1.1.2.2 If the request is for a generic when there is a brand available and the brand is the preferred formulation, ONE of the following:

- The generic is being requested because of an adverse reaction, allergy, or sensitivity to the brand. (specify the adverse reaction, allergy, or sensitivity)
- The generic is being requested due to an incomplete response with the brand as documented by submission of medical records
- The generic is being requested because transition to the brand could result in destabilization of the patient
- Special clinical circumstances exist that preclude the use of the brand equivalent of the generic medication for the patient. (document special clinical circumstances)

OR

2.1.2 There are no preferred formulary alternatives for the requested drug

AND

2.2 One of the following:

2.2.1 The requested drug must be used for an FDA-approved indication

OR

2.2.2 The use of this drug is supported by information from the appropriate compendia of current literature

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF)

AND

2.3 The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

Notes	*RI PDL Link may be found at: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

2 . Revision History

Date	Notes
6/10/2022	Rearrangement of criteria. Updated requirements for failure, contrain dication, and intolerance. Updated criteria for submission of medical r ecords and/or documentation.

Northera

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148217
Guideline Name	Northera
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Brand Northera, generic droxidopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by ONE of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

- At least a 20 millimeters of mercury (mm Hg) fall in systolic pressure
- At least a 10 mm Hg fall in diastolic pressure

AND

2 - nOH caused by ONE of the following:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

AND

4 - The patient has tried at least TWO of the following non-pharmacologic interventions:

- Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
- Raising the head of the bed 10 to 20 degrees
- Compression garments to the lower extremities or abdomen
- Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
- Increased salt and water intake, if appropriate
- Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

AND

5 - No previous diagnosis of supine hypertension

AND

6 - Prescribed by or in consultation with ONE of the following specialists:

- Cardiologist
- Neurologist
- Nephrologist

AND

7 - ONE of the following:

7.1 Failure (after a trial of at least 30 days) of BOTH of the following confirmed by claims history or submitted medical records:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

OR

7.2 History of contraindication or intolerance to BOTH of the following:

- fludrocortisone (generic Florinef)
- midodrine (generic ProAmatine)

Product Name:Brand Northera, generic droxidopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

AND **2** - Physiological countermeasures for neurogenic orthostatic hypotension (nOH) continue to be employed

2 . Revision History

Date	Notes
6/6/2024	Updated initial authorization duration to 12 months.

Nourianz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164688
Guideline Name	Nourianz
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing "off" episodes

AND

3 - ONE of the following:

3.1 Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes) as confirmed by claims history or submission of medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

OR

3.2 History of contraindication or intolerance to ALL anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from all classes) (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nourianz therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
2/4/2025	Updated formularies. Updated initial auth duration

Nourianz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164688
Guideline Name	Nourianz
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Used as adjunctive treatment to levodopa/carbidopa in patients experiencing "off" episodes

AND

3 - ONE of the following:

3.1 Failure to TWO anti-Parkinson's disease therapies from the following adjunctive pharmacotherapy classes (trial must be from two different classes) as confirmed by claims history or submission of medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

OR

3.2 History of contraindication or intolerance to ALL anti-Parkinson's disease therapy from the following adjunctive pharmacotherapy classes (trial must be from all classes) (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., rasagiline, selegiline)

Product Name:Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nourianz therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

2 . Revision History

Date	Notes
2/4/2025	Updated formularies. Updated initial auth duration

Nubeqa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134709
Guideline Name	Nubeqa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Nubeqa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Disease is non-metastatic

AND

2.1.2 Disease is castration-resistant or recurrent

OR

2.2 ALL of the following:

2.2.1 Disease is metastatic

AND

2.2.2 Disease is hormone-sensitive

AND

2.2.3 Nubeqa will be used in combination with docetaxel

AND

3 - ONE of the following:

3.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

3.2 Patient has had bilateral orchiectomy

Product Name:Nubeqa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Nubeqa therapy

Product Name:Nubeqa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Nubeqa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Nubeqa therapy	

2 . Revision History

Date	Notes
10/12/2023	Updated formularies.

Nucala

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155037
Guideline Name	Nucala
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of EGPA

AND

2 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following

- Reduction in the frequency and/or severity of relapses
- Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
- Disease remission
- Reduction in severity or frequency of EGPA-related symptoms

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by one of the following

- Allergist
- Immunologist
- Pulmonologist
- Rheumatologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA) as defined by ALL of the following:

1.1 Diagnosis of EGPA

AND

1.2 Past medical history or presence of asthma

AND

1.3 Presence of at least TWO of the following characteristics typical of EGPA:

1.3.1 Histopathological evidence of ALL of the following:

- Eosinophilic vasculitis
- Perivascular eosinophilic infiltration
- Eosinophil-rich granulomatous inflammation

OR

1.3.2 Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)

OR

1.3.3 Pulmonary infiltrates, non-fixed

OR

1.3.4 Sino-nasal abnormality

OR

1.3.5 Cardiomyopathy [established by echocardiography or magnetic resonance imaging (MRI)]

OR

1.3.6 Glomerulonephritis (hematuria, red cell casts, proteinuria)

OR

1.3.7 Alveolar hemorrhage

OR

1.3.8 Palpable purpura

OR

1.3.9 Anti-neutrophil cytoplasmic antibody (ANCA) positive

AND

1.4 History of relapsing or refractory disease defined as ONE of the following:

1.4.1 Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)

OR

1.4.2 Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

AND

2 - Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone)] with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab) as supported by claims history or submitted medical records

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist
- Rheumatologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

1.1 Reduction in the frequency and/or severity of relapses

OR

1.2 Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant

OR

1.3 Disease remission

OR

1.4 Reduction in severity or frequency of eosinophilic granulomatosis with polyangiitis (EGPA)-related symptoms

AND

2 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

2 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following

- Reduction in the frequency of exacerbations
- Decreased utilization of rescue medications
- Increase in percent predicted FEV1 from pretreatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Reduction in oral corticosteroid requirements

AND

3 - Nucala is being used in combination with an inhaled corticosteroid (ICS) containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

4 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

2.1 Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal)]

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter

AND

4 - Nucala will be used in combination with ONE of the following:

4.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

4.2 Combination therapy including BOTH of the following:

4.2.1 ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

4.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

5 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]

- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

6 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Pulmonologist

AND

7 - ONE of the following:

- Failure to a 4 month trial of Fasenra (benralizumab) as confirmed by claims history or submitted medical records
- History of contraindication or intolerance to Fasenra (benralizumab) (please specify intolerance or contraindication)

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

1.1 Reduction in the frequency of exacerbations

OR

1.2 Decreased utilization of rescue medications

OR

1.3 Increase in percent predicted forced expiratory volume in 1 second (FEV1) from pretreatment baseline

OR

1.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

OR

1.5 Reduction in oral corticosteroid requirements

AND

2 - Nucala is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Hypereosinophilic Syndrome (HES)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of hypereosinophilic syndrome (HES).

AND

2 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least one of the following

- Reduction in frequency of HES flares
- Maintenance or reduction in background HES therapy requirements

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

Product Name:Nucala auto-injector and pre-filled syringe

Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hypereosinophilic Syndrome (HES) greater than or equal to 6 months ago

AND

2 - Both of the following:

2.1 There is no identifiable non-hematologic secondary cause of the patient's HES [e.g., drug hypersensitivity, parasitic helminth infection, HIV (human immunodeficiency virus) infection, non-hematologic malignancy]

AND

2.2 HES is not FIP1L1-PDGFR alpha (gene) kinase-positive

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting both of the following:

3.1 Baseline [pre-Nucala (mepolizumab) treatment] blood eosinophil level greater than or equal to 1000 cells/microliter within the past 4 weeks

AND

3.2 Patient is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy)

AND

4 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by ONE of the following:

- Allergist
- Cardiologist
- Hematologist
- Immunologist
- Pulmonologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy as demonstrated by at least ONE of the following:

1.1 Reduction in the frequency of Hypereosinophilic Syndrome (HES) flares

OR

1.2 Maintenance or reduction in background HES therapy requirements

AND

2 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Nucala under an active UnitedHealthcare medical benefit prior authorization for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP).

AND

2 - Documentation of positive clinical response to Nucala therapy

AND

3 - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

4 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by ONE of the following

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization – Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by ALL of the following:

1.1 Two or more of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

AND

1.2 One of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus

- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

1.3 ONE of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

AND

1.4 ONE of the following:

1.4.1 Patient has required prior sinus surgery

OR

1.4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years

OR

1.4.3 Patient has been unable to obtain symptom relief after trial of TWO of the following classes of agents:

- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

AND

2 - Patient will receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by ONE of the following:

- Allergist
- Immunologist
- Otolaryngologist
- Pulmonologist

Product Name:Nucala auto-injector and pre-filled syringe	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nucala therapy

AND

2 - Patient will continue to receive Nucala as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is not receiving Nucala in combination with ONE of the following

- Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
- Anti-IgE (immunoglobulin E) therapy [e.g., Xolair (omalizumab)]
- Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- Thymic stromal lymphopoietin (TSLP) inhibitor therapy [e.g., Tezspire (tezepelumab)]

2 . Revision History

Date	Notes
9/17/2024	Specified existing prior authorization for under the medical benefit.

Nuedexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129314
Guideline Name	Nuedexta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Nuedexta	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pseudobulbar affect (PBA)

2 . Revision History

Date	Notes
8/3/2023	Updated formularies.

Nuplazid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120081
Guideline Name	Nuplazid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

Note:

Effective Date:12/01/2019

1 . Criteria

Product Name:Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is currently experiencing hallucinations and delusions associated with Parkinson's disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

Product Name:Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nuplazid therapy

Nuplazid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-120081
Guideline Name	Nuplazid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

Note:

Effective Date:12/01/2019

1 . Criteria

Product Name:Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is currently experiencing hallucinations and delusions associated with Parkinson's disease psychosis (i.e., hallucination and delusion symptoms started after Parkinson's disease diagnosis)

Product Name:Nuplazid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Nuplazid therapy

Nurtec, Qulipta, Ubrelvy, Zavzpret

Prior Authorization Guideline

Guideline ID	GL-206564
Guideline Name	Nurtec, Qulipta, Ubrelvy, Zavzpret
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - One of the following:

2.1 Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to TWO of the following as confirmed by claims history or submission of medical records:

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

AND

3 - One of the following:

3.1 Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]

- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 Patient has less than 4 migraine days per month

OR

3.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Ubrelvy, Zavzpret)

Notes	* Timolol, candesartan, Ajovy and Qulipta are non-preferred and shoul d not be included in denial to provider **Vyepti, OnabotulinumtoxinA are medical benefits and should not be i ncluded in denial to provider. ***CGRP antagonists for preventive treatment of migraines require a p rior authorization.

Product Name:Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic migraines with greater than or equal to 4 migraine days per month

AND

2 - Used for preventive treatment of migraines

AND

3 - One of the following:

3.1 Failure (after a trial of at least two months), to TWO of the following prophylactic therapies as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan* (generic Atacand)
- Divalproex sodium (generic Depakote/Depakote ER)
- Topiramate (generic Topamax)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 History of contraindication or intolerance to TWO of the following prophylactic therapies (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan* (generic Atacand)
- Divalproex sodium (generic Depakote/Depakote ER)
- Topiramate (generic Topamax)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another CGRP (calcitonin gene-related peptide) antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Vyepti)

Notes	* Timolol and candesartan are non-preferred and should not be includ ed in denial to provider

Product Name:Nurtec ODT	
Diagnosis	Acute Treatment of Migraine, Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - ONE of the following:

2.1 Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Ubrelvy, Zavzpret)

OR

2.2 Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Vyepti)

Product Name:Zavzpret	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - One of the following:

2.1 Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to BOTH of the following as confirmed by claims history or submission of medical records:

2.1.1 TWO preferred 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray

AND

2.1.2 ONE of the following:

- Nurtec ODT
- Ubrelvy

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- TWO preferred 5-HT1 receptor agonist (triptan) alternatives (e.g., sumatriptan, rizatriptan, or naratriptan), one of which must be sumatriptan nasal spray
- Nurtec ODT
- Ubrelvy

AND

3 - One of the following:

3.1 Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 Patient has less than 4 migraine days per month

OR

3.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Nurtec ODT, Ubrelvy)

Notes	* Timolol, candesartan, Ajovy and Qulipta are non-preferred and shoul d not be included in denial to provider **Vyepti, OnabotulinumtoxinA are medical benefits and should not be i

	ncluded in denial to provider. ***CGRP antagonists for preventive treatment of migraines require a p rior authorization.

Product Name:Ubrelvy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for acute treatment of migraine

AND

2 - One of the following:

2.1 Failure (after at least 3 migraine episodes and a minimum of a 30-day trial) to TWO of the following as confirmed by claims history or submission of medical records:

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance)

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

AND

3 - One of the following:

3.1 Patient is currently treated with ONE of the following prophylactic therapies or classes as confirmed by claims or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 Patient has less than 4 migraine days per month

OR

3.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies or classes (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol)*
- Candesartan* (generic Atacand)
- A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**] ***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (e.g., Nurtec ODT, Zavzpret)

Notes	* Timolol, Ajovy, Qulipta and candesartan are non-preferred and shoul d not be included in denial to provider **Vyepti, OnabotulinumtoxinA are medical benefit and should not be i ncluded in denial to provider. ***CGRP antagonists for preventive treatment of migraines require a p rior authorization.

Product Name:Ubrelvy, Zavzpret	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonist (e.g., Nurtec ODT)

Product Name:Qulipta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

AND

2 - ONE of the following:

2.1 Patient has 4 to 7 migraine days per month and at least ONE of the following:

2.1.1 Less than 15 headache days per month

OR

2.1.2 Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not different, non-migrainous condition)

OR

2.2 Greater than or equal to 8 migraine days per month

AND

3 - One of the following:

3.1 Failure (after a trial of at least two months) to TWO of the following prophylactic therapies as confirmed by claims history or submission of medical records:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan* (Atacand)
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

3.2 History of contraindication or intolerance to TWO of the following prophylactic therapies (please specify contraindication or intolerance):

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan* (Atacand)
- Divalproex sodium (Depakote/Depakote ER)
- OnabotulinumtoxinA** (generic Botox)
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

4 - One of the following:

4.1 Failure (after a trial of at least three months) to Nurtec ODT as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to Nurtec ODT (please specify contraindication or intolerance)

AND

5 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g. Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)

Notes	* Timolol, candesartan are non-preferred and should not be included i n denial to provider **OnabotulinumtoxinA is a medical benefit and should not be included in denial to provider.

Product Name:Qulipta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)

2 . Background

Benefit/Coverage/Program Information
PDL Links: CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/3/2025	Updated formularies. Added eletriptan and zolmitriptan as step thera py option. Updated prophylactic therapy requirement contraindication /intolerance count from all to two. Updated PDL links

Nuzyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144714
Guideline Name	Nuzyra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Nuzyra tablets	
Guideline Type	Prior Authorization
Approval Criteria **1** - For continuation of therapy upon hospital discharge	

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - ALL of the following:

3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

3.3 ONE of the following:

3.3.1 Failure to THREE of the following antibiotics or antibiotic regimens, as confirmed by claims history or submitted medical records:

- Amoxicillin
- A macrolide
- Doxycycline
- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

OR

3.3.2 History of intolerance or contraindication to ALL of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication):

- Amoxicillin
- A macrolide
- Doxycycline

- A fluoroquinolone
- Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

OR

4 - ALL of the following:

4.1 ONE of the following diagnoses:

4.1.1 BOTH of the following:

4.1.1.1 Acute bacterial skin and skin structure infections

AND

4.1.1.2 Infection caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

4.1.2 BOTH of the following:

4.1.2.1 Empirical treatment of a patient with acute bacterial skin and skin structure infections

AND

4.1.2.2 Presence of MRSA infection is likely

AND

4.2 ONE of the following:

4.2.1 Failure to linezolid (generic Zyvox) as confirmed by claims history or submitted medical records

OR

4.2.2 History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

AND

4.3 ONE of the following:

4.3.1 Failure to ONE of the following antibiotics as confirmed by claims history or submitted medical records:

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

4.3.2 History of intolerance or contraindication to ALL of the following antibiotics (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- A tetracycline
- Clindamycin

OR

5 - ALL of the following:

5.1 Diagnosis of acute bacterial skin and skin structure infections

AND

5.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Nuzyra

AND

5.3 ONE of the following:

5.3.1 Failure to THREE of the following antibiotics confirmed by claims history or submitted medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

OR

5.3.2 History of intolerance or contraindication to ALL of the following antibiotics (please specify intolerance or contraindication):

- A penicillin
- A cephalosporin
- A tetracycline
- Sulfamethoxazole-trimethoprim (SMZ-TMP)
- Clindamycin

OR

6 - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

Notes	Authorization duration for CABP and acute bacterial skin and skin structure infections will be issued for up to 14 days. For all IDSA recognized indications, authorization duration is based on provider and IDSA recommended treatment durations, up to 6 months.

2 . Revision History

Date	Notes
3/20/2024	Updated product name section to specify Nuzyra "tablets". No changes to clinical criteria.

OAB Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149323
Guideline Name	OAB Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/2/2024

1 . Criteria

Product Name:generic tolterodine IR	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to treatment with oxybutynin immediate release as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to oxybutynin immediate release (please specify contraindication or intolerance)

Product Name:generic tolterodine ER	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Failure to treatment with oxybutynin extended-release as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to oxybutynin extended-release (please specify contraindication or intolerance)

Product Name:Brand Detrol LA, Brand Ditropan XL, darifenacin ER, Gelnique, Gemtesa, trospium ER, Brand Vesicare	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)

- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

Product Name:Oxytrol (Rx)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of THREE of the following, confirmed by claims history or submission of medical records:

- Oxytrol for Women (oxybutynin OTC) patch
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Oxytrol for Women (oxybutynin OTC) patch
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

Product Name:flavoxate, oxybutynin oral solution, Brand Detrol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of ALL of the following, confirmed by claims history or submission of medical records:

- oxybutynin syrup or tablet
- tolterodine tablet (generic Detrol)
- trospium tablet

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup or tablet
- tolterodine tablet (generic Detrol)
- trospium tablet

Product Name:Vesicare LS	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2 - ONE of the following:

2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

Product Name:Brand Myrbetriq tabs, generic mirabegron tabs, generic fesoterodine ER, Brand Toviaz	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of overactive bladder (OAB)

AND

1.2 ONE of the following:

1.2.1 Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet

- solifenacin tablet (generic Vesicare)

OR

1.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - BOTH of the following:

2.1 Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2.2 ONE of the following:

2.2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

Product Name:Myrbetriq granules	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2 - ONE of the following:

2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

AND

3 - ONE of the following:

3.1 Patient is 3 years of age to (including) 17 years of age

OR

3.2 BOTH of the following:

3.2.1 Physician has provided rationale for needing to use this medication in an unapproved age range

AND

3.2.2 The use of this medication for a patient outside the FDA (Food and Drug Administration) approved age range is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia - National Formulary (USP-NF)

2 . Revision History

Date	Notes
7/3/2024	Addition of generic mirabegron. Clarified tolterodine ER as capsule formulation.

OAB Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149323
Guideline Name	OAB Agents
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/2/2024

1 . Criteria

Product Name:generic tolterodine IR	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to treatment with oxybutynin immediate release as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to oxybutynin immediate release (please specify contraindication or intolerance)

Product Name:generic tolterodine ER	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Failure to treatment with oxybutynin extended-release as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to oxybutynin extended-release (please specify contraindication or intolerance)

Product Name:Brand Detrol LA, Brand Ditropan XL, darifenacin ER, Gelnique, Gemtesa, trospium ER, Brand Vesicare	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)

- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

Product Name:Oxytrol (Rx)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of THREE of the following, confirmed by claims history or submission of medical records:

- Oxytrol for Women (oxybutynin OTC) patch
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Oxytrol for Women (oxybutynin OTC) patch
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

Product Name:flavoxate, oxybutynin oral solution, Brand Detrol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to a trial of ALL of the following, confirmed by claims history or submission of medical records:

- oxybutynin syrup or tablet
- tolterodine tablet (generic Detrol)
- trospium tablet

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup or tablet
- tolterodine tablet (generic Detrol)
- trospium tablet

Product Name:Vesicare LS	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2 - ONE of the following:

2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

Product Name:Brand Myrbetriq tabs, generic mirabegron tabs, generic fesoterodine ER, Brand Toviaz	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of overactive bladder (OAB)

AND

1.2 ONE of the following:

1.2.1 Failure to a trial of THREE of the following confirmed by claims history or submission of medical records:

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet

- solifenacin tablet (generic Vesicare)

OR

1.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin extended-release tablet (generic Ditropan XL)
- tolterodine immediate release (generic Detrol) or tolterodine extended-release capsule (generic Detrol LA)
- trospium tablet
- solifenacin tablet (generic Vesicare)

OR

2 - BOTH of the following:

2.1 Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2.2 ONE of the following:

2.2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

Product Name:Myrbetriq granules	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurogenic detrusor overactivity (NDO) (neurogenic bladder)

AND

2 - ONE of the following:

2.1 Failure to a trial of ONE of the following, as confirmed by claims history or submission of medical records:

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oxybutynin syrup
- oxybutynin tablet
- oxybutynin extended release tablet (generic Ditropan XL)

AND

3 - ONE of the following:

3.1 Patient is 3 years of age to (including) 17 years of age

OR

3.2 BOTH of the following:

3.2.1 Physician has provided rationale for needing to use this medication in an unapproved age range

AND

3.2.2 The use of this medication for a patient outside the FDA (Food and Drug Administration) approved age range is supported by information from ONE of the following appropriate compendia:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia - National Formulary (USP-NF)

2 . Revision History

Date	Notes
7/3/2024	Addition of generic mirabegron. Clarified tolterodine ER as capsule formulation.

Ocaliva

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164691
Guideline Name	Ocaliva
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Michigan • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis

AND

2 - ONE of the following:

- Patient does not have cirrhosis
- Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Used in combination with ursodeoxycholic acid (e.g., Urso, ursodiol)
- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g., Urso, ursodiol)

OR

3.2 History of contraindication or intolerance to ursodeoxycholic acid (e.g., Urso, ursodiol) (please specify contraindication or intolerance)

AND

4 - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

5 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

Product Name:Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., laboratory values) documenting a reduction in alkaline phosphatase (ALP) level from pre-treatment baseline (i.e., prior to Ocaliva therapy)

AND

2 - ONE of the following:

- Patient does not have cirrhosis
- Patient has compensated cirrhosis without evidence of portal hypertension

AND

3 - Patient is not receiving Ocaliva in combination with Iqirvo (elafibranor) or Livdelzi (seladelpar)

AND

4 - Prescribed by ONE of the following:

- Hepatologist
- Gastroenterologist

2 . Revision History

Date	Notes
2/4/2025	Updated formularies. Minor formatting changes. Added concurrent use criteria

Odomzo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160617
Guideline Name	Odomzo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nodal metastatic basal cell carcinoma (BCC)

OR

2 - Diagnosis of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC)

OR

3 - BOTH of the following:

3.1 Diagnosis of locally advanced basal cell carcinoma

AND

3.2 ONE of the following:

- Cancer has recurred following surgery
- Cancer has recurred following radiation
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Odomzo therapy

Product Name:Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Odomzo therapy	

2 . Revision History

Date	Notes
11/13/2024	Updated criteria per NCCN recommendations to reflect that Odomzo is recommended for basal cell carcinoma with nodal metastases but not with distant metastases

Odomzo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160617
Guideline Name	Odomzo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nodal metastatic basal cell carcinoma (BCC)

OR

2 - Diagnosis of diffuse basal cell carcinoma (BCC) formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC)

OR

3 - BOTH of the following:

3.1 Diagnosis of locally advanced basal cell carcinoma

AND

3.2 ONE of the following:

- Cancer has recurred following surgery
- Cancer has recurred following radiation
- Patient is not a candidate for surgery
- Patient is not a candidate for radiation

Product Name:Odomzo	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Odomzo therapy

Product Name:Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Odomzo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Odomzo therapy	

2 . Revision History

Date	Notes
11/13/2024	Updated criteria per NCCN recommendations to reflect that Odomzo is recommended for basal cell carcinoma with nodal metastases but not with distant metastases

Ogsiveo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-186193
Guideline Name	Ogsiveo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Ogsiveo	
Diagnosis	Desmoid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of desmoid tumor

AND

2 - Disease is progressive

AND

3 - Patient requires systemic treatment

Product Name:Ogsiveo	
Diagnosis	Desmoid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ogsiveo therapy

Product Name:Ogsiveo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Ogsiveo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Ogsiveo therapy	

2 . Revision History

Date	Notes
2/21/2025	Combined formularies. Added new GPIs for Ogsiveo (IN previously al ready had new GPIs included). No changes to clinical criteria.

Ohtuvayre

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158245
Guideline Name	Ohtuvayre
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Ohtuvayre	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

2.1 Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7

AND

2.2 Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than 80%

AND

3 - Both of the following:

3.1 One of the following:

3.1.1 FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

OR

3.1.2 All of the following:

3.1.2.1 FEV1 less than 50% of predicted

AND

3.1.2.2 History of chronic bronchitis

AND

3.1.2.3 One of the following:

- Failure to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] as confirmed by claims history or submission of medical record
- History of contraindication or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] (please specify contraindication or intolerance)

AND

3.2 One of the following:

3.2.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.2 Patient has a failure to all of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.3 Patient has a contraindication or intolerance to all of the following (please specify contraindication or intolerance):

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.4 Both of the following:

3.2.4.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Respimat) to control their COPD due to one of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute))

AND

3.2.4.2 Patient requires the use of both of the following as confirmed by claims history or submission of medical records:

- A nebulized LABA [i.e., arformoterol (generic Brovana), formoterol (generic Perforomist)]
- A nebulized long-acting antimuscarinic agent [LAMA (i.e., Yupelri)]

AND

4 - Patient experiences dyspnea during everyday activities (e.g., short of breath when walking up a slight hill)

AND

5 - Prescribed by or in consultation with a Pulmonologist

Product Name:Ohtuvayre	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ohtuvayre therapy demonstrated by both of the following:

1.1 Improved COPD (chronic obstructive pulmonary disease) symptoms (e.g., dyspnea) **AND** **1.2** Improved FEV1 (forced expiratory volume)

2 . Revision History

Date	Notes
10/30/2024	New guideline

Ohtuvayre

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158245
Guideline Name	Ohtuvayre
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Ohtuvayre	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

2.1 Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7

AND

2.2 Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than 80%

AND

3 - Both of the following:

3.1 One of the following:

3.1.1 FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

OR

3.1.2 All of the following:

3.1.2.1 FEV1 less than 50% of predicted

AND

3.1.2.2 History of chronic bronchitis

AND

3.1.2.3 One of the following:

- Failure to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] as confirmed by claims history or submission of medical record
- History of contraindication or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)] (please specify contraindication or intolerance)

AND

3.2 One of the following:

3.2.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.2 Patient has a failure to all of the following as confirmed by claims history or submission of medical records:

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.3 Patient has a contraindication or intolerance to all of the following (please specify contraindication or intolerance):

- A long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
- A long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
- A LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
- An ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

OR

3.2.4 Both of the following:

3.2.4.1 Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Respimat) to control their COPD due to one of the following:

- Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
- Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is less than 60 liters per minute))

AND

3.2.4.2 Patient requires the use of both of the following as confirmed by claims history or submission of medical records:

- A nebulized LABA [i.e., arformoterol (generic Brovana), formoterol (generic Perforomist)]
- A nebulized long-acting antimuscarinic agent [LAMA (i.e., Yupelri)]

AND

4 - Patient experiences dyspnea during everyday activities (e.g., short of breath when walking up a slight hill)

AND

5 - Prescribed by or in consultation with a Pulmonologist

Product Name:Ohtuvayre	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ohtuvayre therapy demonstrated by both of the following:

1.1 Improved COPD (chronic obstructive pulmonary disease) symptoms (e.g., dyspnea) **AND** **1.2** Improved FEV1 (forced expiratory volume)

2 . Revision History

Date	Notes
10/30/2024	New guideline

Ojemda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151303
Guideline Name	Ojemda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Ojemda	
Diagnosis	Pediatric Low-Grade Glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric low-grade glioma

AND

2 - Disease is relapsed or refractory

AND

3 - Presence of one of the following genetic mutations:

- BRAF fusion or rearrangement
- BRAF V600 mutation

Product Name:Ojemda	
Diagnosis	Pediatric Low-Grade Glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Ojemda therapy

Product Name:Ojemda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Ojemda will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Product Name:Ojemda	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ojemda therapy

2 . Revision History

Date	Notes
8/12/2024	New Guideline

Ojjaara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164101
Guideline Name	Ojjaara
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Ojjaara	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic lower-risk myelofibrosis

OR

2 - All of the following:

2.1 Diagnosis of higher-risk myelofibrosis

AND

2.2 Presence of symptomatic splenomegaly and/or constitutional symptoms

AND

2.3 One of the following:

- Used as continued therapy near the start of conditioning therapy in a transplant candidate
- Patient is not a transplant candidate or transplant not currently feasible

OR

3 - Diagnosis of myelofibrosis-associated anemia

OR

4 - Both of the following:

4.1 Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

4.2 One of the following:

- Used for the improvement of splenomegaly or other disease-related symptoms

- Continued treatment as a single agent near to the start of conditioning therapy in transplant candidates for the improvement of splenomegaly and other disease-related symptoms

Product Name:Ojjaara	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Ojjaara*	
Notes	*If documentation does not provide evidence of symptom improvement or reduction in spleen volume while on Ojjaara, authorization will be issued for 2 months to allow for dose titration with discontinuation of therapy.

Product Name:Ojjaara	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Ojjaara	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Ojjaara therapy	

2 . Revision History

Date	Notes
1/22/2025	Updated clinical criteria.

Olumiant

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164719
Guideline Name	Olumiant
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Olumiant	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Patient is not receiving Olumiant in combination with any of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Olumiant therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

- Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify contraindication or intolerance)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi

(golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

4.2.2 ONE of the following:

- Failure to at least ONE TNF (tumor necrosis factor) antagonist therapy as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to at least ONE TNF antagonist therapy (please specify intolerance or contraindication)
- Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

Product Name:Olumiant	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Olumiant therapy

AND

2 - Patient is not receiving Olumiant in combination with any of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Product Name:Olumiant

Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe alopecia areata

AND

2 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecia, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

AND

3 - Patient has a current episode of alopecia areata lasting more than 6 months and at least 50% scalp hair loss

AND

4 - Patient is not receiving Olumiant in combination with any of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

5 - Prescribed by or in consultation with a dermatologist

Product Name:Olumiant	
Diagnosis	Alopecia Areata

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Olumiant therapy

AND

2 - Patient is not receiving Olumiant in combination with any of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib), Litfulo (ritlecitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

2 . Revision History

Date	Notes
2/4/2025	Updated guideline name and formularies. Updated safety language. Minor formatting changes

Omega

Prior Authorization Guideline

Guideline ID	GL-136324
Guideline Name	Omega
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe hypertriglyceridemia [pre-treatment triglyceride level of greater than or equal to 500 milligrams/deciliter (mg/dL)]

AND

2 - Patient is on an appropriate lipid-lowering diet and exercise regimen

AND

3 - ONE of the following:

3.1 Failure to at least 90 days of a fibric acid derivative, as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to a fibric acid derivative (please specify contraindication or intolerance)

AND

4 - If the request is for a non-preferred* product, ONE of the following:

4.1 Failure to omega-3-acid ethyl esters (generic Lovaza), as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to omega-3-acid ethyl esters (generic Lovaza) (please specify contraindication or intolerance)

Notes	*Omega 3-acid esters (generic Lovaza) is preferred. Other omega-3 a cid derivatives are non-preferred.

Product Name:Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is on an appropriate lipid-lowering diet and exercise regimen

Product Name:Brand Vascepa, generic icosapent ethyl	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypertriglyceridemia [pre-treatment triglyceride level greater than or equal to 150 milligrams/deciliter (mg/dL)]

AND

2 - Patient currently has or is considered high or very high risk for cardiovascular disease (CVD) as evidenced by ONE of the following:

2.1 BOTH of the following:

2.1.1 At least 45 years of age

AND

2.1.2 Established CVD confirmed by ONE of the following:

- Acute coronary syndrome
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease

OR

2.2 ALL of the following:

2.2.1 Diagnosis of Type 2 diabetes

AND

2.2.2 TWO of the following risk factors for developing cardiovascular disease:

- Men at least 55 years and women at least 65 years
- Cigarette smoker or stopped smoking within the past 3 months
- Hypertension [pretreatment blood pressure greater than or equal to 140 millimeters of mercury (mmHg) systolic or greater than or equal to 90 mmHg diastolic]
- HDL-C (high-density lipoprotein cholesterol) less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
- High-sensitivity C-reactive protein greater than 3.0 mg/L (liter)
- Creatinine clearance greater than 30 and less than 60 milliliters/minute (mL/min)
- Retinopathy
- Micro- or macro-albuminuria
- Ankle-brachial index (ABI) less than 0.9 without symptoms of intermittent claudication

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose

OR

3.2 BOTH of the following:

3.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

3.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily, or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

AND

4 - Submission of medical record (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

4.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (generic Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

4.2 History of contraindication or intolerance to ezetimibe (please specify contraindication or intolerance)

OR

4.3 Patient has an LDL-C (low density lipoprotein cholesterol) less than 100 mg/dL while on maximally tolerated statin therapy

AND

5 - Used as an adjunct to a low-fat diet and exercise

AND

6 - Prescribed by or in consultation with ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

Product Name:Brand Vascepa, generic icosapent ethyl	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is on an appropriate low-fat diet and exercise regimen

AND **3** - Patient is receiving maximally tolerated statin therapy

2 . Revision History

Date	Notes
11/14/2023	Audit language removed

Omega

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136324
Guideline Name	Omega
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe hypertriglyceridemia [pre-treatment triglyceride level of greater than or equal to 500 milligrams/deciliter (mg/dL)]

AND

2 - Patient is on an appropriate lipid-lowering diet and exercise regimen

AND

3 - ONE of the following:

3.1 Failure to at least 90 days of a fibric acid derivative, as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to a fibric acid derivative (please specify contraindication or intolerance)

AND

4 - If the request is for a non-preferred* product, ONE of the following:

4.1 Failure to omega-3-acid ethyl esters (generic Lovaza), as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to omega-3-acid ethyl esters (generic Lovaza) (please specify contraindication or intolerance)

Notes	*Omega 3-acid esters (generic Lovaza) is preferred. Other omega-3 a cid derivatives are non-preferred.

Product Name:Brand Lovaza, generic omega-3-acid ethyl esters, Brand Vascepa, generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is on an appropriate lipid-lowering diet and exercise regimen

Product Name:Brand Vascepa, generic icosapent ethyl	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypertriglyceridemia [pre-treatment triglyceride level greater than or equal to 150 milligrams/deciliter (mg/dL)]

AND

2 - Patient currently has or is considered high or very high risk for cardiovascular disease (CVD) as evidenced by ONE of the following:

2.1 BOTH of the following:

2.1.1 At least 45 years of age

AND

2.1.2 Established CVD confirmed by ONE of the following:

- Acute coronary syndrome
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease

OR

2.2 ALL of the following:

2.2.1 Diagnosis of Type 2 diabetes

AND

2.2.2 TWO of the following risk factors for developing cardiovascular disease:

- Men at least 55 years and women at least 65 years
- Cigarette smoker or stopped smoking within the past 3 months
- Hypertension [pretreatment blood pressure greater than or equal to 140 millimeters of mercury (mmHg) systolic or greater than or equal to 90 mmHg diastolic]
- HDL-C (high-density lipoprotein cholesterol) less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
- High-sensitivity C-reactive protein greater than 3.0 mg/L (liter)
- Creatinine clearance greater than 30 and less than 60 milliliters/minute (mL/min)
- Retinopathy
- Micro- or macro-albuminuria
- Ankle-brachial index (ABI) less than 0.9 without symptoms of intermittent claudication

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose

OR

3.2 BOTH of the following:

3.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

3.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily, or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

AND

4 - Submission of medical record (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

4.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (generic Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

4.2 History of contraindication or intolerance to ezetimibe (please specify contraindication or intolerance)

OR

4.3 Patient has an LDL-C (low density lipoprotein cholesterol) less than 100 mg/dL while on maximally tolerated statin therapy

AND

5 - Used as an adjunct to a low-fat diet and exercise

AND

6 - Prescribed by or in consultation with ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

Product Name:Brand Vascepa, generic icosapent ethyl	
Diagnosis	Cardiovascular Risk Reduction
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is on an appropriate low-fat diet and exercise regimen

AND **3** - Patient is receiving maximally tolerated statin therapy

2 . Revision History

Date	Notes
11/14/2023	Audit language removed

Omnipod 5

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164189
Guideline Name	Omnipod 5
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Omnipod 5	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of diabetes

AND

2 - ALL of the following:

2.1 Patient has done ONE of the following for at least 8 weeks:

- Regularly tests blood glucose at least 4 times/day
- Utilizes a continuous glucose monitor (CGM)

AND

2.2 Patient has completed a diabetes management program

AND

2.3 Patient injects insulin at least 3 times/day

AND

3 - ONE of the following:

- Unexplained, nocturnal, or severe hypoglycemia
- Hypoglycemia unawareness
- Dawn phenomenon blood glucose greater than 200 mg/dL (milligrams/deciliter)
- Wide and unpredictable (erratic) swings in blood glucose levels
- Glycemic targets within individualized range but lifestyle requires increased flexibility of insulin pump use
- HbA1C greater than 7% or outside individualized targets

AND

4 - BOTH of the following:

4.1 Patient or caregiver is motivated to assume responsibility for self-care and insulin management

AND

4.2 Patient or caregiver demonstrates knowledge of importance of nutrition including carbohydrate counting and meal planning

AND

5 - Prescriber attests that there is a reason or special circumstance the patient cannot use external insulin pumps obtained on the medical benefit

Notes	If patient meets criteria, approve using NDC List OMNIPOD5

Product Name:Omnipod 5	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

Notes	If patient meets criteria, approve using NDC List OMNIPOD5

Product Name:Omnipod 5 pods	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician confirmation that the patient requires a greater quantity

Notes	Authorization for quantity limit overrides should be entered at the NDC level for the requested Omnipod 5 pods, for the requested quantity.

2 . Revision History

Date	Notes
1/23/2025	Updated GPIs. Updated product name and note of QL section.

Omvoh

Prior Authorization Guideline

Guideline ID	GL-204189
Guideline Name	Omvoh
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Omvoh SC	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 Patient has been established on therapy with Omvoh under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

2.2 Patient is currently on Omvoh for subcutaneous use therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Omvoh SC	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Omvoh therapy

AND

2 - Patient is NOT receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Zeposia (ozanimod)]

2 . Revision History

Date	Notes
2/27/2025	Updated formularies. Updated GPIs. Reworded criteria for established therapy through a medical prior authorization for clarity. Updated safety language.

Onureg

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164740
Guideline Name	Onureg
Formulary	• Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) • Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Onureg	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia

AND

2 - Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy

AND

3 - Patient is not able to complete intensive curative therapy (e.g., transplant-ineligible)

Product Name:Onureg	
Diagnosis	Peripheral T-cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following T-cell lymphomas:

- Angioimmunoblastic T-cell lymphoma (AITL)
- Nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH)
- Follicular T-cell lymphoma (FTCL)

AND

2 - One of the following:

- Used as initial palliative intent therapy
- Used as second-line and subsequent therapy

Product Name:Onureg	
Diagnosis	Acute Myeloid Leukemia, Peripheral T-cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Onureg therapy

Product Name:Onureg	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Onureg	
Diagnosis	NCCN Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - There is documentation of positive clinical response to Onureg therapy

2 . Revision History

Date	Notes
2/5/2025	Updated formularies. Added criteria for Peripheral T-cell Lymphoma

Opfolda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143281
Guideline Name	Opfolda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Opfolda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease as confirmed by ONE of the following:

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of acid alpha-glucosidase (GAA) activity in lymphocytes, fibroblasts or muscle

OR

1.2 Molecular genetic testing for deletion or mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.)

AND

3 - Provider attests that the patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme) for the treatment of late-onset Pompe disease and this therapy will be stopped

AND

4 - Patient weighs at least 40kg

AND

5 - Opfolda will be prescribed in combination with Pombiliti (cipaglucosidase alfa-atga)

Product Name:Opfolda	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Opfolda plus Pombiliti

AND

2 - Opfolda continues to be prescribed in combination with Pombiliti

2 . Revision History

Date	Notes
2/22/2024	New

Opfolda

Prior Authorization Guideline

Guideline ID	GL-143281
Guideline Name	Opfolda
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Opfolda	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease as confirmed by ONE of the following:

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of acid alpha-glucosidase (GAA) activity in lymphocytes, fibroblasts or muscle

OR

1.2 Molecular genetic testing for deletion or mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.)

AND

3 - Provider attests that the patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme) for the treatment of late-onset Pompe disease and this therapy will be stopped

AND

4 - Patient weighs at least 40kg

AND

5 - Opfolda will be prescribed in combination with Pombiliti (cipaglucosidase alfa-atga)

Product Name:Opfolda	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Opfolda plus Pombiliti

AND

2 - Opfolda continues to be prescribed in combination with Pombiliti

2 . Revision History

Date	Notes
2/22/2024	New

Ophthalmic Antihistamine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161390
Guideline Name	Ophthalmic Antihistamine
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:azelastine ophth soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

Product Name:olopatadine ophth soln (Rx formulation)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

AND

2 - ONE of the following:

2.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

2 . Revision History

Date	Notes
11/27/2024	Removed CO (RMHCAID, RMHCHP, RMHWRP) formulary from ben efit coverage section. No other changes to guideline made.

Ophthalmic Antihistamine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161390
Guideline Name	Ophthalmic Antihistamine
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:azelastine ophth soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

2 - History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

Product Name:olopatadine ophth soln (Rx formulation)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Failure to Pataday OTC (over-the-counter), as confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to Pataday OTC (please specify contraindication or intolerance)

AND

2 - ONE of the following:

2.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Azelastine ophthalmic solution
- Ketotifen
- Cromolyn

2 . Revision History

Date	Notes
11/27/2024	Removed CO (RMHCAID, RMHCHP, RMHWRP) formulary from ben efit coverage section. No other changes to guideline made.

Opzelura

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164757
Guideline Name	Opzelura
Formulary	• Medicaid - Community & State Hawaii • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis*

AND

2 - ONE of the following:

2.1 Patient is currently on Opzelura therapy as confirmed by claims history or submission of medical records

OR

2.2 For mild atopic dermatitis:

2.2.1 Failure to TWO of the following topical therapeutic classes as confirmed by claims history or submission of medical records:

- A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.2.2 History of intolerance or contraindication to ALL of the following topical therapeutic classes (please specify intolerance or contraindication):

- A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.3 For moderate atopic dermatitis:

2.3.1 Failure to TWO of the following topical therapeutic classes as confirmed by claims history or submission of medical records:

- A topical corticosteroid of at least a medium- to high-potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

OR

2.3.2 History of intolerance or contraindication to ALL of the following topical therapeutic classes (please specify intolerance or contraindication):

- A topical corticosteroid of at least a medium- to high-potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
- One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
- Eucrisa (crisaborole)

AND

3 - Patient is NOT receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] nor JAK inhibitor [e.g., Jakafi (ruxolitinib), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

4 - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)

Notes	*Opzelura when used solely for the treatment of nonsegmental vitiligo is considered cosmetic, is excluded, and is to be denied as a benefit e xclusion.

Product Name:Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND **2** - Patient is NOT receiving Opzelura in combination with another biologic medication [e.g., Dupixent (dupilumab), Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Avsola/Inflectra (infliximab)] nor JAK inhibitor [e.g., Jakafi (ruxolitinib, Xeljanz (tofacitinib), Rinvoq (upadacitinib)] **AND** **3** - Patient is NOT receiving Opzelura in combination with a potent immunosuppressant medication (e.g., azathioprine, cyclosporine)	
Notes	Opzelura when used solely for the treatment of nonsegmental vitiligo i s considered cosmetic, is excluded, and is to be denied as a benefit e xclusion.

2 . Revision History

Date	Notes
2/5/2025	Updated guideline name. Updated T/F language of Atopic Dermatitis.

Orencia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206565
Guideline Name	Orencia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Orencia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis

AND

1.2 One of the following:

1.2.1 Failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

AND

1.3 Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 ONE of the following:

1.4.1 BOTH of the following:

1.4.1.1 Failure of one of the preferred adalimumab products*, confirmed by claims history or submitted medical records

AND

1.4.1.2 Failure of TWO of the following confirmed by claims history or submitted medical records:

- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

OR

1.4.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Olumiant (baricitinib)
- Tyenne (tocilizumab-aazg)

AND

1.5 Prescribed by, or in consultation with, a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Orencia therapy as confirmed by claims history or submitted medical records

AND

2.2 Diagnosis of moderately to severely active rheumatoid arthritis

AND

2.3 Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by, or in consultation with, a rheumatologist

Notes	*See PDL links in Background

Product Name:Orencia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]]

AND

1.3 Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.4 BOTH of the following:

1.4.1 ONE of the following:

1.4.1.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

1.4.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)

- One of the preferred ustekinumab products*

AND

1.4.2 ONE of the following:

1.4.2.1 Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

OR

1.4.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

AND

1.5 Prescribed by, or in consultation with, ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Orencia therapy as confirmed by claims history or submitted medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz

(ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Notes	*See PDL links in Background

Product Name:Orencia	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis

AND

2 - Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - ONE of the following:

3.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*

- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

OR

3.2 History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

OR

3.3 Patient is currently on Orencia therapy as confirmed by claims history or submitted medical records

AND

4 - Prescribed by, or in consultation with, a rheumatologist

Notes	*See PDL links in Background

Product Name:Orencia	
Diagnosis	Rheumatoid Arthritis (RA), Psoriatic Arthritis, Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orencia therapy

AND

2 - Patient is NOT receiving Orencia in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*	
Notes	*Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

3 . Revision History

Date	Notes
3/4/2025	Added ustekinumab as a step therapy option in PsA. Changed "Stelara" to "ustekinumab" .

Orfadin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127303
Guideline Name	Orfadin
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1

AND

2 - Special clinical circumstances exist that precludes the use of Nityr (nitisinone) tablets for the patient (document special clinical circumstance)

Product Name:Brand Orfadin, generic nitisinone	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient shows evidence of positive clinical response (e.g., decrease in urinary/plasma succinylacetone and alpha-1-microglobulin levels) while on Orfadin therapy

2 . Revision History

Date	Notes
6/29/2023	Removed RMH and ACUAZ Formularies. Added ACUCO formulary. Updated GPI list.

Orgovyx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123454
Guideline Name	Orgovyx
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced prostate cancer

AND

2 - Patient is a candidate for at least one year of continuous androgen-deprivation therapy

AND

3 - ONE of the following:

- Evidence of biochemical [PSA (prostate-specific antigen)] or clinical relapse after local primary intervention with curative intent
- Newly diagnosed hormone-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

AND

4 - Patient has been without any major adverse cardiovascular events within 6 months before initiation (e.g., myocardial infarction, stroke)

Product Name:Orgovyx	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Orgovyx	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orgovyx therapy

2 . Revision History

Date	Notes
3/17/2023	Updated formularies.

Oriahnn_MyFembree

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144990
Guideline Name	Oriahnn_MyFembree
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Oriahnn, MyFembree	
Diagnosis	Uterine Fibroids
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine fibroids (leiomyomas)

AND

2 - Used for the management of heavy menstrual bleeding

AND

3 - ONE of the following:

3.1 Failure after a three-month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Estrogen/progestin contraceptive (e.g., Loestrin FE)
- Progestin-releasing intrauterine devices (IUDs) (e.g., Mirena)*
- Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

OR

3.2 Contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Estrogen/progestin contraceptive (e.g., Loestrin FE)
- Progestin-releasing intrauterine devices (IUDs) (e.g., Mirena)*
- Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

AND

4 - ONE of the following:

4.1 Failure after a three-month trial of tranexamic acid (e.g., Lysteda) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to tranexamic acid (e.g., Lysteda) (please specify contraindication or intolerance)

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes	*This is a medical benefit, should not be included in denial to provider.

Product Name:Oriahnn, MyFembree	
Diagnosis	Uterine Fibroids
Approval Length	12 months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months*

Notes	*Authorization will be issued for 12 months up to a maximum treatment duration of 24 months. Oriahnn and MyFembree are indicated for a maximum treatment duration of 24 months.

Product Name:MyFembree	
Diagnosis	Pain Associated with Endometriosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - ONE of the following:

2.1 Failure (e.g., inadequate pain relief) to a three-month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Failure to a three-month trial of ONE of the following, as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

OR

3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Notes	*This is a medical benefit, should not be included in denial to provider.

Product Name:MyFembree	
Diagnosis	Pain Associated with Endometriosis
Approval Length	12 months*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months*

Notes	*Authorization will be issued for 12 months up to a maximum treatment duration of 24 months. MyFembree are indicated for a maximum treatment duration of 24 months.

2 . Revision History

Date	Notes
4/18/2024	Updated indications and authorization durations.

Orilissa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144995
Guideline Name	Orilissa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Orilissa 150 mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - ONE of the following:

2.1 Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Failure to a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Treatment duration of Orilissa 150 mg once daily has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Product Name:Orilissa 150 mg	
Approval Length	12 months up to a maximum treatment duration of 24 months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records

Product Name:Orilissa 200 mg	
Approval Length	Up to a maximum of 6 months
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - ONE of the following:

2.1 Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen), as confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 Failure after a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Treatment duration of Orilissa 200 mg twice daily has not exceeded a total of 6 months, as confirmed by claims history or submission of medical records

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

2 . Revision History

Date	Notes
4/18/2024	Updated authorization durations of 150mg strength only.

Orilissa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144995
Guideline Name	Orilissa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Orilissa 150 mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - ONE of the following:

2.1 Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify contraindication or intolerance)

AND

3 - ONE of the following:

3.1 Failure to a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Treatment duration of Orilissa 150 mg once daily has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

Product Name:Orilissa 150 mg	
Approval Length	12 months up to a maximum treatment duration of 24 months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Impact to bone mineral density has been considered

AND

3 - Treatment duration has not exceeded a total of 24 months, as confirmed by claims history or submission of medical records

Product Name:Orilissa 200 mg	
Approval Length	Up to a maximum of 6 months
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - ONE of the following:

2.1 Failure (e.g., inadequate pain relief) to a three month trial of TWO analgesics (e.g., ibuprofen, meloxicam, naproxen), as confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to TWO analgesics (e.g., ibuprofen, meloxicam, naproxen) (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 Failure after a three month trial to ONE of the following as confirmed by claims history or submission of medical records:

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Hormonal contraceptives
- Progestins [e.g., norethindrone (generic Aygestin)]

AND

4 - Treatment duration of Orilissa 200 mg twice daily has not exceeded a total of 6 months, as confirmed by claims history or submission of medical records

AND

5 - Prescribed by or in consultation with ONE of the following:

- Obstetrics/Gynecologist (OB/GYN)
- Reproductive endocrinologist

2 . Revision History

Date	Notes
4/18/2024	Updated authorization durations of 150mg strength only.

Orkambi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151768
Guideline Name	Orkambi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Orkambi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

AND

3 - The patient is greater than or equal to 1 years of age

AND

4 - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

Product Name:Orkambi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orkambi therapy (e.g., improved lung function, stable lung function)

2 . Revision History

Date	Notes
8/14/2024	Removed prescriber requirement from reauthorization criteria

Orkambi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151768
Guideline Name	Orkambi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Orkambi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

AND

3 - The patient is greater than or equal to 1 years of age

AND

4 - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

Product Name:Orkambi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orkambi therapy (e.g., improved lung function, stable lung function)

2 . Revision History

Date	Notes
8/14/2024	Removed prescriber requirement from reauthorization criteria

Orladeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147202
Guideline Name	Orladeyo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Orladeyo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown

AND

2 - ALL of the following:

2.1 Prescribed for the prophylaxis of HAE attacks

AND

2.2 Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)

AND

2.3 Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Orladeyo

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

4 - ONE of the following:

4.1 Failure to Haegarda as confirmed by history or submission of medical records

OR

4.2 History of contraindication, or intolerance to Haegarda (please specify a contraindication or intolerance)

OR

4.3 Patient is unable to self-inject Haegarda due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) for specific phobia diagnostic criteria]

OR

4.4 Patient is currently on Orladeyo therapy, as confirmed by claims history or submission of medical records

Product Name:Orladeyo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orladeyo therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest), as confirmed by claims history or submission of medical records, while on Orladeyo therapy

AND

3 - BOTH of the following:

3.1 Prescribed for the prophylaxis of HAE attacks

AND

3.2 Not used in combination with other products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes

5/9/2024	Update to diagnostic criteria for HAE with normal C1 inhibitor levels. Updated and simplified reauthorization criteria.

Orladeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147202
Guideline Name	Orladeyo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Orladeyo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown

AND

2 - ALL of the following:

2.1 Prescribed for the prophylaxis of HAE attacks

AND

2.2 Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)

AND

2.3 Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Orladeyo

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

4 - ONE of the following:

4.1 Failure to Haegarda as confirmed by history or submission of medical records

OR

4.2 History of contraindication, or intolerance to Haegarda (please specify a contraindication or intolerance)

OR

4.3 Patient is unable to self-inject Haegarda due to ONE of the following:

- Physical impairment
- Visual impairment
- Lipohypertrophy
- Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) for specific phobia diagnostic criteria]

OR

4.4 Patient is currently on Orladeyo therapy, as confirmed by claims history or submission of medical records

Product Name:Orladeyo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Orladeyo therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest), as confirmed by claims history or submission of medical records, while on Orladeyo therapy

AND

3 - BOTH of the following:

3.1 Prescribed for the prophylaxis of HAE attacks

AND

3.2 Not used in combination with other products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes

5/9/2024	Update to diagnostic criteria for HAE with normal C1 inhibitor levels. Updated and simplified reauthorization criteria.

Orserdu

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147243
Guideline Name	Orserdu
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Orserdu	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of an ESR1 gene mutation

AND

6 - Patient is ONE of the following:

- Postmenopausal woman
- Male
- Premenopausal woman treated with ovarian ablation/suppression

AND

7 - Disease has progressed following at least one line of endocrine therapy

Product Name:Orserdu	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Orserdu therapy

Product Name:Orserdu	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Orserdu	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to Orserdu therapy

2 . Revision History

Date	Notes
5/10/2024	Specified postmenopausal “woman” and added premenopausal wom an treated with ovarian ablation/suppression to coverage criteria per NCCN.

Orserdu

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147243
Guideline Name	Orserdu
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Orserdu	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of an ESR1 gene mutation

AND

6 - Patient is ONE of the following:

- Postmenopausal woman
- Male
- Premenopausal woman treated with ovarian ablation/suppression

AND

7 - Disease has progressed following at least one line of endocrine therapy

Product Name:Orserdu	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Orserdu therapy

Product Name:Orserdu	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Orserdu	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to Orserdu therapy

2 . Revision History

Date	Notes
5/10/2024	Specified postmenopausal “woman” and added premenopausal wom an treated with ovarian ablation/suppression to coverage criteria per NCCN.

Osphena

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147609
Guideline Name	Osphena
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Osphena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Estradiol vaginal cream
- Estradiol vaginal tablet

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Estradiol vaginal cream
- Estradiol vaginal tablet

Notes	*Treatment of dyspareunia is a benefit exclusion.

Product Name:Osphena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
5/21/2024	Updated formularies. No change to clinical criteria.

Osphena

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147609
Guideline Name	Osphena
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Osphena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause*

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- Estradiol vaginal cream
- Estradiol vaginal tablet

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Estradiol vaginal cream
- Estradiol vaginal tablet

Notes	*Treatment of dyspareunia is a benefit exclusion.

Product Name:Osphena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
5/21/2024	Updated formularies. No change to clinical criteria.

Otezla

Prior Authorization Guideline

Guideline ID	GL-205230
Guideline Name	Otezla
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Otezla	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 One of the following:

1.2.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose, as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Skyrizi (risankizumab-rzaa)]

AND

1.3 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name:Otezla	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of plaque psoriasis in those who are candidates for phototherapy or systemic therapy

AND

1.2 One of the following:

1.2.1 All of the following:

1.2.1.1 Greater than or equal to 3 percent body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.2.1.2 One of the following:

1.2.1.2.1 Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

AND

1.2.1.3 One of the following:

1.2.1.3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

1.2.1.3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

1.3 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.4 Prescribed by or in consultation with a dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of plaque psoriasis in those who are candidates for phototherapy or systemic therapy

AND

2.3 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Product Name:Otezla	
Diagnosis	Behcet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of Behcet's Disease

AND

1.2 Patient has active oral ulcers attributed to Behcet's Disease

AND

1.3 One of the following:

1.3.1 Failure to one non-biologic (e.g., corticosteroids, colchicine) used for treating Behcet's Disease, as confirmed by claims history or submission of medical records

OR

1.3.2 History of contraindication or intolerance to one non-biologic (e.g., corticosteroids, colchicine) used for treating Behcet's Disease (please specify contraindication or intolerance)

OR

1.3.3 Patient has been previously treated with a targeted immunomodulator used for the treatment of Behcet's Disease as confirmed by claims history or submission of medical records [e.g., Remicade (infliximab), adalimumab, Enbrel (etanercept)]

AND

1.4 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

OR

2 - All of the following:

2.1 Patient is currently on Otezla therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of Behcet's Disease

AND

2.3 Patient has active oral ulcers attributed to Behcet's Disease

AND

2.4 Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.5 Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

Product Name:Otezla	
Diagnosis	Psoriatic Arthritis, Behcet's Disease, Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Otezla therapy

AND

2 - Patient is not receiving Otezla in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

2 . Revision History

Date	Notes
3/3/2025	Added NM to formulary list. Replaced Stelara with ustekinumab and updated language to state "targeted immunomodulator"

Oxbryta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145507
Guideline Name	Oxbryta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is at least 4 years of age

AND

3 - ONE of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Failure to hydroxyurea therapy as confirmed by claims history or submission of medical records

OR

3.3 History of contraindication or intolerance to hydroxyurea therapy (please specify contraindication or intolerance)

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin (Hb) is less than or equal to 10.5 g/dL (grams/deciliter)

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name:Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least ONE of the following:

1.1 Increase in hemoglobin (Hb) by greater than or equal to 1 g/dL (gram/deciliter) from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso-occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

4 - Prescribed by, or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
4/18/2024	Updated initial authorization duration to 12 months.

Oxbryta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145507
Guideline Name	Oxbryta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is at least 4 years of age

AND

3 - ONE of the following:

3.1 Patient is currently receiving hydroxyurea therapy

OR

3.2 Failure to hydroxyurea therapy as confirmed by claims history or submission of medical records

OR

3.3 History of contraindication or intolerance to hydroxyurea therapy (please specify contraindication or intolerance)

AND

4 - Patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months

AND

5 - Baseline hemoglobin (Hb) is less than or equal to 10.5 g/dL (grams/deciliter)

AND

6 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

7 - Patient is not to receive Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

8 - Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease

Product Name:Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oxbryta therapy as demonstrated by at least ONE of the following:

1.1 Increase in hemoglobin (Hb) by greater than or equal to 1 g/dL (gram/deciliter) from baseline

OR

1.2 Decrease in indirect bilirubin from baseline

OR

1.3 Decrease in percent reticulocyte count from baseline

OR

1.4 Patient has experienced a reduction in sickle cell-related vaso-occlusive crises

AND

2 - Patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)

AND

3 - Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy

AND

4 - Prescribed by, or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease

2 . Revision History

Date	Notes
4/18/2024	Updated initial authorization duration to 12 months.

Oxervate

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123519
Guideline Name	Oxervate
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Oxervate	
Diagnosis	Neurotrophic keratitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Stage 2 or 3 neurotrophic keratitis

AND

2 - Failure to at least ONE OTC (over the counter) ocular artificial tear product (e.g., Systane Ultra, Akwa Tears, Refresh Optive, Soothe XP) as confirmed by claims history or submission of medical records

AND

3 - Prescribed by or in consultation with ONE of the following:

- Ophthalmologist
- Optometrist

2 . Revision History

Date	Notes
3/20/2023	Updated T/F criteria.

PAH

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206558
Guideline Name	PAH
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Adempas, Brand Letairis, generic ambrisentan, Opsumit, generic sildenafil 20 mg, Brand Revatio tabs/susp, generic sildenafil susp, Tracleer, generic bosentan, Brand Adcirca, Alyq, generic tadalafil (PAH, generic of Adcirca)	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (PAH)

Product Name:Liqrev, Tadliq	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

OR

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2 - ONE of the following:

2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

2.1.1 ONE of the following:

- Adempas

- Sildenafil citrate oral suspension (generic Revatio)

AND

2.1.2 An ERA (endothelin receptor antagonist) [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

2.2.1 ONE of the following:

- Adempas
- Sildenafil citrate oral suspension (generic Revatio)

AND

2.2.2 An ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

Product Name:Opsynvi	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

OR

1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2 - Failure to BOTH of the following taken together as confirmed by claims history or submission of medical records:

- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]
- A preferred ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

Product Name:Orenitram, Tyvaso DPI, Uptravi titration pack, Uptravi tabs	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 As continuation of therapy

AND

1.2 Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

AND

1.3 Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist

OR

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 BOTH of the following:

- Pulmonary arterial hypertension is symptomatic
- Diagnosis of pulmonary arterial hypertension that is confirmed by right heart catheterization

OR

2.1.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

2.2 ONE of the following:

2.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

2.2.1.1 ONE of the following:

- Adempas
- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]

AND

2.2.1.2 An ERA (endothelin receptor antagonist) [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

OR

2.2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

2.2.2.1 ONE of the following:

- Adempas
- A PDE-5 inhibitor [e.g., sildenafil citrate (generic Revatio), tadalafil (generic Adcirca)]

AND

2.2.2.2 An ERA [e.g., ambrisentan (generic Letairis), Opsumit, or bosentan (generic Tracleer)]

AND

2.3 Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil) as long-term concomitant therapy*

Notes	*Concomitant use will be allowable for patients to transition from one of these agents to the other.

Product Name:Tadliq, Liqrev, Opsynvi	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to therapy

Product Name:Orenitram, Tyvaso DPI, Uptravi titration pack, Uptravi tabs	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to therapy

AND

2 - Patient is not taking the requested medication in combination with a prostanoid/prostacyclin analogue (e.g., epoprostenol, iloprost, treprostinil)

Product Name:Adempas	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

Product Name:Tyvaso DPI	
Diagnosis	Pulmonary Hypertension Associated with Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of pulmonary hypertension associated with interstitial lung disease [WHO (World Health Organization) group 3] confirmed by right heart catheterization

AND

1.2 Interstitial lung disease is diagnosed based on evidence of diffuse parenchymal lung disease on computed tomography of the chest

AND

1.3 Pulmonary hypertension is symptomatic

AND

2 - Prescribed by or in consultation with a cardiologist, pulmonologist, or rheumatologist

Product Name:Tyvaso DPI	
Diagnosis	Pulmonary Hypertension Associated with Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy (e.g., improved exercise ability)

2 . Revision History

Date	Notes
3/3/2025	Updated criteria to add generic Adcirca as step therapy option for ap plicable drugs.

Palforzia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123890
Guideline Name	Palforzia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE (immunoglobulin E) level of greater than or equal to 0.35 kUA/L (kilounits of allergen/liter)

AND

1.2 A mean wheal diameter that is at least 3 mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have any of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months

- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist/immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name:Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist/immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes
3/28/2023	Updated formularies and cleaned up criteria.

Palforzia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123890
Guideline Name	Palforzia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by BOTH of the following:

1.1 A serum peanut-specific IgE (immunoglobulin E) level of greater than or equal to 0.35 kUA/L (kilounits of allergen/liter)

AND

1.2 A mean wheal diameter that is at least 3 mm (millimeters) larger than the negative control on skin-prick testing for peanut

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 BOTH of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Used in conjunction with a peanut-avoidant diet

AND

4 - Patient does not have any of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months

- Severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist/immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

Product Name:Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Palforzia therapy

AND

2 - Used in conjunction with a peanut-avoidant diet

AND

3 - Prescribed by or in consultation with an allergist/immunologist

AND

4 - Prescriber is certified/enrolled in the Palforzia REMS (Risk Evaluation and Mitigation Strategy) Program

2 . Revision History

Date	Notes
3/28/2023	Updated formularies and cleaned up criteria.

Palynziq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155063
Guideline Name	Palynziq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Palynziq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - ONE of the following:

3.1 Failure to a one- to four-week trial of sapropterin as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to sapropterin therapy (please specify contraindication or intolerance)

AND

4 - Physician attestation that the patient will not be receiving Palynziq in combination with sapropterin dihydrochloride

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles/liter

Product Name:Palynziq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles/liter

OR

2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 Patient is in initial titration/maintenance phase of dosing regimen and dose is being titrated based on blood phenylalanine concentration response up to maximum labeled dosage of 60 milligrams once daily

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with sapropterin dihydrochloride (Prescription claim history that does not show any concomitant sapropterin dihydrochloride claim within 60 days of reauthorization request may be used as documentation)

2 . Revision History

Date	Notes
9/17/2024	Updated authorization durations to 12 months

Palynziq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155063
Guideline Name	Palynziq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Palynziq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient is actively on a phenylalanine-restricted diet

AND

3 - ONE of the following:

3.1 Failure to a one- to four-week trial of sapropterin as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to sapropterin therapy (please specify contraindication or intolerance)

AND

4 - Physician attestation that the patient will not be receiving Palynziq in combination with sapropterin dihydrochloride

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration greater than 600 micromoles/liter

Product Name:Palynziq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is actively on a phenylalanine-restricted diet

AND

2 - ONE of the following:

2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has a blood phenylalanine concentration less than 600 micromoles/liter

OR

2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline

OR

2.3 Patient is in initial titration/maintenance phase of dosing regimen and dose is being titrated based on blood phenylalanine concentration response up to maximum labeled dosage of 60 milligrams once daily

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is not receiving Palynziq in combination with sapropterin dihydrochloride (Prescription claim history that does not show any concomitant sapropterin dihydrochloride claim within 60 days of reauthorization request may be used as documentation)

2 . Revision History

Date	Notes
9/17/2024	Updated authorization durations to 12 months

Panretin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164747
Guideline Name	Panretin
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington • Medicaid - Community & State Nebraska • Medicaid - Community & State New Mexico • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Panretin	
Diagnosis	Kaposi’s Sarcoma
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi's Sarcoma (KS)

AND

2 - Patient is not receiving systemic anti-KS treatment

Product Name:Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Panretin	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Panretin therapy

2 . Revision History

Date	Notes
2/5/2025	Added IN formulary. No change to clinical criteria.

Pemazyre

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160646
Guideline Name	Pemazyre
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is ONE of the following:

- Unresectable locally advanced
- Resected gross residual (R2)
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement

AND

4 - Patient has been previously treated

Product Name:Pemazyre	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid/mixed lineage neoplasms with eosinophilia

AND

2 - Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement

Product Name:Pemazyre	
Diagnosis	Cholangiocarcinoma, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pemazyre therapy

Product Name:Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Pemazyre will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Pemazyre	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Pemazyre therapy

2 . Revision History

Date	Notes
11/14/2024	Updated criteria for cholangiocarcinoma

Phexxi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149915
Guideline Name	Phexxi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Phexxi	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Used for the prevention of pregnancy

AND

2 - ONE of the following:

2.1 Failure to ALL of the following methods of contraception as confirmed by claims history or submission of medical records:

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

OR

2.2 History of intolerance or contraindication to ALL of the following methods of contraception (please document intolerance or contraindication):

- Injection (e.g., Depo-Provera)
- Oral Contraceptive [e.g., norethindrone (generic Micronor), Yaz]
- Transdermal Patch (e.g., Twirla, Xulane)
- Vaginal Contraceptive Ring (e.g., Annovera, NuvaRing)
- Diaphragm
- Cervical Cap (e.g., FemCap)
- Female Condom

AND

3 - ONE of the following:

3.1 Failure to nonoxynol-9 based spermicide as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to nonoxynol-9 based spermicide (please document intolerance or contraindication)

AND

4 - Provider attests they have counseled the patient regarding higher rate of pregnancy prevention with the use of other methods of contraception (e.g., injection, oral contraception, transdermal patch, vaginal ring) compared to Phexxi

2 . Revision History

Date	Notes
8/1/2024	Minor update in criterion 2.1 to remove "other" verbiage. No changes to clinical intent.

Piqray

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147143
Guideline Name	Piqray
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Piqray	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - ONE of the following:

- Advanced
- Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA mutations

AND

6 - Used in combination with fulvestrant

AND

7 - Disease has progressed on or after an endocrine-based regimen

Product Name:Piqray

Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Piqray therapy

Product Name:Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Piqray	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Piqray therapy

2 . Revision History

Date	Notes
5/7/2024	Removed requirement for postmenopausal, premenopausal with ovarian ablation/suppression, or male under BC initial auth section; Minor verbiage update to NCCN Recommended Regimens initial auth section (with no changes to clinical intent).

Pomalyst

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150814
Guideline Name	Pomalyst
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/2/2024

1 . Criteria

Product Name:Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - ONE of the following:

2.1 Failure of ONE of the following, confirmed by claims history or submitted medical records:

- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g., Velcade (bortezomib)]

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Immunomodulatory agent [e.g., Revlimid (lenalidomide)]
- Proteasome inhibitor [e.g., Velcade (bortezomib)]

OR

2.3 Induction therapy for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome

Product Name:Pomalyst	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with dexamethasone

Product Name:Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma

OR

2 - BOTH of the following:

2.1 Diagnosis of AIDS (acquired immunodeficiency syndrome)-related Kaposi Sarcoma

AND

2.2 Patient is currently being treated with antiretroviral therapy (ART), confirmed by claims history or submitted medical records

Product Name:Pomalyst	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary central nervous system (CNS) lymphoma

AND

2 - Used as second-line or subsequent therapy

Product Name:Pomalyst	
Diagnosis	Multiple Myeloma, Systemic Light Chain Amyloidosis, Kaposi Sarcoma, Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Pomalyst therapy

Product Name:Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Pomalyst	
Diagnosis	NCCN Recommended Regimen
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Pomalyst therapy

2 . Revision History

Date	Notes
8/2/2024	Annual review. Updated criteria for multiple myeloma and Kaposi sar coma. Updated background and references.

PPI (Proton Pump Inhibitors)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161201
Guideline Name	PPI (Proton Pump Inhibitors)
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic lansoprazole ODT, generic esomeprazole magnesium susp packets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - The patient is less than 2 years of age

OR

2 - ONE of the following:

2.1 Failure to BOTH of the following, as confirmed by claims history or submission of medical records

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance)

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration

Product Name:Prilosec OTC, omeprazole tabs, Brand Protonix tabs, Brand Prevacid, Prevacid 24HR, Brand Aciphex, generic rabeprazole tabs, Brand Dexilant, generic dexlansoprazole, Brand Nexium caps, Brand Nexium 24HR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to at least a 30 day trial of THREE of the following as confirmed by claims history or submission of medical records:

- Omeprazole capsule (generic Prilosec)
- Pantoprazole tablet (generic Protonix)
- Lansoprazole delayed release (DR) capsule (generic Prevacid)

- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Omeprazole capsule (generic Prilosec)
- Pantoprazole tablet (generic Protonix)
- Lansoprazole DR capsule (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium)

Product Name:Prilosec susp packets, Brand Protonix susp packets, Brand Prevacid Solutab, Brand Nexium susp packets, generic pantoprazole susp packets, Rabeprazole Sprinkle	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure to at least a 30 day trial to THREE of the following products as confirmed by claims history or submission of medical records:

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)
- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration
- Lansoprazole oral disintegrating tablet (generic Prevacid Solutab) (Prior authorization required)
- Esomeprazole magnesium granule suspension (generic Nexium granule suspension) (Prior authorization required)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Lansoprazole DR capsule as sprinkle administration (generic Prevacid)

- Esomeprazole magnesium OTC capsule (generic Nexium capsule 24 HR OTC) or esomeprazole magnesium capsule (generic Nexium) as sprinkle administration
- Lansoprazole oral disintegrating tablet (generic Prevacid Solutab)
- Esomeprazole magnesium granule suspension (generic Nexium granule suspension)

Product Name:omeprazole caps, Prilosec, Prilosec OTC, omeprazole tabs, generic pantoprazole tabs/susp packets, Brand Protonix tabs/susp packets, generic lansoprazole, Brand Prevacid, Prevacid 24HR, generic lansoprazole ODT, Brand Prevacid Solutab, generic esomeprazole magnesium caps, Nexium, Brand Aciphex, generic rabeprazole, Brand Dexilant, generic esomeprazole magnesium susp packets, generic dexlansoprazole, Brand Nexium, Brand Nexium 24HR, Rabeprazole Sprinkle, generic esomeprazole magnesium tabs (OTC)	
Therapy Stage	Initial Authorization
Guideline Type	Quantity Limit

Approval Criteria

1 - The patient did not exhibit an adequate response to treatment within the quantity limit*

OR

2 - The patient has documented erosive disease*

OR

3 - The patient has documented symptoms of complicated disease (e.g., dysphagia, bleeding, weight loss, choking, chest pain)*

OR

4 - The patient has a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple endocrine adenomas, or systemic mastocytosis**

Notes	Authorization will be issued based on circumstance. *Authorization will be issued for 8 weeks. **Authorization of therapy will be issued for 12 months.

Product Name:omeprazole caps, Prilosec, Prilosec OTC, omeprazole tabs, generic pantoprazole tabs/susp packets, Brand Protonix tabs/susp packets, generic lansoprazole, Brand Prevacid, Prevacid 24HR, generic lansoprazole ODT, Brand Prevacid Solutab, generic esomeprazole magnesium caps, Nexium, Brand Aciphex, generic rabeprazole, Brand Dexilant, generic esomeprazole magnesium susp packets, generic dexlansoprazole, Brand Nexium, Brand Nexium 24HR, Rabeprazole Sprinkle, generic esomeprazole magnesium tabs (OTC)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Quantity Limit

Approval Criteria

1 - The patient is continuing therapy for a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple adenomas, or systemic mastocytosis

2 . Revision History

Date	Notes
11/25/2024	Updated guideline and criteria to reflect PDL change (esomeprazole moved to preferred without PA)

Praluent

Prior Authorization Guideline

Guideline ID	GL-145514
Guideline Name	Praluent
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Praluent (all labelers)	
Diagnosis	Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia (HeFH) and Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) of ONE of the following:

- Greater than or equal to 190 milligrams/deciliter (mg/dL)
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C of ONE of the following:

- Greater than or equal to 190 mg/dL
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low density lipoprotein), apoB (apolipoprotein B), or PCSK9 (proprotein convertase subtilisin/kexin type 9) gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia with pre-treatment LDL-C greater than or equal to 190 mg/dL

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy [i.e., atorvastatin 40-80 milligrams (mg), rosuvastatin 20-40 mg] and will continue to receive high intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]

- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily, or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.3.2 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe (please specify intolerance or contraindication)

AND

4 - Patient has received comprehensive counseling regarding appropriate diet

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist

- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

AND

7 - Not used in combination with Leqvio (inclisiran)

Product Name:Praluent (all labelers)	
Diagnosis	Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia (HeFH) and Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

AND

4 - Not used in combination with Leqvio (inclisiran)

Product Name:Praluent (all labelers)	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Submission of medical records (e.g., chart notes, laboratory values) confirming genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 BOTH of the following:

1.2.1 Pre-treatment low density lipoprotein cholesterol (LDL-C) greater than 400 milligrams/deciliter (mg/dL)

AND

1.2.2 ONE of the following:

1.2.2.1 Xanthoma before 10 years of age

OR

1.2.2.2 Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Patient has received comprehensive counseling regarding appropriate diets

AND

3 - Patient is receiving other lipid-lowering therapy confirmed by claims history or submitted medical records (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

AND

6 - Not used in combination with Juxtapid (lomitapide)

Product Name:Praluent (all labelers)	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting low density lipoprotein cholesterol (LDL-C) reduction while on Praluent therapy

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Repatha (evolocumab)]

AND

4 - Not used in combination with Juxtapid (lomitapide)

Product Name:Praluent (Non-72733 labelers)	
Diagnosis	Non-Preferred*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - History of failure to at least THREE preferred alternatives as confirmed by claims history or submission of medical records.* NOTE: In instances where there are fewer than three

preferred alternatives, the patient must have a history of failure to all of the preferred products. **OR** **2** - History of contraindication or intolerance to THREE preferred alternatives (please specify contraindication or intolerance).* NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of contraindication or intolerance to all of the preferred products.	
Notes	*Reference Non-Preferred Drugs policy. Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. PDL links listed in Background.

2 . Background

Benefit/Coverage/Program Information
PDL links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
4/8/2024	Updated diagnostic criteria per European Atherosclerosis Society gui dance. Streamlined reauthorization criteria.

Preferred Non-Solid Dosage Forms

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123842
Guideline Name	Preferred Non-Solid Dosage Forms
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Preferred non-solid dosage forms	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 Requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from one of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 The patient is able to swallow a solid dosage form

AND

3.1.2 ONE of the following:

3.1.2.1 ONE of the following*:

- The patient had an inadequate response with at least THREE different generic or preferred solid oral dosage forms, if available (Prior trials of generic or preferred solid oral dosage forms alternatives must sufficiently demonstrate that the generic or preferred solid oral dosage form alternatives are either ineffective or inappropriate at the time of the request)
- There are fewer than three generic or preferred solid oral dosage form alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the generic or preferred solid oral dosage form alternatives (Prior trials of generic or preferred solid oral dosage form alternatives must sufficiently demonstrate that the

generic or preferred solid oral dosage form alternatives are either ineffective or inappropriate at the time of the request)

OR

3.1.2.2 The patient had a documented side effect and/or intolerance to a trial with at least THREE different generic or preferred solid oral dosage forms, if available

OR

3.1.2.3 Documentation that ALL of the generic or preferred solid oral dosage form alternatives are contraindicated for this patient's specific condition

OR

3.1.2.4 Documentation that there is a reason or special circumstance that all of the generic or preferred solid oral dosage form alternatives are not clinically appropriate for the patient

OR

3.1.2.5 There are no generic or preferred solid oral dosage form alternatives for the requested drug

OR

3.2 Patient is unable to swallow a solid dosage form

OR

3.3 Patient utilizes a feeding tube for medication administration

OR

3.4 Request is for a nebulized formulation of an inhaled agent for a patient who has an inability to effectively utilize an agent in an inhaler formulation due to neuromuscular or

cognitive disability, or other evidence of lack of response to the inhaled formulation supported by clinical documentation	
Notes	*RI PDL Link may be found at: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

2 . Revision History

Date	Notes
3/27/2023	Updated to add criteria for nebulizer formulations of therapies.

Pretomanid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125845
Guideline Name	Pretomanid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Jersey

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Pretomanid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB)

OR

1.2 Treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

AND

2 - Pretomanid will be used in combination with bedaquiline and linezolid

2 . Revision History

Date	Notes
5/23/2023	Combined Markets in scope. Revised drug product name.

Prevymis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129061
Guideline Name	Prevymis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Prevymis tabs	
Diagnosis	Cytomegalovirus Prophylaxis
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is a recipient of an allogeneic hematopoietic stem cell transplant

AND

1.2 Patient is cytomegalovirus (CMV)-seropositive

AND

1.3 Provider attests that Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

OR

2 - ALL of the following:

2.1 Patient is a recipient of a kidney transplant

AND

2.2 Patient is CMV-seronegative

AND

2.3 Donor is CMV-seropositive

AND

2.4 Provider attests that Prevymis will be initiated between Day 0 and Day 7 post-transplantation (before or after engraftment) and is being prescribed as prophylaxis and not treatment of CMV infection

2 . Revision History

Date	Notes
7/28/2023	Updated formularies, indication, auth duration, and criteria.

Procysbi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127870
Guideline Name	Procysbi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nephropathic cystinosis

AND

2 - Patient is 1 year of age or older

AND

3 - ONE of the following*:

3.1 Failure to immediate-release cysteamine bitartrate (generic Cystagon), as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to immediate-release cysteamine bitartrate (generic Cystagon) (please specify intolerance or contraindication)

Notes	*UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity.

Product Name:Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Procysbi therapy

2 . Revision History

Date	Notes

7/11/2023	Updated formularies, added asterisk to initial auth criteria.

Procysbi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127870
Guideline Name	Procysbi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Procysbi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nephropathic cystinosis

AND

2 - Patient is 1 year of age or older

AND

3 - ONE of the following*:

3.1 Failure to immediate-release cysteamine bitartrate (generic Cystagon), as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to immediate-release cysteamine bitartrate (generic Cystagon) (please specify intolerance or contraindication)

Notes	*UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity.

Product Name:Procysbi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Procysbi therapy

2 . Revision History

Date	Notes

7/11/2023	Updated formularies, added asterisk to initial auth criteria.

Progesterone - Non-Oral

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124687
Guideline Name	Progesterone - Non-Oral
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Crinone, Endometrin	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Treatment is for non-infertility use (e.g., secondary amenorrhea, reduce the risk of recurrent spontaneous preterm birth)

2 . Revision History

Date	Notes
4/13/2023	Updated formularies

Progesterone - Oral

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161394
Guideline Name	Progesterone - Oral
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Prometrium, generic progesterone caps	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of ONE of the following:	

- Amenorrhea
- Endometrial hyperplasia or prevention of endometrial hyperplasia
- Abnormal uterine or vaginal bleeding
- History of preterm birth
- Prevention of preterm delivery for current pregnancy

2 . Revision History

Date	Notes
11/27/2024	Updated formularies

Promacta, Alvaiz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-160665
Guideline Name	Promacta, Alvaiz
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Promacta, Alvaiz	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic thrombocytopenic purpura (ITP)

AND

2 - ONE of the following:

2.1 Failure to at least ONE of the following as confirmed by claims history or submission of medical records:

- Corticosteroids
- Immunoglobulins
- Splenectomy

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

3 - If the request is for Alvaiz, one of the following:

3.1 Failure to Promacta as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Promacta (please specify intolerance or contraindication)

AND

4 - If the request is for Promacta powder for oral suspension, ONE of the following:

4.1 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- oral/motor difficulties
- dysphagia

OR

4.2 Patient utilizes a feeding tube for medication administration

Product Name:Promacta, Alvaiz	
Diagnosis	Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta or Alvaiz therapy

Product Name:Promacta, Alvaiz	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - ONE of the following:

- Planning to initiate and maintain interferon-based treatment
- Currently receiving interferon-based treatment

AND

3 - If the request is for Alvaiz, one of the following:

3.1 Failure to Promacta as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Promacta (please specify intolerance or contraindication)

AND

4 - If the request is for Promacta powder for oral suspension, one of the following:

4.1 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- oral/motor difficulties
- dysphagia

OR

4.2 Patient utilizes a feeding tube for medication administration

Product Name:Promacta, Alvaiz	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Promacta or Alvaiz therapy

AND

2 - Patient is currently on antiviral interferon therapy for treatment of chronic hepatitis C

Product Name:Promacta, Alvaiz	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

2 - ONE of the following:

2.1 Used in combination with standard immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

OR

2.2 History of failure, contraindication, or intolerance to at least one course of

immunosuppressive therapy [e.g., Atgam (antithymocyte globulin equine), Thymoglobulin (antithymocyte globulin rabbit), cyclosporine]

AND

3 - If the request is for Alvaiz, one of the following:

3.1 Failure to Promacta as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Promacta (please specify intolerance or contraindication)

AND

4 - If the request is for Promacta powder for oral suspension, one of the following:

4.1 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- oral/motor difficulties
- dysphagia

OR

4.2 Patient utilizes a feeding tube for medication administration

Product Name:Promacta, Alvaiz	
Diagnosis	Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to Promacta or Alvaiz therapy

2 . Revision History

Date	Notes
11/14/2024	Added non-solid dosage form questions for Promacta packets

Provigil, Nuvigil

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128000
Guideline Name	Provigil, Nuvigil
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Provigil, generic modafinil, Brand Nuvigil, generic armodafinil	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following diagnoses:	

- Narcolepsy
- Excessive sleepiness due to obstructive sleep apnea
- Excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)
- Idiopathic hypersomnia
- Diagnosis of multiple sclerosis (MS)
- Diagnosis of major depressive disorder or bipolar depression

2 . Revision History

Date	Notes
7/14/2023	combined fatigue due to MS into criteria A; removed ST requirement for adjunctive therapy for the treatment of MDD or bipolar disorder al ong with requirement for adjunctive therapy. Combined MDD or bipol ar disorder section will be combined into section A to allow for DX2R X. Combined all Cag's

Pulmozyme

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145581
Guideline Name	Pulmozyme
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Pulmozyme	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cystic fibrosis

2 . Revision History

Date	Notes
4/9/2024	Combined all CORE formularies into one guideline. Updated generic name in GPI table. Removed dx header and minor cosmetic updates. No changes to clinical intent.

Pyrukynd

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150402
Guideline Name	Pyrukynd
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Pyrukynd Taper Pack, Pyrukynd	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyruvate kinase (PK) deficiency based on ALL of the following:

1.1 Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant

AND

1.2 Patient is not homozygous for the c.1436G > A (p.R479H) variant

AND

1.3 Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

2 - Used for the treatment of hemolytic anemia

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Baseline hemoglobin less than or equal to 10 grams/deciliter (g/dL)

AND

3.1.2 Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

OR

3.2 Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

AND **4** - Prescribed by a nephrologist or hematologist

Product Name:Pyrukynd Taper Pack, Pyrukynd	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following*: **1.1** Documentation of positive clinical response to Pyrukynd therapy **AND** **1.2** Prescribed by, or in consultation with, a nephrologist or hematologist **OR** **2** - Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy**	
Notes	*If criteria is met under step 1, authorization length is 12 months. **If criteria is met under step 2, authorization length is 4 weeks.

2 . Revision History

Date	Notes
7/24/2024	Updated initial approval duration from 6 months to 12 months. Simplified reauthorization criteria.

Pyrukynd

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150402
Guideline Name	Pyrukynd
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Pyrukynd Taper Pack, Pyrukynd	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pyruvate kinase (PK) deficiency based on ALL of the following:

1.1 Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant

AND

1.2 Patient is not homozygous for the c.1436G > A (p.R479H) variant

AND

1.3 Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

2 - Used for the treatment of hemolytic anemia

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Baseline hemoglobin less than or equal to 10 grams/deciliter (g/dL)

AND

3.1.2 Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

OR

3.2 Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

AND **4** - Prescribed by a nephrologist or hematologist

Product Name:Pyrukynd Taper Pack, Pyrukynd	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - BOTH of the following*: **1.1** Documentation of positive clinical response to Pyrukynd therapy **AND** **1.2** Prescribed by, or in consultation with, a nephrologist or hematologist **OR** **2** - Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy**	
Notes	*If criteria is met under step 1, authorization length is 12 months. **If criteria is met under step 2, authorization length is 4 weeks.

2 . Revision History

Date	Notes
7/24/2024	Updated initial approval duration from 6 months to 12 months. Simplified reauthorization criteria.

Qbrexza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158320
Guideline Name	Qbrexza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Qbrexza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of primary axillary hyperhidrosis	

AND

2 - ONE of the following:

2.1 Failure to Xerac-AC as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to Xerac-AC (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
10/31/2024	Updated formulary

Qinlock

Prior Authorization Guideline

Guideline ID	GL-154750
Guideline Name	Qinlock
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/Metastatic

AND

3 - ONE of the following:

3.1 History of failure to ALL of the following as confirmed by claims history or submission of medical records:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- regorafenib (generic Stivarga)

OR

3.2 ALL of the following:

3.2.1 Performance status 0-2

AND

3.2.2 History of progression on imatinib (Gleevec) as confirmed by claims history or submission of medical records

AND

3.2.3 History of intolerance to sunitinib (Sutent) (please specify intolerance) as confirmed by claims history or submission of medical records

OR

3.3 ALL of the following:

3.3.1 PDGFRA exon 18 mutations that are insensitive to imatinib (Gleevec) (including PDGFRA D842V)

AND

3.3.2 History of progression on avapritinib (Ayvakit) as confirmed by claims history or submission of medical records

AND

3.3.3 History of progression on dasatinib (Sprycel) as confirmed by claims history or submission of medical records

Product Name:Qinlock	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous melanoma

AND

2 - Disease is unresectable or metastatic

AND

3 - Disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

AND

4 - Positive for activating mutations of KIT

Product Name:Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Qinlock therapy

Product Name:Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Qinlock therapy

2 . Revision History

Date	Notes
9/11/2024	Updated background and criteria for GIST tumors and added backgr ound and criteria for cutaneous melanoma per NCCN guidelines.

Qinlock

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154750
Guideline Name	Qinlock
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Recurrent/Metastatic

AND

3 - ONE of the following:

3.1 History of failure to ALL of the following as confirmed by claims history or submission of medical records:

- imatinib (generic Gleevec)
- sunitinib (generic Sutent)
- regorafenib (generic Stivarga)

OR

3.2 ALL of the following:

3.2.1 Performance status 0-2

AND

3.2.2 History of progression on imatinib (Gleevec) as confirmed by claims history or submission of medical records

AND

3.2.3 History of intolerance to sunitinib (Sutent) (please specify intolerance) as confirmed by claims history or submission of medical records

OR

3.3 ALL of the following:

3.3.1 PDGFRA exon 18 mutations that are insensitive to imatinib (Gleevec) (including PDGFRA D842V)

AND

3.3.2 History of progression on avapritinib (Ayvakit) as confirmed by claims history or submission of medical records

AND

3.3.3 History of progression on dasatinib (Sprycel) as confirmed by claims history or submission of medical records

Product Name:Qinlock	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous melanoma

AND

2 - Disease is unresectable or metastatic

AND

3 - Disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

AND

4 - Positive for activating mutations of KIT

Product Name:Qinlock	
Diagnosis	Gastrointestinal Stromal Tumor (GIST), Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Qinlock therapy

Product Name:Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Qinlock	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Qinlock therapy

2 . Revision History

Date	Notes
9/11/2024	Updated background and criteria for GIST tumors and added backgr ound and criteria for cutaneous melanoma per NCCN guidelines.

Qlosi, Vuity

Prior Authorization Guideline

Guideline ID	GL-208219
Guideline Name	Qlosi, Vuity
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Vuity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Patient is between the ages of 40 to 55

AND

3 - Patient is unable to use corrective lenses (e.g., glasses, contacts) (document medical rationale why patient is unable to use corrective lenses)

AND

4 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

Product Name:Vuity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Age less than 55

AND

3 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

Product Name:Qlosi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Patient is between the ages of 45 to 64

AND

3 - Patient is unable to use corrective lenses (e.g., glasses, contacts) (document medical rationale why patient is unable to use corrective lenses)

AND

4 - Prescribed by ONE of the following:

- Optometrist

- Ophthalmologist

Product Name:Qlosi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Age less than 64

AND

3 - Prescribed by ONE of the following:

- Optometrist
- Ophthalmologist

2 . Revision History

Date	Notes
3/5/2025	Updated formularies. Updated GPIs

Quantity Limits

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128955
Guideline Name	Quantity Limits
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The request falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria **1** - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is perm itted

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
7/25/2023	Updated guideline name. Defined FDA and reformatted step 2 of Qu antity limit review (General) section.

Quantity Limits

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128955
Guideline Name	Quantity Limits
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review (General)
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for an FDA (Food and Drug Administration)-approved indication

OR

1.2 The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The request falls within dosing guidelines found in ONE of the following compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

AND

4 - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Quantity limit review for the treatment of gender dysphoria*
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The use of this drug is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Notes	* If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Monthly prescription limit review for migraine therapy, benzodiazepines, or muscle relaxants
Approval Length	1 month(s)
Guideline Type	Administrative

Approval Criteria **1** - Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Notes	*If deemed medically necessary, longer authorization duration is perm itted

Product Name:Quantity Limit, Prescription Limit	
Diagnosis	Topical products exceeding the allowable package size per fill OR the allowable quantity per month
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The physician attests that a larger quantity is needed for treatment of a larger surface area.

2 . Revision History

Date	Notes
7/25/2023	Updated guideline name. Defined FDA and reformatted step 2 of Qu antity limit review (General) section.

Radicava ORS

Prior Authorization Guideline

Guideline ID	GL-155384
Guideline Name	Radicava ORS
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Radicava ORS	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient has been established on therapy with Radicava for amyotrophic lateral sclerosis (ALS) under an active UnitedHealthcare medical benefit prior authorization

AND

1.2 ALL of the following:

1.2.1 Diagnosis of “definite” or “probable” ALS per the El Escorial/revised Airlie House diagnostic criteria

AND

1.2.2 Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

1.2.3 Patient is currently receiving Radicava therapy

AND

1.2.4 Patient is not dependent on invasive ventilation or tracheostomy

OR

2 - ALL of the following:

2.1 Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of “definite” or “probable” ALS per the El Escorial/revised Airlie House diagnostic criteria

AND

2.2 Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

2.3 Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient has scores greater than or equal to 2 in all items of the ALSFRS-R criteria at the start of treatment

AND

2.4 Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a % forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

Product Name:Radicava ORS	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) per the El Escorial/revised Airlie House diagnostic criteria

AND

2 - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient is currently receiving Radicava ORS therapy

AND **4** - Patient is not dependent on invasive ventilation or tracheostomy

2 . Revision History

Date	Notes
9/20/2024	Clarified criteria for existing prior authorization to be under the medic al benefit. Updated initial and reauth durations to 12 months.

Ravicti

Prior Authorization Guideline

Guideline ID	GL-123420
Guideline Name	Ravicti
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urea cycle disorders (UCDs)

AND

2 - Inadequate response to ONE of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

3 - Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

4 - ONE of the following:

4.1 Failure to sodium phenylbutyrate (Buphenyl) as confirmed by claims history or submission of medical records*

OR

4.2 History of intolerance or contraindication to sodium phenylbutyrate (Buphenyl) (please specify contraindication or intolerance)*

Notes	*UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity

Product Name:Ravicti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ravicti therapy

AND

2 - Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

2 . Revision History

Date	Notes
3/17/2023	Updated T/F criteria, cleaned up note.

Rayos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134712
Guideline Name	Rayos
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Rayos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Rayos must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The intended use of Rayos is supported by information from ONE of the following appropriate compendia of current literature:

- American Hospital Formulary Service Drug Information
- National Comprehensive Cancer Network Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

AND

2 - Rayos is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan's program

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting an intolerance to generic prednisone tablets which is unable to be resolved with attempts to minimize the adverse effects where appropriate

AND

4 - ONE of the following:

4.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- Dexamethasone tablet/oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet/oral solution

OR

4.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Dexamethasone tablet/oral solution
- Hydrocortisone tablet
- Methylprednisolone tablet
- Prednisolone tablet/oral solution

2 . Revision History

Date	Notes
10/12/2023	Updated formularies, cleaned up criteria.

Rectiv

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161186
Guideline Name	Rectiv
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Rectiv ointment, generic nitroglycerin ointment	
Diagnosis	Pain Associated with Chronic Anal Fissures
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of moderate to severe pain associated with chronic anal fissures

2 . Revision History

Date	Notes
11/22/2024	Added generic Nitroglycerin ointment.

Regranex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117466
Guideline Name	Regranex
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Regranex	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has a lower extremity diabetic neuropathic ulcer

2 . Revision History

Date	Notes
11/30/2022	Updated Markets in Scope. No changes to clinical criteria

Relistor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129133
Guideline Name	Relistor
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Relistor Injection	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation (e.g. chart notes) demonstrating a diagnosis of opioid induced constipation in a patient with advanced illness receiving palliative care

OR

2 - Documentation (e.g. chart notes) demonstrating BOTH of the following:

2.1 ONE of the following:

2.1.1 Diagnosis of opioid induced constipation with chronic, non-cancer pain

OR

2.1.2 Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2.2 ONE of the following:

2.2.1 The patient is not able to swallow oral medications

OR

2.2.2 ALL of the following:

2.2.2.1 ONE of the following:

2.2.2.1.1 Failure to ONE of the following as confirmed by claims history or submitted medical records

- Lactulose
- Polyethylene glycol (Miralex)

OR

2.2.2.1.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication)

- Lactulose
- Polyethylene glycol (Miralex)

AND

2.2.2.2 ONE of the following:

2.2.2.2.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

2.2.2.2.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

AND

2.2.2.3 ONE of the following:

2.2.2.3.1 Failure to Movantik as confirmed by claims history or submitted medical records

OR

2.2.2.3.2 History of contraindication or intolerance to Movantik (please specify intolerance or contraindication)

Product Name:Relistor Injection	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Relistor Injection therapy

Product Name:Relistor tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of opioid induced constipation with chronic, non-cancer pain

OR

1.2 Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

AND

2 - ALL of the following:

2.1 ONE of the following:

2.1.1 Failure to ONE of the following as confirmed by claims history or submitted medical records

- Lactulose
- Polyethylene glycol (Miralex)

OR

2.1.2 History of contraindication or intolerance to BOTH of the following (please specify intolerance or contraindication)

- Lactulose
- Polyethylene glycol (Miralex)

AND

2.2 ONE of the following:

2.2.1 Failure to lubiprostone (generic of Amitiza) as confirmed by claims history or submission of medical records

OR

2.2.2 History of intolerance or contraindication to lubiprostone (generic of Amitiza) (please specify intolerance or contraindication)

AND

2.3 ONE of the following:

2.3.1 Failure to Movantik as confirmed by claims history or submitted medical records

OR

2.3.2 History of contraindication or intolerance to Movantik (please specify intolerance or contraindication)

Product Name:Relistor tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Relistor Tablet therapy

2 . Revision History

Date	Notes
8/7/2023	Aligned step therapy agents to be more consistent among similar ag ents within the class. Adding the option for ST lactulose or PEG and added a ST lubiprostone (generic Amitiza)

Relyvrio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-210215
Guideline Name	Relyvrio
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Indiana • Medicaid - Community & State Nebraska • Medicaid - Community & State New Mexico • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

3 - Provider attestation that the patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)

AND

4 - Patient is not dependent on invasive ventilation or tracheostomy

Product Name:Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient is currently receiving Relyvrio therapy

AND

4 - Provider attestation that the patient has slowed disease progression from baseline

AND

5 - Patient is not dependent on invasive ventilation or tracheostomy

2 . Revision History

Date	Notes
3/6/2025	Removing PA CAID for 4/1/25, no replacement, set to default. No change to clinical criteria.

Repatha

Prior Authorization Guideline

Guideline ID	GL-145759
Guideline Name	Repatha
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Repatha	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) is ONE of the following:

- Greater than or equal to 190 milligrams/deciliter (mg/dL)
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C is ONE of the following:

- Greater than or equal to 190 mg/dL
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low-density lipoprotein), apoB (Apolipoprotein B), or PCSK9 (Proprotein convertase subtilisin/kexin type 9) gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia with pre-treatment LDL-C greater than or equal to 190 mg/dL

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]

- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

OR

2.3.2 Patient has a labeled contraindication to all statins as confirmed by medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the

following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe (please specify intolerance or contraindication)

AND

4 - Patient has received comprehensive counseling regarding appropriate diet

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

7 - Not used in combination with Leqvio (inclisiran)

Product Name:Repatha	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

2 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

4 - Not used in combination with Leqvio (inclisiran)

Product Name:Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 BOTH of the following:

1.2.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 400 mg/dL (milligrams/deciliter)

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Patient has received comprehensive counseling regarding appropriate diet

AND

3 - Patient is receiving other lipid-lowering therapy confirmed by claims history or submitted medical records (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

6 - Not used in combination with Juxtapid (lomitapide)

Product Name:Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid Specialist

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

4 - Not used in combination with Juxtapid (lomitapide)

2 . Revision History

Date	Notes
4/23/2024	For HeFH initial auth section, under criterion 1.1.2.1, added verbiage "or equal to" in second bullet. For HoFH initial auth section, updated diagnostic criteria per European Atherosclerosis Society guidance. Si mplified reauth criteria for both primary hyperlipidemia and HoFH.

Repatha

Prior Authorization Guideline

Guideline ID	GL-145759
Guideline Name	Repatha
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Repatha	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by ONE of the following:

1.1.1 BOTH of the following:

1.1.1.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) is ONE of the following:

- Greater than or equal to 190 milligrams/deciliter (mg/dL)
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.1.2 ONE of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of heterozygous or homozygous familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 BOTH of the following:

1.1.2.1 Pre-treatment LDL-C is ONE of the following:

- Greater than or equal to 190 mg/dL
- Greater than or equal to 155 mg/dL if less than 16 years of age

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

- Functional mutation in LDL (low-density lipoprotein), apoB (Apolipoprotein B), or PCSK9 (Proprotein convertase subtilisin/kexin type 9) gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by ONE of the following:

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia with pre-treatment LDL-C greater than or equal to 190 mg/dL

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

2.1 Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive high-intensity statin at maximally tolerated dose

OR

2.2 BOTH of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia [muscle symptoms without creatine kinase (CK) elevations]

- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

AND

2.2.2 Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than or equal to 10 mg, pravastatin greater than or equal to 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40 mg twice daily or Livalo (pitavastatin) greater than or equal to 1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by ONE of the following:

2.3.1 ONE of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis [muscle symptoms with CK elevations less than 10 times upper limit of normal (ULN)]

OR

2.3.2 Patient has a labeled contraindication to all statins as confirmed by medical records

OR

2.3.3 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3 - ONE of the following:

3.1 Submission of medical records (e.g., laboratory values) documenting ONE of the

following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 BOTH of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting ONE of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days or 120 days prior to starting PCSK9 inhibitor therapy:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2.2.2 Patient has a history of contraindication or intolerance to ezetimibe (please specify intolerance or contraindication)

AND

4 - Patient has received comprehensive counseling regarding appropriate diet

AND

5 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

7 - Not used in combination with Leqvio (inclisiran)

Product Name:Repatha	
Diagnosis	Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia) and ASCVD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

2 - Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

4 - Not used in combination with Leqvio (inclisiran)

Product Name:Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by submission of medical records (e.g., chart notes, laboratory values) documenting ONE of the following:

1.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 BOTH of the following:

1.2.1 Pre-treatment LDL-C (low-density lipoprotein cholesterol) greater than 400 mg/dL (milligrams/deciliter)

AND

1.2.2 ONE of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Patient has received comprehensive counseling regarding appropriate diet

AND

3 - Patient is receiving other lipid-lowering therapy confirmed by claims history or submitted medical records (e.g., statin, ezetimibe, LDL apheresis)

AND

4 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

6 - Not used in combination with Juxtapid (lomitapide)

Product Name:Repatha	
Diagnosis	Homozygous Familial Hypercholesterolemia (HoFH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C (low-density lipoprotein cholesterol) reduction while on Repatha therapy

AND

2 - Prescribed by ONE of the following:

- Cardiologist
- Endocrinologist
- Lipid Specialist

AND

3 - Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

AND

4 - Not used in combination with Juxtapid (lomitapide)

2 . Revision History

Date	Notes
4/23/2024	For HeFH initial auth section, under criterion 1.1.2.1, added verbiage "or equal to" in second bullet. For HoFH initial auth section, updated diagnostic criteria per European Atherosclerosis Society guidance. Si mplified reauth criteria for both primary hyperlipidemia and HoFH.

Repository Corticotropins

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-114247
Guideline Name	Repository Corticotropins
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Colorado SP (RMHCAID, RMHCHP, RMHWRP) • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2022

1 . Criteria

Product Name:Acthar, Cortrophin	
Diagnosis	Infantile spasm (i.e., West Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile spasms (i.e., West Syndrome)*

AND

2 - Patient is less than 2 years old

AND

3 - Both of following:

3.1 Initial dose: 75 U/m^2 (units/square meters) intramuscular (IM) twice daily for 2 weeks

AND

3.2 After 2 weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM every other morning for 6 days (3 doses)

Notes	*Acthar gel and Cortrophin gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis. See Background for more information.

Product Name:Acthar, Cortrophin	
Diagnosis	Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome)*

AND **2** - If the request is for Acthar gel, provider submits documentation of reason or special circumstance patient cannot use Cortrophin Gel	
Notes	*Acthar gel and Cortrophin gel are not medically necessary for treatm ent of acute exacerbations of multiple sclerosis. See Background for more information.

2 . Background

Benefit/Coverage/Program Information
More Information: The Acthar Gel and Purified Cortrophin Gel package inserts have listed other conditions in which it may be used. UHCP has determined that use of Acthar Gel and Purified Cortrophin Gel is not medically necessary for treatment of the following disorders and diseases: multiple sclerosis; rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state.

3 . Revision History

Date	Notes
9/22/2022	Updated background

Retevmo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164067
Guideline Name	Retevmo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name:Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.2 Disease is one of the following:

- Advanced

- Metastatic

AND

1.3 Disease has presence of RET gene mutation

AND

1.4 Disease requires treatment with systemic therapy

OR

2 - All of the following:

2.1 Diagnosis of thyroid cancer

AND

2.2 Disease is one of the following:

- Advanced
- Metastatic

AND

2.3 Disease is RET gene fusion-positive

AND

2.4 Disease requires treatment with systemic therapy

AND

2.5 One of the following:

- Patient is radioactive iodine-refractory
- Treatment with radioactive iodine is not appropriate

Product Name:Retevmo	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following histiocytic neoplasms:

- Langerhans Cell Histiocytosis
- Erdheim-Chester disease
- Rosai-Dorfman disease

AND

2 - Used for RET fusion target as a single agent

Product Name:Retevmo	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of RET gene fusion-positive solid tumor

AND

2 - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

Product Name:Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer, Histiocytic Neoplasms, Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Retevmo therapy

Product Name:Retevmo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Retevmo

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Retevmo therapy

2 . Revision History

Date	Notes
1/21/2025	Updated GPI

Retevmo

Prior Authorization Guideline

Guideline ID	GL-164067
Guideline Name	Retevmo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of RET gene fusion-positive or RET rearrangement positive tumors

Product Name:Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of medullary thyroid cancer (MTC)

AND

1.2 Disease is one of the following:

- Advanced

- Metastatic

AND

1.3 Disease has presence of RET gene mutation

AND

1.4 Disease requires treatment with systemic therapy

OR

2 - All of the following:

2.1 Diagnosis of thyroid cancer

AND

2.2 Disease is one of the following:

- Advanced
- Metastatic

AND

2.3 Disease is RET gene fusion-positive

AND

2.4 Disease requires treatment with systemic therapy

AND

2.5 One of the following:

- Patient is radioactive iodine-refractory
- Treatment with radioactive iodine is not appropriate

Product Name:Retevmo	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following histiocytic neoplasms:

- Langerhans Cell Histiocytosis
- Erdheim-Chester disease
- Rosai-Dorfman disease

AND

2 - Used for RET fusion target as a single agent

Product Name:Retevmo	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of RET gene fusion-positive solid tumor

AND

2 - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

Product Name:Retevmo	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Thyroid Cancer, Histiocytic Neoplasms, Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Retevmo therapy

Product Name:Retevmo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Retevmo

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Retevmo therapy

2 . Revision History

Date	Notes
1/21/2025	Updated GPI

Revlimid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151088
Guideline Name	Revlimid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of multiple myeloma

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 ALL of the following:

2.2.1.1 Serum erythropoietin levels less than or equal to 500 mU/mL

AND

2.2.1.2 One of the following:

- Ring sideroblasts < 15%
- Ring sideroblasts < 5% with an SF3B1 mutation

AND

2.2.1.3 History of failure, contraindication or intolerance to one of the following:

- Erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa
- Reblozyl (luspatercept-aamt)

AND

2.2.1.4 Used in combination with an erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa

OR

2.2.2 ALL of the following:

2.2.2.1 Serum erythropoietin levels less than or equal to 500 mU/mL

AND

2.2.2.2 One of the following:

- Ring sideroblasts ≥ 15%
- Ring sideroblasts ≥ 5% with an SF3B1 mutation

AND

2.2.2.3 History of failure, contraindication or intolerance to both of the following:

- Erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa
- Reblozyl (luspatercept-aamt)

OR

2.2.3 All of the following:

2.2.3.1 Serum erythropoetin levels > 500 mU/mL

AND

2.2.3.2 One of the following:

- Ring sideroblasts < 15%
- Ring sideroblasts < 5% with an SF3B1 mutation

AND

2.2.3.3 One of the following:

- Poor probability to respond to immunosuppressive therapy (e.g., azacitidine, decitabine)
- History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azacitidine, decitabine)

OR

2.2.4 All of the following:

2.2.4.1 Serum erythropoetin levels > 500 mU/mL

AND

2.2.4.2 One of the following:

- Ring sideroblasts ≥ 15%
- Ring sideroblasts ≥ 5% with an SF3B1 mutation

AND

2.2.4.3 History of failure, contraindication or intolerance to Reblozyl (luspatercept-aamt)

OR

3 - BOTH of the following:

3.1 Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

AND

3.2 One of the following:

- Patient has SF3B1 mutation and thrombocytosis
- Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Classic follicular lymphoma
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

OR

2 - BOTH of the following:

2.1 ONE of the following diagnoses:

- HIV-related B-cell lymphoma
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

2.2 Used as second line or subsequent therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Hodgkin lymphoma

AND

2 - Disease is refractory to at least 3 prior lines of therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with ONE of the following:

- Dexamethasone
- Dexamethasone and cyclophosphamide
- Dexamethasone and Ninlaro® (ixazomib)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND

2 - Disease is relapsed or refractory

AND

3 - Used after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor and venetoclax-based regimens

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Peripheral T-cell lymphoma
- T-cell leukemia/lymphoma
- Hepatosplenic gamma-delta T-cell lymphoma

AND

2 - Used as second-line or subsequent therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of primary central nervous system lymphoma

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Patient has a diagnosis of human immunodeficiency virus (HIV)-negative Kaposi Sarcoma

OR

1.1.2 BOTH of the following:

1.1.2.1 Diagnosis of HIV-related Kaposi Sarcoma

AND

1.1.2.2 Patient is currently being treated with antiretroviral therapy (ART) confirmed by claims history or submission of medical records

AND

1.2 Disease has progressed or not responded to two different systemic first-line systemic therapies (e.g., liposomal doxorubicin, sirolimus, paclitaxel)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Langerhans Cell Histiocytosis, Rosai-Dorfman disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans cell histiocytosis
- Rosai-Dorfman disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Multicentric Castleman Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of multicentric castleman disease

AND

2 - One of the following:

- Progressed following treatment of relapsed/refractory disease
- Considered progressive disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	*Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, T-Cell Lymphomas, Primary CNS Lymphomas, Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman disease, Multicentric Castleman Disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of myelofibrosis-associated anemia

AND

2 - Presence of del(5q) mutation

AND

3 - No symptomatic splenomegaly and/or constitutional symptoms

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response while on Revlimid

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Revlimid therapy	

2 . Revision History

Date	Notes
8/7/2024	Updated criteria per NCCN for myelodysplastic syndrome, b-cell lym phomas, myelofibrosis-associated anemia, Hodgkin lymphoma, syste mic light chain amyloidosis, chronic lymphocytic leukemia/small lymp hocytic lymphoma, t-cell lymphoma, and kaposi sarcoma. Renamed

	and updated criteria for histiocytic neoplasms. Moved castleman dise ase from b-cell lymphoma into its own criteria.

Revlimid

Prior Authorization Guideline

Guideline ID	GL-151088
Guideline Name	Revlimid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of multiple myeloma

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) WITHOUT deletion 5q

AND

2.2 ONE of the following:

2.2.1 ALL of the following:

2.2.1.1 Serum erythropoietin levels less than or equal to 500 mU/mL

AND

2.2.1.2 One of the following:

- Ring sideroblasts < 15%
- Ring sideroblasts < 5% with an SF3B1 mutation

AND

2.2.1.3 History of failure, contraindication or intolerance to one of the following:

- Erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa
- Reblozyl (luspatercept-aamt)

AND

2.2.1.4 Used in combination with an erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa

OR

2.2.2 ALL of the following:

2.2.2.1 Serum erythropoietin levels less than or equal to 500 mU/mL

AND

2.2.2.2 One of the following:

- Ring sideroblasts ≥ 15%
- Ring sideroblasts ≥ 5% with an SF3B1 mutation

AND

2.2.2.3 History of failure, contraindication or intolerance to both of the following:

- Erythropoietin stimulating agent (ESA) [e.g., Epogen, Procrit, Retacrit (epoetin alfa)] or darbepoetin alfa
- Reblozyl (luspatercept-aamt)

OR

2.2.3 All of the following:

2.2.3.1 Serum erythropoetin levels > 500 mU/mL

AND

2.2.3.2 One of the following:

- Ring sideroblasts < 15%
- Ring sideroblasts < 5% with an SF3B1 mutation

AND

2.2.3.3 One of the following:

- Poor probability to respond to immunosuppressive therapy (e.g., azacitidine, decitabine)
- History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azacitidine, decitabine)

OR

2.2.4 All of the following:

2.2.4.1 Serum erythropoetin levels > 500 mU/mL

AND

2.2.4.2 One of the following:

- Ring sideroblasts ≥ 15%
- Ring sideroblasts ≥ 5% with an SF3B1 mutation

AND

2.2.4.3 History of failure, contraindication or intolerance to Reblozyl (luspatercept-aamt)

OR

3 - BOTH of the following:

3.1 Diagnosis of myelodysplastic/myeloproliferative neoplasms (MDS/MPN) overlap neoplasm

AND

3.2 One of the following:

- Patient has SF3B1 mutation and thrombocytosis
- Patient has ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	B-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Mantle cell lymphoma (MCL)
- Extranodal marginal zone lymphoma of nongastric sites (noncutaneous)
- Extranodal marginal zone lymphoma (EMZL) of the stomach
- Classic follicular lymphoma
- Nodal marginal zone lymphoma
- Splenic marginal zone lymphoma

OR

2 - BOTH of the following:

2.1 ONE of the following diagnoses:

- HIV-related B-cell lymphoma
- Diffuse large B-cell lymphoma
- High-grade B-cell lymphoma
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Post-transplant lymphoproliferative disorders

AND

2.2 Used as second line or subsequent therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Hodgkin Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of Hodgkin lymphoma

AND

2 - Disease is refractory to at least 3 prior lines of therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of systemic light chain amyloidosis

AND

2 - Used in combination with ONE of the following:

- Dexamethasone
- Dexamethasone and cyclophosphamide
- Dexamethasone and Ninlaro® (ixazomib)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

AND

2 - Disease is relapsed or refractory

AND

3 - Used after prior therapy with Bruton Tyrosine Kinase (BTK) inhibitor and venetoclax-based regimens

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	T-Cell Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Peripheral T-cell lymphoma
- T-cell leukemia/lymphoma
- Hepatosplenic gamma-delta T-cell lymphoma

AND

2 - Used as second-line or subsequent therapy

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Primary CNS Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of primary central nervous system lymphoma

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 ONE of the following:

1.1.1 Patient has a diagnosis of human immunodeficiency virus (HIV)-negative Kaposi Sarcoma

OR

1.1.2 BOTH of the following:

1.1.2.1 Diagnosis of HIV-related Kaposi Sarcoma

AND

1.1.2.2 Patient is currently being treated with antiretroviral therapy (ART) confirmed by claims history or submission of medical records

AND

1.2 Disease has progressed or not responded to two different systemic first-line systemic therapies (e.g., liposomal doxorubicin, sirolimus, paclitaxel)

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Langerhans Cell Histiocytosis, Rosai-Dorfman disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans cell histiocytosis
- Rosai-Dorfman disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Multicentric Castleman Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of multicentric castleman disease

AND

2 - One of the following:

- Progressed following treatment of relapsed/refractory disease
- Considered progressive disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revlimid therapy

Notes	*Multiple Myeloma, Myelodysplastic Syndromes (MDS), B-Cell Lymphomas, Hodgkin Lymphoma, Systemic Light Chain Amyloidosis, Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, T-Cell Lymphomas, Primary CNS Lymphomas, Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman disease, Multicentric Castleman Disease

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of myelofibrosis-associated anemia

AND

2 - Presence of del(5q) mutation

AND

3 - No symptomatic splenomegaly and/or constitutional symptoms

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	Myelofibrosis-Associated Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response while on Revlimid

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Revlimid will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Brand Revlimid, generic lenalidomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Revlimid therapy	

2 . Revision History

Date	Notes
8/7/2024	Updated criteria per NCCN for myelodysplastic syndrome, b-cell lym phomas, myelofibrosis-associated anemia, Hodgkin lymphoma, syste mic light chain amyloidosis, chronic lymphocytic leukemia/small lymp hocytic lymphoma, t-cell lymphoma, and kaposi sarcoma. Renamed

	and updated criteria for histiocytic neoplasms. Moved castleman dise ase from b-cell lymphoma into its own criteria.

Revuforj

Prior Authorization Guideline

Guideline ID	GL-202195
Guideline Name	Revuforj
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Revuforj	
Diagnosis	Acute Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute leukemia

AND

2 - Disease is relapsed or refractory

AND

3 - Positive for lysine methyltransferase 2A gene (KMT2A) translocation

Product Name:Revuforj	
Diagnosis	Acute Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Revuforj therapy

Product Name:Revuforj	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Revuforj	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Revuforj therapy	

2 . Revision History

Date	Notes
2/26/2025	New program.

Reyvow

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206577
Guideline Name	Reyvow
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Reyvow	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Used for acute treatment of migraine

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

3.1 Failure (after at least 3 migraine episodes and a minimum of a 30-day trial), to BOTH of the following as confirmed by claims history or submission of medical records:

3.1.1 TWO of the following:

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)

AND

3.1.2 ONE of the following:

- Nurtec ODT
- Ubrelvy

OR

3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- eletriptan (generic Relpax)
- naratriptan (generic Amerge)
- rizatriptan (generic Maxalt/Maxalt MLT)
- sumatriptan (generic Imitrex)
- zolmitriptan (generic Zomig)
- Nurtec ODT

- Ubrelvy

AND

4 - Prescribed by or in consultation with ONE of the following specialists with expertise in the acute treatment of migraine:

- Neurologist
- Pain Specialist
- Headache Specialist [Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS)]

AND

5 - Prescriber attests to BOTH of the following:

5.1 Patient has been informed the use of Reyvow may result in significant CNS (central nervous system) impairment, and may impact the patient's ability to drive or operate machinery for 8 hours after each dose

AND

5.2 If used concurrently with a benzodiazepine or other drugs that could potentially cause CNS depression, the prescriber has acknowledged that they have completed an assessment of increased risk for sedation and other cognitive and/or neuropsychiatric adverse events

AND

6 - ONE of the following:

6.1 Patient is currently treated with ONE of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan (generic Atacand)*
- A calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab), Nurtec ODT, Qulipta*, Vyepti (eptinezumab-jjmr)**]***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]

- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

OR

6.2 Patient has less than 4 migraine days per month

OR

6.3 Patient has greater than or equal to 4 migraine days per month and has contraindication or intolerance to TWO of the following prophylactic therapies:

- A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)
- Candesartan (generic Atacand)*
- A calcitonin gene-related peptide receptor (CGRP) antagonist for preventive treatment of migraine [i.e., Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab), Nurtec ODT, Qulipta*, Vyepti (eptinezumab-jjmr)**]***
- Divalproex sodium (generic Depakote/Depakote ER)
- OnabotulinumtoxinA (generic Botox)**
- A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]
- Topiramate (generic Topamax)
- A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

Notes	*Timolol, candesartan, Ajovy, and Qulipta are non-preferred and shoul d not be included in denial to provider. **Vyepti and OnabotulinumtoxinA (generic Botox) are medical benefit, should not be included in denial to provider. ***CGRP antagonists for preventive treatment of migraines require a p rior authorization.

Product Name:Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
3/4/2025	Updated formularies. Added eletriptan and zolmitriptan as step thera py option. Updated prophylactic therapy requirements

Rezdiffra

Prior Authorization Guideline

Guideline ID	GL-195187
Guideline Name	Rezdiffra
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia • Medicaid - Community & State Washington

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Rezdiffra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]

AND

2 - Disease is fibrosis stage F2 or F3 as confirmed by ONE of the following:

2.1 Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g., FibroScan)

OR

2.2 LSM by magnetic resonance elastography (MRE)

OR

2.3 Liver biopsy within the past 12 months

AND

3 - Patient has received comprehensive counseling regarding lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program)

AND

4 - Prescribed by or in consultation with a gastroenterologist or hepatologist

Product Name:Rezdiffra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rezdiffra therapy (e.g., improvement in or stabilization of fibrosis) **AND** **2** - Patient has NOT progressed to cirrhosis **AND** **3** - Prescribed by or in consultation with a gastroenterologist or hepatologist	

2 . Revision History

Date	Notes
2/24/2025	Combined formularies. Revised initial auth criteria for confirming fibro sis stage F2 or F3. Added criterion to reauth section that patient has not progressed to cirrhosis.

Rezlidhia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123321
Guideline Name	Rezlidhia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Rezlidhia	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g., R132C, R132H, R132G, R132S, R132L)

AND

3 - Disease is relapsed or refractory

Product Name:Rezlidhia	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rezlidhia therapy

Product Name:Rezlidhia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rezlidhia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rezlidhia therapy

2 . Revision History

Date	Notes
3/16/2023	New guideline

Rezlidhia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123321
Guideline Name	Rezlidhia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • • • •

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name:Rezlidhia	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Positive for a susceptible isocitrate dehydrogenase-1 (IDH1) mutation (e.g., R132C, R132H, R132G, R132S, R132L)

AND

3 - Disease is relapsed or refractory

Product Name:Rezlidhia	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rezlidhia therapy

Product Name:Rezlidhia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rezlidhia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rezlidhia therapy

2 . Revision History

Date	Notes
3/16/2023	New guideline

Rezurock

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157762
Guideline Name	Rezurock
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Rezurock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease (chronic GVHD)

AND

2 - History of failure of at least TWO prior lines of systemic therapy (e.g., corticosteroids, mycophenolate, tacrolimus, etc.) confirmed by claims history or submitted medical records

Product Name:Rezurock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rezurock therapy

2 . Revision History

Date	Notes
10/21/2024	Removed age requirement in initial auth section.

Rezurock

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157762
Guideline Name	Rezurock
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Rezurock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of chronic graft-versus-host disease (chronic GVHD) **AND** **2** - History of failure of at least TWO prior lines of systemic therapy (e.g., corticosteroids, mycophenolate, tacrolimus, etc.) confirmed by claims history or submitted medical records

Product Name:Rezurock	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rezurock therapy	

2 . Revision History

Date	Notes
10/21/2024	Removed age requirement in initial auth section.

Rinvoq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206574
Guideline Name	Rinvoq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses as confirmed by claims history or submission of medical records

OR

2.1.1.2 History of intolerance or contraindication to ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)

OR

2.1.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Olumiant (baricitinib), Xeljanz/Xeljanz XR (tofacitinib)]

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

- Enbrel (etanercept)

- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

OR

2.1.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Enbrel (etanercept)
- One of the preferred adalimumab products*
- Tyenne (tocilizumab-aazg)

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

2.1.3 ONE of the following:

2.1.3.1 Failure to Olumiant as confirmed by claims history or submission of medical records

OR

2.1.3.2 History of contraindication or intolerance to Olumiant (please specify contraindication or intolerance)

OR

2.2 Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to a 3 month trial of methotrexate at maximally indicated dose as confirmed by claims history or submission of medical records

OR

2.1.1.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

2.1.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Otezla (apremilast), Skyrizi (risankizumab-rzaa)]

AND

2.1.2 ONE of the following:

2.1.2.1 BOTH of the following:

2.1.2.1.1 ONE of the following:

2.1.2.1.1.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

2.1.2.1.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

2.1.2.1.2 ONE of the following:

2.1.2.1.2.1 Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

OR

2.1.2.1.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

OR

2.1.2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

OR

2.2 Patient is currently on Rinvoq or Rinvoq LQ therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Rinvoq or Rinvoq LQ in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]
- Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist

• Dermatologist	
Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe chronic atopic dermatitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to TWO of the following therapeutic classes of topical therapies, as confirmed by claims history or submission of medical records:

- One medium to very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

OR

2.1.1.2 History of intolerance or contraindication to ALL of the following therapeutic classes of topical therapies (please specify intolerance or contraindication):

- One medium to very-high potency topical corticosteroid [e.g., mometasone furoate (generic Elocon), fluocinolone acetonide (generic Synalar), fluocinonide (generic Lidex)] (see Table 1 in Background)
- One topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)]
- Eucrisa (crisaborole)

AND

2.1.2 ONE of the following:

2.1.2.1 BOTH of the following:

2.1.2.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial of a systemic drug product for the treatment of atopic dermatitis [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.]

AND

2.1.2.1.2 Physician attests that the patient was not adequately controlled with the documented systemic drug product

OR

2.1.2.2 Physician attests that systemic treatment with BOTH of the following FDA (Food and Drug Administration)-approved atopic dermatitis therapy is inadvisable (document drug and contraindication rationale):

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure [refer to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision (DSM-V-TR) 300.29 for specific phobia diagnostic criteria]

OR

2.2 Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

Product Name:Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.1.1.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz/XR (tofacitinib)]

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

OR

2.1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

OR

2.1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

OR

2.2 Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 ONE of the following:

1.2.1 Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)]

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 ONE of the following:

1.3.1.1.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)

OR

1.3.1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)

AND

1.3.1.2 ONE of the following:

1.3.1.2.1 Failure to Cosentyx (secukinumab), as confirmed by claims history or submission of medical records

OR

1.3.1.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

OR

1.3.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.4 Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Rinvoq therapy, as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq	
Diagnosis	Non-Radiographic Axial Spondyloarthritis (nr-axSpA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-radiographic axial spondyloarthritis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

2.1.1.2 History of intolerance or contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

2.1.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), Cosentyx (secukinumab)]

AND

2.1.2 ONE of the following:

2.1.2.1 ONE of the following:

2.1.2.1.1 Failure to Cosentyx (secukinumab), as confirmed by claims history or submission of medical records

OR

2.1.2.1.2 History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

OR

2.1.2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

OR

2.2 Patient is currently on Rinvoq therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name:Rinvoq	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn’s Disease

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to ONE of the following conventional therapy drugs or classes at maximally indicated dose confirmed by claims history or submitted medical records:

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.1.1.2 History of intolerance or contraindication to ALL of the following conventional therapy drugs or classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Methotrexate (Rheumatrex, Trexall)

OR

2.1.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab]

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*

- One of the preferred ustekinumab products*

OR

2.1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- One of the preferred ustekinumab products*

OR

2.2 Patient is currently on Rinvoq therapy for moderately to severely active Crohn's disease as confirmed by claims history or submitted medical records

AND

3 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - One of the following:

2.1 One of the following:

2.1.1 Failure to ALL of the following as confirmed by claims history or submission of medical records

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

OR

2.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- Tyenne (tocilizumab-aazg)

OR

2.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria5)

OR

2.3 Patient is currently on Rinvoq or Rinvoq LQ therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is not receiving Rinvoq or Rinvoq LQ in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Xeljanz (tofacitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	*See Table 2 in Background for PDL links.

Product Name:Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA), Ulcerative Colitis (UC), Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]*

• Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

Product Name:Rinvoq, Rinvoq LQ	
Diagnosis	Psoriatic Arthritis (PsA), Polyarticular Juvenile Idiopathic Arthritis (pJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq or Rinvoq LQ therapy

AND

2 - Patient is NOT receiving Rinvoq or Rinvoq LQ in combination with either of the following:

- Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Otezla (apremilast)]*
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

Product Name:Rinvoq	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rinvoq therapy

AND

2 - Patient is NOT receiving Rinvoq in combination with either of the following:

- Targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Cibinqo (abrocitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
- Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Dermatologist
- Allergist
- Immunologist

2 . Background

Benefit/Coverage/Program Information

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05

	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1

Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: PDL links

Colorado	https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html
Hawaii	https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html
Maryland	https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html
New Jersey	https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html
New York	https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html
Rhode Island	https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html
Pennsylvania CHIP	https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP
New Mexico	https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

3 . Revision History

Date	Notes

3/4/2025	Added NM to scope. Added ustekinumab as a step therapy option in CD, UC and PsA. Changed "Stelara" to "ustekinumab" .

Rivfloza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148897
Guideline Name	Rivfloza
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/2/2024

1 . Criteria

Product Name:Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient has been established on therapy with Rivfloza under an active UnitedHealthcare medical benefit prior authorization for the treatment of primary hyperoxaluria type 1 (PH1)

AND

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)

AND

1.3 Patient has NOT received a liver transplant

AND

1.4 Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m^2)

AND

1.5 Patient is NOT receiving Rivfloza in combination with Oxlumo (lumasiran)

AND

1.6 Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

OR

2 - ALL of the following:

2.1 Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2.2 Confirmation of diagnosis based on BOTH of the following:

2.2.1 Metabolic testing demonstrating ONE of the following:

2.2.1.1 Increased urinary oxalate excretion (e.g., greater than 1 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day], increased urinary oxalate: creatinine ratio relative to normative values for age)

OR

2.2.1.2 Increased plasma oxalate and glyoxylate concentrations

AND

2.2.2 Genetic testing has confirmed a mutation in the alanine: glyoxylate aminotransferase (AGT or AGXT) gene

AND

2.3 Patient has NOT received a liver transplant

AND

2.4 Patient is at least 9 years of age or older

AND

2.5 Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m^2)

AND

2.6 Patient is NOT receiving Rivfloza in combination with Oxlumo (lumasiran)

AND

2.7 Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

Product Name:Rivfloza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a positive clinical response to therapy from pre-treatment baseline (e.g., decreased urinary oxalate concentrations, decreased urinary oxalate: creatinine ratio, decreased plasma oxalate concentrations)

AND

2 - Patient has NOT received a liver transplant

AND

3 - Patient has relatively preserved kidney function (e.g., eGFR [estimated glomerular filtration rate] greater than or equal to 30 mL/min/1.73 m^2)

AND

4 - Patient is NOT receiving Rivfloza in combination with Oxlumo (lumasiran)

AND **5** - Prescribed by, or in consultation with, a specialist (e.g., geneticist, nephrologist, urologist) with expertise in the treatment of PH1

2 . Revision History

Date	Notes
7/2/2024	New program.

Rozerem

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125888
Guideline Name	Rozerem
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Rozerem, generic ramelteon	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Failure of at least 2 weeks to ALL of the following sedative-hypnotic alternatives confirmed by claims history or submitted medical records:

- Zolpidem or zolpidem ER (generic Ambien, generic Ambien CR)
- Zaleplon (generic Sonata)
- Eszopiclone (generic Lunesta)

OR

2 - History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Zolpidem or zolpidem ER (generic Ambien, generic Ambien CR)
- Zaleplon (generic Sonata)
- Eszopiclone (generic Lunesta)

OR

3 - History of or potential for a substance abuse disorder

2 . Revision History

Date	Notes
5/23/2023	Updated step therapy criteria.

Rozlytrek

Prior Authorization Guideline

Guideline ID	GL-183188
Guideline Name	Rozlytrek
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Disease is ROS1 (gene)-positive

Product Name:Rozlytrek	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumors [e.g., sarcoma, non-small cell lung cancer (NSCLC), salivary, breast, thyroid, colorectal, neuroendocrine, pancreatic, gynecological, cholangiocarcinoma, etc.]

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion [e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.]

AND

3 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]

AND

4 - Disease is ONE of the following:

- Metastatic
- Unresectable

Product Name:Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rozlytrek therapy

Product Name:Rozlytrek	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rozlytrek	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rozlytrek therapy

2 . Revision History

Date	Notes
2/20/2025	Combined formularies. Minor update to dx check criterion in NSCLC i nitial auth section, with no changes to clinical intent. Minor cosmetic updates.

Rubraca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125926
Guideline Name	Rubraca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - BOTH of the following:

2.1 Cancer has a deleterious BRCA mutation

AND

2.2 To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy

Product Name:Rubraca	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic, castration-resistant prostate cancer

AND

2 - Cancer has a deleterious BRCA mutation

AND

3 - ONE of the following:

3.1 Failure to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] as confirmed by claims history or submission of medical records

OR

3.2 Contraindication or intolerance to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] (please specify intolerance or contraindication

AND

4 - History of failure, contraindication, or intolerance to taxane-based chemotherapy (e.g., docetaxel, Jevtana (cabazitaxel))

AND

5 - ONE of the following:

5.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

5.2 Patient has had bilateral orchiectomy

Product Name:Rubraca	
Diagnosis	Uterine cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA altered uterine leiomyosarcoma (uLMS)

AND

2 - Disease has progressed following prior treatment with ONE of the following:

- Gemcitabine plus docetaxel
- Doxorubicin

Product Name:Rubraca	
Diagnosis	Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of ONE of the following:

3.1 Deleterious or suspected deleterious germline or somatic BRCA1/2 mutation

OR

3.2 Deleterious or suspected deleterious germline or somatic PALB2 mutation

AND

4 - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name:Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, Prostate cancer, Uterine cancer, Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does NOT show evidence of progressive disease while on Rubraca therapy

Product Name:Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rubraca therapy

2 . Revision History

Date	Notes
5/22/2023	Updated criteria for recurrent ovarian cancer indication .

Rubraca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125926
Guideline Name	Rubraca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

AND

2 - BOTH of the following:

2.1 Cancer has a deleterious BRCA mutation

AND

2.2 To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy

Product Name:Rubraca	
Diagnosis	Prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic, castration-resistant prostate cancer

AND

2 - Cancer has a deleterious BRCA mutation

AND

3 - ONE of the following:

3.1 Failure to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] as confirmed by claims history or submission of medical records

OR

3.2 Contraindication or intolerance to androgen receptor-directed therapy [e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide)] (please specify intolerance or contraindication

AND

4 - History of failure, contraindication, or intolerance to taxane-based chemotherapy (e.g., docetaxel, Jevtana (cabazitaxel))

AND

5 - ONE of the following:

5.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

5.2 Patient has had bilateral orchiectomy

Product Name:Rubraca	
Diagnosis	Uterine cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA altered uterine leiomyosarcoma (uLMS)

AND

2 - Disease has progressed following prior treatment with ONE of the following:

- Gemcitabine plus docetaxel
- Doxorubicin

Product Name:Rubraca	
Diagnosis	Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic adenocarcinoma

AND

2 - Disease is metastatic

AND

3 - Presence of ONE of the following:

3.1 Deleterious or suspected deleterious germline or somatic BRCA1/2 mutation

OR

3.2 Deleterious or suspected deleterious germline or somatic PALB2 mutation

AND

4 - Disease has NOT progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

Product Name:Rubraca	
Diagnosis	Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, Prostate cancer, Uterine cancer, Pancreatic cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does NOT show evidence of progressive disease while on Rubraca therapy

Product Name:Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rubraca	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rubraca therapy

2 . Revision History

Date	Notes
5/22/2023	Updated criteria for recurrent ovarian cancer indication .

Ruconest

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148123
Guideline Name	Ruconest
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Ruconest	
Diagnosis	Hereditary Angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

- Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6
- Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
- Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

Product Name:Ruconest	
Diagnosis	Hereditary Angioedema (HAE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ruconest therapy

AND

2 - Prescribed for the acute treatment of HAE attacks

AND

3 - Not used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr)

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

2 . Revision History

Date	Notes

6/5/2024	Update to types of genetic variant(s) and diagnostic criteria with nor mal C1 inhibitor levels in initial auth section and minor language upd ate in reauth section; Minor cosmetic updates.

Rukobia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-202202
Guideline Name	Rukobia
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Mexico • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Rukobia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has been diagnosed with multidrug-resistant HIV-1 (human immunodeficiency virus type 1) infection	

AND **2** - Patient is currently taking or will be prescribed an optimized background antiretroviral regimen

2 . Revision History

Date	Notes
2/27/2025	Minor update to definition of HIV-1 in criteria, with no changes to clini cal intent. Removed NY and NY EPP from markets in scope as Ruko bia moving to open access for these markets.

Rydapt

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127938
Guideline Name	Rydapt
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FLT3 mutation-positive

AND

3 - Rydapt will be used in combination with standard induction and consolidation therapy

Product Name:Rydapt	
Diagnosis	Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

Product Name:Rydapt	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

- Patient has a FGFR1 rearrangement
- Patient has a FLT3 rearrangement

Product Name:Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML), Systemic Mastocytosis, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rydapt therapy

Product Name:Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rydapt therapy	

2 . Revision History

Date	Notes
7/13/2023	Updated formularies, cleaned up criteria in NCCN section.

Rydapt

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127938
Guideline Name	Rydapt
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FLT3 mutation-positive

AND

3 - Rydapt will be used in combination with standard induction and consolidation therapy

Product Name:Rydapt	
Diagnosis	Systemic Mastocytosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

Product Name:Rydapt	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

- Patient has a FGFR1 rearrangement
- Patient has a FLT3 rearrangement

Product Name:Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML), Systemic Mastocytosis, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Rydapt therapy

Product Name:Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Rydapt	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Rydapt therapy	

2 . Revision History

Date	Notes
7/13/2023	Updated formularies, cleaned up criteria in NCCN section.

Samsca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127872
Guideline Name	Samsca
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Brand Samsca, generic tolvaptan	
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

- Diagnosis of clinically significant euvolemic hyponatremia
- Diagnosis of clinically significant hypervolemic hyponatremia

AND

2 - Patient has not responded to fluid restriction

AND

3 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge

2 . Revision History

Date	Notes
7/11/2023	Updated formularies, cleaned up GPI and criteria.

Sandostatin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138793
Guideline Name	Sandostatin
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - ONE of the following:

2.1 Inadequate response to ONE of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 NOT a candidate for any of the following:

- Surgery
- Radiotherapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of meningioma

AND

2 - Disease is surgically inaccessible

AND

3 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

4 - Additional radiation is not possible

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has neuroendocrine tumors [e.g., carcinoid tumors, Islet cell tumors, gastrinomas, glucagonomas, insulinomas, lung tumors, somatostatinomas, tumors of the pancreas, GI (gastrointestinal) tract, lung and thymus, adrenal glands, and vasoactive intestinal polypeptidomas (VIPomas)]

OR

2 - ALL of the following:

- Diagnosis of Pheochromocytoma or Paraganglioma

- Disease is locally unresectable or distant metastases
- Disease is somatostatin receptor positive
- Presence of symptomatic disease

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

OR

2 - Documentation of positive clinical response (e.g., suppression of severe diarrhea, flushing, etc.) to the requested therapy

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymoma or thymic carcinoma

AND

2 - ONE of the following:

2.1 Used as a second-line therapy for ONE of the following:

2.1.1 Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis

OR

2.1.2 Extrathoracic metastatic disease

OR

2.2 BOTH of the following:

2.2.1 Used as first line therapy for ONE of the following:

- Unresectable locally advanced disease in combination with radiation therapy
- Potentially resectable locally advanced disease
- Potentially resectable solitary metastasis or ipsilateral pleural metastasis
- Consideration following surgery for solitary metastasis or ipsilateral pleural metastasis
- Medically inoperable/unresectable solitary metastasis or ipsilateral pleural metastasis
- Extrathoracic metastatic disease
- Postoperative treatment for thymoma after R2 resection

AND

2.2.2 Patient is unable to tolerate first-line combination regimens

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Meningioma, Thymoma or Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Malignant Bowel Obstruction
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of malignant bowel obstruction

AND

2 - Gut function cannot be maintained

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Chemotherapy- and/or Radiation-Induced Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diarrhea due to concurrent cancer chemotherapy and/or radiation

AND

2 - ONE of the following:

2.1 Presence of Grade 3 or 4 severe diarrhea

OR

2.2 Patient is in palliative or end of life care

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	HIV/AIDS-Related Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)/AIDS (acquired immunodeficiency syndrome)-related diarrhea

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Bleeding Gastroesophageal Varices
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bleeding gastroesophageal varices associated with liver disease

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Sandostatin, generic octreotide	
Diagnosis	Acromegaly, Malignant Bowel Obstruction, Chemotherapy- and/or Radiation-Induced Diarrhea, HIV/AIDS-Related Diarrhea, Bleeding Gastroesophageal Varices, NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to the requested therapy

2 . Revision History

Date	Notes
1/9/2024	Added criteria for solitary metastasis or ipsilateral pleural metastasis based off of NCCN guidelines.

Savaysa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-205208
Guideline Name	Savaysa
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Savaysa	
Diagnosis	Therapy upon hospital discharge
Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Medication is being used as continuation of therapy upon hospital discharge

Product Name:Savaysa	
Diagnosis	Stroke & Systemic Embolism Prevention in Adult Patients with Non-Valvular Atrial Fibrillation
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atrial fibrillation (AF)

AND

2 - Patient does not have an artificial heart valve

AND

3 - One of the following:

3.1 Failure to Eliquis as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)

OR

3.3 Continuation of prior Savaysa therapy

Product Name:Savaysa	
Diagnosis	Deep Vein Thrombosis or Pulmonary Embolism Treatment in Adult Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Deep vein thrombosis (DVT)
- Pulmonary embolism (PE)

AND

2 - Patient does not have an artificial heart valve

AND

3 - One of the following:

3.1 Failure to Eliquis as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)

OR

3.3 Continuation of prior Savaysa therapy

2 . Revision History

Date	Notes
2/28/2025	New

Scemblix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164748
Guideline Name	Scemblix
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Scemblix	
Diagnosis	Chronic Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myeloid leukemia (CML)

AND

2 - Disease is Philadelphia chromosome (Ph+) or BCR::ABL1-positive

AND

3 - ONE of the following:

- Used in newly diagnosed chronic phase CML (CP-CML)
- Used in previously treated chronic phase CML (CP-CML)
- Used in chronic phase CML (CP-CML) positive for a T315I mutation
- Used in accelerated phase CML as primary treatment as a single agent

Product Name:Scemblix	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and ABL1 rearrangement

AND

2 - Disease is in chronic or blast phase

Product Name:Scemblix	
Diagnosis	Chronic Myeloid Leukemia (CML), Myeloid/Lymphoid Neoplasms with Eosinophilia and ABL1 Gene Rearrangement
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Scemblix therapy

Product Name:Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Scemblix	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Scemblix therapy

2 . Revision History

Date	Notes
2/5/2025	Updated formularies. Updated GPIs. Updated initial auth criteria.

Sensipar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134726
Guideline Name	Sensipar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - ONE of the following:

2.1 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.2 ALL of the following:

2.2.1 Diagnosis of primary hyperparathyroidism (HPT)

AND

2.2.2 Severe hypercalcemia [serum calcium level greater than 12.5 mg/dL (milligrams/deciliter)] due to primary HPT

AND

2.2.3 Patient is unable to undergo parathyroidectomy

OR

2.3 ALL of the following:

2.3.1 Diagnosis of secondary hyperparathyroidism with chronic kidney disease

AND

2.3.2 Patient is on dialysis

AND

2.3.3 BOTH of the following:

2.3.3.1 ONE of the following:

- Patient has therapeutic failure to ONE phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) confirmed by claims history or submitted medical records
- Patient has intolerance or contraindication to ONE phosphate binders (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) (please specify intolerance or contraindication)

AND

2.3.3.2 ONE of the following:

- Patient has therapeutic failure to ONE vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.) confirmed by claims history or submitted medical records
- Patient has intolerance or contraindication to ONE vitamin D analogs (e.g., calcitriol, Hectorol, Zemplar, etc.) (please specify intolerance or contraindication)

Product Name:Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a reduction in serum calcium from baseline

2 . Revision History

Date	Notes
10/12/2023	Updated formularies, cleaned up criteria.

Sensipar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134726
Guideline Name	Sensipar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist

AND

2 - ONE of the following:

2.1 Diagnosis of hypercalcemia with parathyroid carcinoma

OR

2.2 ALL of the following:

2.2.1 Diagnosis of primary hyperparathyroidism (HPT)

AND

2.2.2 Severe hypercalcemia [serum calcium level greater than 12.5 mg/dL (milligrams/deciliter)] due to primary HPT

AND

2.2.3 Patient is unable to undergo parathyroidectomy

OR

2.3 ALL of the following:

2.3.1 Diagnosis of secondary hyperparathyroidism with chronic kidney disease

AND

2.3.2 Patient is on dialysis

AND

2.3.3 BOTH of the following:

2.3.3.1 ONE of the following:

- Patient has therapeutic failure to ONE phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) confirmed by claims history or submitted medical records
- Patient has intolerance or contraindication to ONE phosphate binders (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) (please specify intolerance or contraindication)

AND

2.3.3.2 ONE of the following:

- Patient has therapeutic failure to ONE vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.) confirmed by claims history or submitted medical records
- Patient has intolerance or contraindication to ONE vitamin D analogs (e.g., calcitriol, Hectorol, Zemplar, etc.) (please specify intolerance or contraindication)

Product Name:Brand Sensipar, generic cinacalcet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a reduction in serum calcium from baseline

2 . Revision History

Date	Notes
10/12/2023	Updated formularies, cleaned up criteria.

Sevelamer carbonate

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129223
Guideline Name	Sevelamer carbonate
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Generic sevelamer carbonate tablets	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - The patient did not exhibit an adequate response to treatment with at least an 8-week trial of calcium acetate as supported by claims history or submitted medical records

OR

2 - The patient experienced an intolerance/adverse reaction to previous therapy with calcium acetate (please indicate intolerance/adverse reaction)

OR

3 - The patient has a documented contraindication to treatment with calcium acetate (please indicate contraindication)

2 . Revision History

Date	Notes
8/2/2023	Updated guideline name, GPIs and product name to remove Brand R envela - step therapy only applies to generic.

SGLT2 Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-197221
Guideline Name	SGLT2 Inhibitors
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Steglatro, Segluromet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records
- History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

Product Name:Steglatro, Segluromet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Jardiance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For diagnosis of type 2 diabetes mellitus, BOTH of the following:

1.1 ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500mg daily for 90 days confirmed by claims history or submission of medical records
- History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

AND

1.2 ONE of the following:

1.2.1 Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

OR

1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

OR

2 - For diagnosis of heart failure (NYHA class II-IV), ONE of the following:

- Failure to dapagliflozin (Farxiga authorized generic) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to dapagliflozin (Farxiga authorized generic) (please specify intolerance or contraindication)

OR

3 - For diagnosis of chronic kidney disease (CKD), BOTH of the following:

3.1 ONE of the following:

- Patient is currently taking an ACE inhibitor or ARB, confirmed by claims history or submission of medical records
- History of intolerance or contraindication to ACE inhibitor or ARB (please specify intolerance or contraindication)

AND

3.2 ONE of the following:

- Failure to dapagliflozin (Farxiga authorized generic) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to dapagliflozin (Farxiga authorized generic) (please specify intolerance or contraindication)

Product Name:Jardiance	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - ONE of the following:

2.1 For diagnosis of heart failure or CKD, the prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)

OR

2.2 For diagnosis of type 2 diabetes mellitus, the prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic), Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) (please document reason/special circumstance)

Product Name:Invokana	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records
- History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 ONE of the following:

3.1.1 Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

OR

3.1.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

OR

3.2 Documented history of diabetic nephropathy with albuminuria

Product Name:Invokana	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic), Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) (please document reason/special circumstance)

Product Name:Dapagliflozin (Farxiga authorized generic)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For diagnosis of type 2 diabetes mellitus, ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500mg daily for 90 days, as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to metformin (please specify contraindication or intolerance)

OR

2 - Diagnosis of heart failure (NYHA class II-IV)

OR

3 - For diagnosis of chronic kidney disease, ONE of the following:

- Patient currently taking an ACE inhibitor or ARB, confirmed by claims history or submission of medical records
- Patient has documentation of intolerance or contraindication to ACE inhibitor or ARB (please specify intolerance or contraindication)

Product Name:Dapagliflozin (Farxiga authorized generic)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name:Farxiga	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 For diagnosis of type 2 diabetes mellitus, ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records

- History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

OR

1.2 Diagnosis of heart failure (NYHA class II-IV)

OR

1.3 For diagnosis of chronic kidney disease, ONE of the following:

- Patient is currently taking an ACE inhibitor or ARB confirmed by claims history or submission of medical records
- Patient has documentation of intolerance or contraindication to ACE inhibitor or ARB (please specify intolerance or contraindication)

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)

Product Name:Farxiga	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is

unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)

Product Name:Brenzavvy, Bexagliflozin, Synjardy, Synjardy XR, Invokamet, Invokamet XR, Xigduo XR, Dapagliflozin/Metformin ER	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus

AND

2 - ONE of the following:

- Suboptimal response to metformin at a minimum dose of 1500 mg daily for 90 days confirmed by claims history or submission of medical records
- History of intolerance or contraindication to metformin (please specify intolerance or contraindication)

AND

3 - ONE of the following:

3.1 Failure to ONE of the following therapies for 90 days confirmed by claims history or submission of medical records:

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

OR

3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin)
- Dapagliflozin (Farxiga authorized generic)

Product Name:Brenzavvy, Bexagliflozin, Synjardy, Synjardy XR, Invokamet, Invokamet XR, Xigduo XR, Dapagliflozin/Metformin ER	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic), Steglatro (ertugliflozin) OR Segluromet (ertugliflozin/metformin) (please document reason/special circumstance)

Product Name:Inpefa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 The patient has a diagnosis of heart failure

OR

1.2 ALL of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Diagnosis of chronic kidney disease

AND

1.2.3 At least ONE additional cardiovascular risk factor such as:

- History of heart failure
- Obesity
- Dyslipidemia
- Hypertension
- Elevated cardiac and inflammatory biomarkers

AND

2 - ONE of the following:

- Failure to dapagliflozin (Farxiga authorized generic) confirmed by claims history or submission of medical records
- History of contraindication or intolerance to dapagliflozin (Farxiga authorized generic) (please specify contraindication or intolerance)

Product Name:Inpefa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND **2** - The prescriber has given a clinical reason or special circumstance why the patient is unable to use dapagliflozin (Farxiga authorized generic) (please document reason/special circumstance)

2 . Revision History

Date	Notes
2/27/2025	Rhode Island market specific version to maintain metformin step thru . Added reauthorization criteria. Separated Farxiga and AG Farxiga. Updated CKD diagnosis language

Short-Acting Opioid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161930
Guideline Name	Short-Acting Opioid Products
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:butorphanol nasal soln, codeine, acetaminophen/codeine, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Brand Ascomp/codeine, generic butalbital/aspirin/caffeine/codeine, morphine tabs/oral soln/supp, generic hydrocodone/acetaminophen, Brand Xodol, hydrocodone/acetaminophen soln, hydrocodone/ibuprofen, Lortab, generic hydromorphone tabs/liqd, Brand Dilaudid, hydromorphone supp, generic oxycodone, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen, Endocet, Prolate, Brand Roxybond, Brand Oxycodone, oxymorphone, pentazocine/naloxone, Brand Ultram, generic tramadol, Qdolo, tramadol oral soln, generic tramadol/acetaminophen, Brand Ultracet, Synapryn Fusepaq, Nucynta, meperidine tab/oral soln, levorphanol, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium, opium, benzhydrocodone/acetaminophen, Apadaz, Seglentis	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - The requested dose cannot be achieved by a higher strength formulary product

AND

2 - The requested dose is within Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists

Notes	This section does NOT apply to cough and cold products.

Product Name:butorphanol nasal soln, codeine, acetaminophen/codeine, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Brand Ascomp/codeine, generic butalbital/aspirin/caffeine/codeine, morphine tabs/oral soln/supp, generic hydrocodone/acetaminophen, Brand Xodol, hydrocodone/acetaminophen soln, hydrocodone/ibuprofen, Lortab, generic hydromorphone tabs/liqd, Brand Dilaudid, hydromorphone supp, generic oxycodone, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen, Endocet, Prolate, Brand Roxybond, Brand Oxycodone, oxymorphone, pentazocine/naloxone, Brand Ultram, generic tramadol, Qdolo, tramadol oral soln, generic tramadol/acetaminophen, Brand Ultracet, Synapryn Fusepaq, Nucynta, meperidine tab/oral soln, levorphanol, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium, opium, benzhydrocodone/acetaminophen, Apadaz, Seglentis	
Diagnosis	Non-Preferred Reviews
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for tramadol 100 milligram (mg) tablets, the physician has provided rationale for needing to use the 100 mg tramadol tablet instead of two 50 mg tramadol tablets

OR

2 - If the request is for tramadol 25 mg tablets, the physician has provided rationale why the patient is unable to use half of a 50 mg tramadol tablet

OR

3 - If the request is for Qdolo (tramadol soln), ONE of the following:

3.1 The patient has a history of failure to a trial of tramadol 50 mg tablets as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to tramadol 50 mg tablets (please specify intolerance or contraindication)

OR

3.3 Patient is unable to swallow a solid dosage form

OR

3.4 Patient utilizes a feeding tube for medication administration

OR

4 - If the request is for another non-preferred* medication, then ONE of the following:

4.1 Failure of at least THREE unique active ingredients from the preferred* short-acting opioids list as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to THREE unique active ingredients from the preferred* short-acting opioids list (please specify intolerance or contraindication)

Notes	This section does NOT apply to cough and cold products. *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:acetaminophen/codeine tabs, morphine supp, generic hydrocodone/acetaminophen tabs, Brand Xodol, hydrocodone/ibuprofen, generic oxycodone caps/tabs, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen tabs, Endocet, Prolate tabs, Brand Ultram, generic tramadol tabs, generic tramadol/acetaminophen, Brand Ultracet, meperidine tabs	
Diagnosis	Opioid Naïve (not having filled an opioid in the past 60 days)
Guideline Type	Quantity Limit/Morphine Milligram Equivalents (MME)*
Approval Criteria **1** - Requests for quantities exceeding 30 MME (morphine milligram equivalents, see Table 1 in Background) and/or 20 units will be approved for patients who meet at least ONE of the following: • End of life care, including hospice care • Palliative care • Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance) • Post-surgery • Sickle cell diagnosis • Attestation from the provider that the patient is not opioid-naïve	
Notes	This section does NOT apply to cough and cold products. *Authorization will be issued for a one-time override to allow for the re quested MME and/or quantity limit

Product Name:butorphanol nasal soln, codeine, acetaminophen/codeine, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Brand Ascomp/codeine, generic butalbital/aspirin/caffeine/codeine, morphine tabs/oral soln/supp, generic hydrocodone/acetaminophen, Brand Xodol, hydrocodone/acetaminophen soln, hydrocodone/ibuprofen, Lortab, generic hydromorphone tabs/liqd, Brand Dilaudid, hydromorphone supp, generic oxycodone, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen, Endocet, Prolate, Brand Roxybond, Brand Oxycodone, oxymorphone, pentazocine/naloxone, Brand Ultram, generic tramadol, Qdolo, tramadol oral soln, generic tramadol/acetaminophen, Brand Ultracet, Synapryn Fusepaq, Nucynta, meperidine tab/oral soln, levorphanol, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium, opium, benzhydrocodone/acetaminophen, Apadaz, Seglentis	
Diagnosis	Cancer-related pain/Hospice/End-of-Life Related Pain Exceeding the 90 MME Cumulative Threshold
Approval Length	12 month(s)

Guideline Type	Morphine Milligram Equivalents (MME) Reviews*

Approval Criteria

1 - Doses exceeding the cumulative morphine milligram equivalents (MME) of 90 milligrams will be approved if the patient has ONE of the following:

- Cancer-related pain (i.e., patients undergoing active cancer treatment; or cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance)
- Hospice pain
- An end-of-life diagnosis

Notes	This section does NOT apply to cough and cold products. *Authorization will be issued for 12 months for cancer-related pain/hospice/end-of-life related pain. The authorization should be entered for an MME of 9999 so as to prevent future disruptions in therapy if the patient's dose is increased.

Product Name:butorphanol nasal soln, codeine, acetaminophen/codeine, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Brand Ascomp/codeine, generic butalbital/aspirin/caffeine/codeine, morphine tabs/oral soln/supp, generic hydrocodone/acetaminophen, Brand Xodol, hydrocodone/acetaminophen soln, hydrocodone/ibuprofen, Lortab, generic hydromorphone tabs/liqd, Brand Dilaudid, hydromorphone supp, generic oxycodone, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen, Endocet, Prolate, Brand Roxybond, Brand Oxycodone, oxymorphone, pentazocine/naloxone, Brand Ultram, generic tramadol, Qdolo, tramadol oral soln, generic tramadol/acetaminophen, Brand Ultracet, Synapryn Fusepaq, Nucynta, meperidine tab/oral soln, levorphanol, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium, opium, benzhydrocodone/acetaminophen, Apadaz, Seglentis

Diagnosis	Non-Cancer-related pain/Non-Hospice/Non-end-of-life Related Pain Exceeding the 90 MME Cumulative Threshold
Therapy Stage	Initial Authorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews*

Approval Criteria

1 - Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

2 - Treatment goals are defined and include estimated duration of treatment (must document treatment goals)

AND

3 - Patient has been screened for underlying depression and/or anxiety. If applicable, any underlying conditions have been or will be addressed

AND

4 - BOTH of the following:

4.1 Patient has tried and failed non-opioid pain medication (document drug name and date of trial)

AND

4.2 Opioid medication doses of less than 90 morphine milligram equivalents (MME) have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

Notes	This section does NOT apply to cough and cold products. *Authorization will be issued for 6 months for non-cancer-related pain/ non-hospice/non-end-of-life related pain up to the current requested M ME plus 90 MME. If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization c riteria requirements, a denial should be issued and a maximum 60-da y authorization may be authorized one time for the requested MME do se.

Product Name:butorphanol nasal soln, codeine, acetaminophen/codeine, generic butalbital/acetaminophen/caffeine/codeine, Brand Fioricet/codeine, Brand Ascomp/codeine, generic butalbital/aspirin/caffeine/codeine, morphine tabs/oral soln/supp, generic hydrocodone/acetaminophen, Brand Xodol, hydrocodone/acetaminophen soln, hydrocodone/ibuprofen, Lortab, generic hydromorphone tabs/liqd, Brand Dilaudid,

hydromorphone supp, generic oxycodone, Brand Roxicodone, Oxaydo, Nalocet, Brand Percocet, generic oxycodone/acetaminophen, Endocet, Prolate, Brand Roxybond, Brand Oxycodone, oxymorphone, pentazocine/naloxone, Brand Ultram, generic tramadol, Qdolo, tramadol oral soln, generic tramadol/acetaminophen, Brand Ultracet, Synapryn Fusepaq, Nucynta, meperidine tab/oral soln, levorphanol, generic acetaminophen/caffeine/dihydrocodeine, Brand Trezix, belladonna/opium, opium, benzhydrocodone/acetaminophen, Apadaz, Seglentis	
Diagnosis	Non-Cancer-related pain/Non-Hospice/Non-end-of-life Related Pain Exceeding the 90 MME Cumulative Threshold
Therapy Stage	Reauthorization
Guideline Type	Morphine Milligram Equivalents (MME) Reviews*

Approval Criteria

1 - Prescriber attests that the patient has been screened for substance abuse/opioid dependence

AND

2 - Documented rationale for not tapering or discontinuing opioid if treatment goals are not met

AND

3 - Documented meaningful improvement in pain and function when assessed against treatment goals (Document improvement in function or pain score improvement)

Notes	This section does NOT apply to cough and cold products. *Authorization will be issued for 6 months for non-cancer-related pain/ non-hospice/non-end-of-life related pain up to the current requested M ME plus 90 MME. If the patient has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization c riteria requirements, a denial should be issued and a maximum 60-da y authorization may be authorized one time for the requested MME do se.

Product Name:Brand Hycodan, generic hydrocodone/homatropine, Hydromet, hydrocodone/chlorpheniramine, Tuxarin ER, Ninjacof-XG, Coditussin AC, Mar-Cof CG Expectorant, codeine/guaifenesin, G Tussin AC, Guaiatussin AC, guaifenesin AC,

guaifenesin/codeine, Maxi-Tuss AC, Virtussin A/C, M-End PE, Poly-Tussin AC, Rydex, Mar-Cof BP, Maxi-Tuss CD, Capcof, Pro-Red AC, Histex-AC, promethazine VC/codeine, promethazine/phenylephrine/codeine, promethazine/codeine, Coditussin DAC, Tusnel C, Tuzistra XR	
Diagnosis	Cough and Cold Products Exceeding the 90 MME Cumulative Threshold
Guideline Type	Morphine Milligram Equivalents (MME) Reviews*
Approval Criteria **1** - The prescriber attests they are aware of patient's current opioid therapy and morphine milligram equivalent (MME) dose and feels the treatment with the requested product is medically necessary	
Notes	*Approval duration: Authorization will be issued for up to 30 days for c ough and cold related treatment. The authorization should be entered for the MME requested.

Product Name:Brand Hycodan, generic hydrocodone/homatropine, Hydromet, hydrocodone/chlorpheniramine, Tuxarin ER, Ninjacof-XG, Coditussin AC, Mar-Cof CG Expectorant, codeine/guaifenesin, G Tussin AC, Guaiatussin AC, guaifenesin AC, guaifenesin/codeine, Maxi-Tuss AC, Virtussin A/C, M-End PE, Poly-Tussin AC, Rydex, Mar-Cof BP, Maxi-Tuss CD, Capcof, Pro-Red AC, Histex-AC, promethazine VC/codeine, promethazine/phenylephrine/codeine, promethazine/codeine, Coditussin DAC, Tusnel C, Tuzistra XR	
Diagnosis	Under the Age of 18 Years for Cough and Cold Products
Approval Length	30 Day(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Prescriber attests they are aware of the Food and Drug Administration (FDA) labeled contraindications regarding use of opioid containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary (Document rationale for use) **AND**	

2 - Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index greater than 30)

AND

3 - Patient has tried and failed at least one non-opioid containing cough and cold remedy

Product Name:Brand Hycodan, generic hydrocodone/homatropine, Hydromet, hydrocodone/chlorpheniramine, Tuxarin ER, Ninjacof-XG, Coditussin AC, Mar-Cof CG Expectorant, codeine/guaifenesin, G Tussin AC, Guaiatussin AC, guaifenesin AC, guaifenesin/codeine, Maxi-Tuss AC, Virtussin A/C, M-End PE, Poly-Tussin AC, Rydex, Mar-Cof BP, Maxi-Tuss CD, Capcof, Pro-Red AC, Histex-AC, promethazine VC/codeine, promethazine/phenylephrine/codeine, promethazine/codeine, Coditussin DAC, Tusnel C, Tuzistra XR	
Diagnosis	Cough and Cold Products Exceeding 120mL per fill and/or 360mL per 30 days*
Guideline Type	Quantity Limit**
Approval Criteria **1** - Doses exceeding the quantity limit will be approved up to the requested amount if the prescriber attests that a larger quantity is medically necessary **AND** **2** - The requested dose is within the Food and Drug Administration (FDA) maximum dose per day, where an FDA maximum dose per day exists	
Notes	*Quantity Limit Rules in place: • 120mL/fill • 360mL/30 days **Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.

Product Name:Brand Hycodan, generic hydrocodone/homatropine, Hydromet, hydrocodone/chlorpheniramine, Tuxarin ER, Ninjacof-XG, Coditussin AC, Mar-Cof CG Expectorant, codeine/guaifenesin, G Tussin AC, Guaiatussin AC, guaifenesin AC, guaifenesin/codeine, Maxi-Tuss AC, Virtussin A/C, M-End PE, Poly-Tussin AC, Rydex, Mar-

Cof BP, Maxi-Tuss CD, Capcof, Pro-Red AC, Histex-AC, promethazine VC/codeine, promethazine/phenylephrine/codeine, promethazine/codeine, Coditussin DAC, Tusnel C, Tuzistra XR	
Diagnosis	Non-Preferred Cough and Cold Product Reviews
Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred* medication, then ONE of the following:

1.1 Failure of at least THREE unique active ingredients from the preferred* cough and cold products list as confirmed by claims history or submission of medical records

OR

1.2 History of intolerance or contraindication to at least THREE unique active ingredients from the preferred* cough and cold products list (please specify intolerance or contraindication)

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

2 . Background

Clinical Practice Guidelines

Table 1.

Drug Name	Dosage Strength	Max # of units/day
Acetaminophen-cod #2 Tablet	300MG-15MG	13.33333333
Acetaminophen-cod #3 Tablet	300MG-30MG	6.666666667
Acetaminophen-cod #4 Tablet	300MG-60MG	3.333333333
Endocet 2.5-325 Mg Tablet	2.5-325 MG	8
Endocet 5-325 Tablet	5 MG-325MG	4

Endocet 7.5-325 Mg Tablet	7.5-325 MG	2.666666667
Hydrocodone-acetaminophen 2.5-325	2.5-325 MG	12
Hydrocodone-acetaminophen 7.5-300	7.5-300 MG	4
Hydrocodone-acetaminophen 7.5-325	7.5-325 MG	4
Hydrocodone-acetaminophen 7.5-750	7.5-750 MG	4
Hydrocodone-acetaminophen 5-300	5 MG-300MG	6
Hydrocodone-acetaminophen 5-325	5 MG-325MG	6
Hydrocodone-acetaminophen 5-500	5 MG-500MG	6
Hydrocodone-acetaminophen 10-300	10MG-300MG	3
Hydrocodone-acetaminophen 10-325	10MG-325MG	3
Hydrocodone-ibuprofen 2.5-200	2.5-200MG	12
Hydrocodone-ibuprofen 5-200 Mg	5MG-200MG	6
Hydrocodone-ibuprofen 7.5-200	7.5-200 MG	4
Hydrocodone-ibuprofen 10-200	10MG-200MG	3
Meperidine 50 Mg Tablet	50 MG	6
Meperidine 100 Mg Tablet	100 MG	3
Morphine 10 Mg Suppository	10 MG	3
Oxaydo 7.5 Mg Tablet	7.5 MG	2.666666667
Oxycodone 5 Mg Capsule	5 MG	4
Oxycodone 5 Mg Tablet	5 MG	4
Oxycodone-aspirin 4.83-325 Mg	4.8355-325	4.136076931
Primlev 5-300 Mg Tablet	5 MG-300MG	4
Tramadol 50 Mg Tablet	50 MG	6
Tramadol-acetaminophen 37.5-325	37.5-325MG	8

3 . Revision History

Date	Notes
12/11/2024	Added hydrocodone/apap 10/325 soln, tramadol 75mg and hydrocod one/apap 2.5/325. Updated Roxybond GPIs and added Brand oxyco done abuse deter GPIs. Updated cancer language.

Signifor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117468
Guideline Name	Signifor
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Signifor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

2 - One of the following:

- Pituitary surgery has not been curative for the patient
- Patient is not a candidate for pituitary surgery

Product Name:Signifor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Signifor therapy

2 . Revision History

Date	Notes
11/30/2022	Updated Markets in Scope. No changes to clinical criteria

Siliq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208187
Guideline Name	Siliq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Siliq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic moderate to severe plaque psoriasis

AND

2 - Patient is not receiving Siliq in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Siliq therapy as confirmed by claims history or submitted medical records

OR

4.2 All of the following:

4.2.1 One of the following:

4.2.1.1 All of the following:

4.2.1.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

4.2.1.1.2 One of the following:

- Failure of ONE of the following topical therapy classes as confirmed by claims history or submitted medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

AND

4.2.1.1.3 One of the following:

- Failure of a 3 month trial of methotrexate, at maximally indicated dose, confirmed by claims history or submitted medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

4.2.1.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

4.2.2 One of the following:

4.2.2.1 Failure to TWO of the following preferred products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

4.2.3 One of the following:

4.2.3.1 Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records

OR

4.2.3.2 History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

Notes	*See PDL links in Background

Product Name:Siliq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Siliq therapy

AND

2 - Patient is not receiving Siliq in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/4/2025	Updated formularies. Removed reference to brand Stelara throughout. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Updated note to reference PDL links in background. Added NM to PDL links in background.

Simponi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208189
Guideline Name	Simponi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Simponi	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Failure to a 3 month trial of ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, confirmed by claims history or submitted medical records

OR

4.2.1.2 History of intolerance or contraindication to ONE non-biologic DMARD (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) (please specify intolerance or contraindication)

OR

4.2.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

AND

4.2.2 ONE of the following:

- Failure to THREE of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products*, Enbrel (etanercept), Olumiant (baricitinib), Tyenne (tocilizumab-aazg)
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, Enbrel (etanercept), Olumiant (baricitinib), Tyenne (tocilizumab-aazg)

Notes	*See PDL links in Background

Product Name:Simponi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz

(ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records

OR

4.2.1.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

4.2.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

AND

4.2.2 BOTH of the following:

4.2.2.1 ONE of the following:

- Failure to TWO of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products*, Enbrel (etanercept), One of the preferred ustekinumab products*
- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, Enbrel (etanercept), One of the preferred ustekinumab products*

AND

4.2.2.2 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Simponi	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - ONE of the following:

4.1 Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks confirmed by claims history or submitted medical records

OR

4.2.1.2 History of intolerance or contraindication to TWO NSAIDs (please specify intolerance or contraindication)

OR

4.2.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)]

AND

4.2.2 BOTH of the following:

4.2.2.1 ONE of the following:

- Failure to BOTH of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products*, Enbrel (etanercept)
- History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, Enbrel (etanercept)

AND

4.2.2.2 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Simponi	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab)]

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - ONE of the following:

4.1 Patient is currently on Simponi therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 ONE of the following:

4.2.1.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records

OR

4.2.1.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

4.2.2 ONE of the following:

- Failure to one of the following as confirmed by claims history or submitted medical records: One of the preferred adalimumab products*, One of the preferred ustekinumab products*

• History of intolerance or contraindication to both of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, One of the preferred ustekinumab products*

Notes	*See PDL links in Background

Product Name:Simponi	
Diagnosis	Rheumatoid Arthritis (RA), Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Simponi therapy

AND

2 - Patient is NOT receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL Links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/4/2025	Updated formularies. Added ustekinumab as a step therapy option in PsA and UC. Replaced Stelara with ustekinumab throughout. Added NM to PDL links in background.

Sivextro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155228
Guideline Name	Sivextro
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Sivextro tablets	
Diagnosis	Skin and Skin Structure Infections
Approval Length	6 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - ALL of the following:

3.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

3.2 ONE of the following:

3.2.1 Infection is caused by methicillin-resistant Staphylococcus aureus (MRSA) documented by culture and sensitivity report

OR

3.2.2 Presence of MRSA infection is likely and empiric treatment is warranted

AND

3.3 ONE of the following:

3.3.1 Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records

OR

3.3.2 History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

AND

3.4 ONE of the following:

3.4.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

3.4.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

4 - ALL of the following:

4.1 Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

AND

4.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

AND

4.3 ONE of the following:

4.3.1 Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records

OR

4.3.2 History of intolerance or contraindication to linezolid (generic Zyvox) (please specify intolerance or contraindication)

AND

4.4 ONE of the following:

4.4.1 Failure of TWO of the following confirmed by claims history or submitted medical records:

- A penicillin
- A cephalosporin
- A tetracycline
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

OR

4.4.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- A Penicillin
- A cephalosporin
- A tetracycline
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Product Name:Sivextro tablets	
Diagnosis	Off-Label Uses
Approval Length	Based on provider and IDSA recommended treatment durations, up to 6 months.

Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of therapy upon hospital discharge

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - BOTH of the following:

3.1 The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

AND

3.2 ONE of the following:

3.2.1 Failure of linezolid (generic Zyvox) confirmed by claims history or submitted medical records, if susceptibility is confirmed by culture

OR

3.2.2 History of intolerance or contraindication to linezolid (generic Zyvox), if susceptibility is confirmed by culture (please specify intolerance or contraindication)

2 . Revision History

Date	Notes

9/18/2024	Added “tablets” to product name to clarify that the policy is specific to oral tablets not IV form

Skyclarys

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127205
Guideline Name	Skyclarys
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Friedreich's ataxia

AND

2 - Confirmed presence of a mutation in the frataxin (FXN) gene

AND

3 - Prescribed by, or in consultation with, one of the following:

- Neurologist
- Neurogeneticist
- Physical Medicine and Rehabilitation physician (i.e., physiatrist)

Product Name:Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Skyclarys therapy

AND

2 - Prescribed by, or in consultation with, one of the following:

- Neurologist
- Neurogeneticist
- Physical Medicine and Rehabilitation physician (i.e., physiatrist)

2 . Revision History

Date	Notes
6/28/2023	New guideline

Skyrizi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208191
Guideline Name	Skyrizi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Skyrizi	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Skyrizi therapy as confirmed by claims history or submission of medical records

OR

4.2 ALL of the following:

4.2.1 One of the following:

4.2.1.1 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, ustekinumab, Tremfya (guselkumab)]

OR

4.2.1.2 All of the following:

4.2.1.2.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

4.2.1.2.2 One of the following:

- Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar
- History of intolerance or contraindication to ALL of the following topical therapies classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

AND

4.2.1.2.3 One of the following:

- Failure to a 3 month trial of methotrexate at maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

AND

4.2.2 One of the following:

4.2.2.1 Failure to TWO of the following preferred products, confirmed by claims history or submitted medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

4.2.3 One of the following:

- Failure to Cosentyx (secukinumab) confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Skyrizi	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Skyrizi therapy as confirmed by claims history or submission of medical records

OR

4.2 BOTH of the following:

4.2.1 One of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)
- Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., adalimumab, Cimzia (certolizumab), Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

AND

4.2.2 Both of the following:

4.2.2.1 One of the following:

- Failure to TWO of the following as confirmed by claims history or submission of medical records: One of the preferred adalimumab products*, Enbrel (etanercept), One of the preferred ustekinumab products*

- History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication): One of the preferred adalimumab products*, Enbrel (etanercept), One of the preferred ustekinumab products*

AND

4.2.2.2 One of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Skyrizi	
Diagnosis	Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn’s disease

AND

2 - One of the following:

2.1 Patient has been established on therapy with Skyrizi under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active Crohn’s disease

OR

2.2 Patient is currently on Skyrizi therapy for moderately to severely active Crohn’s disease as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Skyrizi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Patient has been established on therapy with Skyrizi under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

2.2 Patient is currently on Skyrizi therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, adalimumab]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Skyrizi	
Diagnosis	Plaque Psoriasis, Psoriatic Arthritis (PsA), Crohn's Disease (CD), Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Skyrizi therapy

AND

2 - Patient is NOT receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes

3/4/2025	Updated formularies. Removed reference to brand Stelara throughout. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Added ustekinumab as ST option in PsA. Added NM to PDL links in background.

Sohonos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143178
Guideline Name	Sohonos
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Sohonos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fibrodysplasia ossificans progressiva (FOP)

AND

2 - Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Patient is female
- Patient is 8 years of age or older

OR

3.2 BOTH of the following:

- Patient is male
- Patient is 10 years of age or older

AND

4 - Sohonos is being used to reduce the volume of new heterotopic ossification (HO)

AND

5 - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

Product Name:Sohonos	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response [e.g., reduction in new HO (heterotopic ossification) volume, improved CAJIS (Cumulative Analogue Joint Involvement Scale) and FOP-PFQ (Fibrodysplasia Ossificans Progressiva-Physical Function Questionnaire) scores, improved quality of life]

AND

2 - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

2 . Revision History

Date	Notes
2/21/2024	New guideline

Sohonos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143178
Guideline Name	Sohonos
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Sohonos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fibrodysplasia ossificans progressiva (FOP)

AND

2 - Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene

AND

3 - ONE of the following:

3.1 BOTH of the following:

- Patient is female
- Patient is 8 years of age or older

OR

3.2 BOTH of the following:

- Patient is male
- Patient is 10 years of age or older

AND

4 - Sohonos is being used to reduce the volume of new heterotopic ossification (HO)

AND

5 - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

Product Name:Sohonos	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response [e.g., reduction in new HO (heterotopic ossification) volume, improved CAJIS (Cumulative Analogue Joint Involvement Scale) and FOP-PFQ (Fibrodysplasia Ossificans Progressiva-Physical Function Questionnaire) scores, improved quality of life]

AND

2 - Prescribed by or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, pediatric rheumatologist)

2 . Revision History

Date	Notes
2/21/2024	New guideline

Somavert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129151
Guideline Name	Somavert
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Somavert	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of acromegaly confirmed by ONE of the following:

1.1.1 Serum GH (growth hormone) level greater than 1 ng/mL (nanogram/milliliter) after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis

OR

1.1.2 Elevated serum IGF-1 (insulin-like growth factor-1) levels (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

AND

1.2 ONE of the following:

1.2.1 Inadequate response to ONE of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

1.2.2 NOT a candidate for any of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

1.3 Inadequate response, intolerance, or contraindication to a long-acting somatostatin analog [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)]

OR

2 - Patient is currently on Somavert therapy for acromegaly

Product Name:Somavert	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Somavert therapy (e.g., age-normalized serum IGF-1 level)	

2 . Revision History

Date	Notes
8/1/2023	Updated all criteria sections, removed note, and updated indications.

Soriatane

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121807
Guideline Name	Soriatane
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name:acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe psoriasis

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - ONE of the following:

3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose, as confirmed by claims history or submission of medical records

OR

3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

AND

4 - ONE of the following:

- Greater than or equal to 10% body surface area involvement
- Palmoplantar, facial, or genital involvement
- Severe scalp psoriasis

Product Name:acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to the requested therapy **AND** **2** - Prescribed by or in consultation with a dermatologist

2 . Revision History

Date	Notes
2/28/2023	Updated GPI and product name lists, updated trial and failure criteria , cleaned up criteria.

Sotyktu

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208193
Guideline Name	Sotyktu
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - ONE of the following:

2.1 ALL of the following:

2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

2.1.3 ONE of the following:

2.1.3.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose confirmed by claims history or submission of medical records

OR

2.1.3.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

3 - ONE of the following:

3.1 Patient is currently on Sotyktu therapy as confirmed by claims history or submission of medical records

OR

3.2 BOTH of the following:

3.2.1 ONE of the following:

3.2.1.1 Failure to ALL of the following preferred products confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

OR

3.2.1.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products*
- Enbrel (etanercept)
- One of the preferred ustekinumab products*

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to Cosentyx (secukinumab) confirmed by claims history or submission of medical records

OR

3.2.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

AND

4 - Patient is NOT receiving Sotyktu in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*See PDL links in Background

Product Name:Sotyktu	
Diagnosis	Plaque Psoriasis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sotyktu therapy

AND

2 - Patient is NOT receiving Sotyktu in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

2 . Background

Benefit/Coverage/Program Information

PDL Links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/4/2025	Updated formularies. Removed reference to brand Stelara throughout. Removed Ilumya step in PsO section and added preferred ustekinumab as step therapy option. Added bypass language to patients currently taking Sotyktu. Added NM to PDL links in background.

Spevigo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151119
Guideline Name	Spevigo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/8/2024

1 . Criteria

Product Name:Spevigo SC	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) based on BOTH of the following:

1.1 Presence of primary, sterile, macroscopically visible pustules on non-acral skin

AND

1.2 Pustulation is NOT restricted to psoriatic plaques

AND

2 - BOTH of the following:

- Used to prevent GPP flares
- Patient is NOT currently experiencing a GPP flare

AND

3 - ONE of the following:

3.1 Patient has been established on therapy with Spevigo for GPP under an active UnitedHealthcare medical benefit prior authorization

OR

3.2 Patient is currently on Spevigo therapy for GPP as documented by claims history or submission of medical records (Document date and duration of therapy)

AND

4 - Patient is NOT receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

AND

5 - Prescribed by a dermatologist

Product Name:Spevigo SC	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in the rate and/or number of GPP flares)

AND

2 - Reduction in the utilization of therapy (e.g., intravenous Spevigo) used for GPP flares

AND

3 - Patient is NOT receiving Spevigo in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

AND

4 - Prescribed by a dermatologist

2 . Revision History

Date	Notes
8/7/2024	New program.

Spravato

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150592
Guideline Name	Spravato
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of major depressive disorder (treatment-resistant), according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5-TR) criteria, by a mental health professional

AND

2 - Prescribed by or in consultation with a psychiatrist

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline scoring (prior to starting Spravato) on at least ONE of the following clinical assessments has been completed:

- Baseline score on the 17-item Hamilton Rating Scale for Depression (HAMD17)
- Baseline score on the 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16)
- Baseline score on the 10-item Montgomery-Asberg Depression Rating Scale (MADRS)
- Baseline score on the 9-item Patient Health Questionnaire (PHQ-9)

AND

4 - ONE of the following:

4.1 Failure of THREE different antidepressant medications or treatment regimens at the maximally tolerated dose(s) for at least 8 weeks in the current depressive episode, confirmed by claims history or submitted medical records. An antidepressant or treatment regimen would include any of the following classes or combinations:

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with lithium, Cytomel (liothyronine), antipsychotics, or anticonvulsants

OR

4.2 History of intolerance or contraindication to THREE of the following antidepressant medications or treatment regimens (please specify intolerance or contraindication). An antidepressant or treatment regimen would include any of the following classes or combinations:

- Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline)
- Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.)
- Bupropion
- Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.)
- Mirtazapine
- Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.)
- Serotonin modulators (e.g., nefazodone, trazodone, etc.)
- Augmentation with lithium, Cytomel (liothyronine), antipsychotics, or anticonvulsants

AND

5 - Spravato will be used in combination with an oral antidepressant (one that the patient has not previously failed)

AND

6 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

Product Name:Spravato	
Diagnosis	Major Depressive Disorder (Treatment-Resistant)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of remission or a positive clinical response to Spravato therapy

AND

2 - Spravato will be used in combination with an oral antidepressant (confirmed by claims history or submitted medical records)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting baseline and recent (within the last month) scoring on at least ONE of the following assessments demonstrating remission or clinical response (e.g., score reduction from baseline) as defined by:

- Hamilton Rating Scale for Depression (HAMD17; remission defined as a score of less than or equal to 7)
- Quick Inventory of Depressive Symptomatology (QIDS-C16; remission defined as a score of less than or equal to 5)
- Montgomery-Asberg Depression Rating Scale (MADRS; remission defined as a score of less than or equal to 12)
- Baseline score on the 9-item Patient Health Questionnaire (PHQ-9)

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

AND

5 - Prescribed by or in consultation with a psychiatrist

Product Name:Spravato*	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of major depressive disorder according to the current Diagnostic and Statistical Manual of Mental Disorders (DSM) (i.e., DSM-5-TR) criteria, by a mental health professional

AND

2 - Patient is experiencing an acute suicidal ideation or behavior

AND

3 - Spravato will be used in combination with a newly initiated or optimized oral antidepressant

AND

4 - Provider and/or the provider's healthcare setting is certified in the Spravato REMS (Risk Evaluation and Mitigation Strategy) program

Notes	*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg s trength and 0.43 per day for the 84mg strength. If criteria are met, ent er one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.

Product Name:Spravato*	
Diagnosis	Depressive symptoms in an adult with major depressive disorder (MDD) with acute suicidal ideation or behavior
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - The requested drug is prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature

Notes	*Spravato is hard-coded with a quantity of 0.29 per day for the 56mg s trength and 0.43 per day for the 84mg strength. If criteria are met, ent er one GPI-12 authorization with an MDD override of 1 and a PQE of 24 per 28 days.

2 . Revision History

Date	Notes
7/30/2024	Changed reauth lengths to 12 months. Modified note to detail authori zation MDD and PQE per discussion with policy team and PA Ops.

Sprycel

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161079
Guideline Name	Sprycel
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myeloid leukemia

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib as attested by physician

OR

2.2 Patient is currently on Sprycel therapy

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST) with PDGFRA exon 18 mutations

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic chondrosarcoma

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has an ABL1 (gene) rearrangement

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous melanoma

AND

2 - Tumors are metastatic or unresectable

AND

3 - Contains activating mutations of KIT

AND

4 - Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia, Ph+ALL, GIST, Chondrosarcoma, Chordoma, Myeloid/Lymphoid Neoplasms with Eosinophilia, Cutaneous Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sprycel therapy

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Sprycel, generic dasatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sprycel therapy

2 . Revision History

Date	Notes
11/20/2024	Updated GPIs and product list to add generic. Updated criteria for GI ST

Stivarga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152502
Guideline Name	Stivarga
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Stivarga	
Diagnosis	Colorectal Cancer (CRC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:

- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Fluoropyrimidine-based chemotherapy
- Anti-VEGF therapy-based chemotherapy

AND

3 - ONE of the following:

3.1 Tumor is RAS mutant-type

OR

3.2 BOTH of the following:

3.2.1 Tumor is RAS wild-type

AND

3.2.2 History of failure, contraindication, or intolerance to anti-EGFR therapy [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]

Product Name:Stivarga	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of soft tissue sarcoma (STS)

AND

2 - ONE of the following:

2.1 Extremity/superficial trunk or head/neck that is non-adipocytic with advanced/metastatic disease with disseminated metastases

OR

2.2 Retroperitoneal/intra-abdominal that is non-adipocytic with recurrent unresectable or stage IV disease

OR

2.3 Advanced/metastatic pleomorphic rhabdomyosarcoma

OR

2.4 Angiosarcoma

Product Name:Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is one of the following:

- Gross residual (R2 resection)
- Unresectable primary
- Tumor rupture
- Recurrent/metastatic

AND

3 - One of the following:

3.1 SDH-deficient GIST

OR

3.2 One of the following

3.2.1 Failure to both of the following as confirmed by claims history or submission of medical records:

- imatinib mesylate (generic Gleevec)
- sunitinib malate) (generic Sutent)

OR

3.2.2 History of contraindication or intolerance to both of the following (please specify intolerance or contraindication):

- imatinib mesylate (generic Gleevec)
- sunitinib malate) (generic Sutent)

Product Name:Stivarga

Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic cholangiocarcinoma
- Intrahepatic cholangiocarcinoma

AND

1.2 Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

OR

2 - BOTH of the following:

2.1 Diagnosis of hepatocellular carcinoma

AND

2.2 Used as subsequent-line therapy for disease progression

Product Name:Stivarga	
Diagnosis	Bone Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Osteosarcoma
- Dedifferentiated chondrosarcoma
- High grade undifferentiated pleomorphic sarcoma (UPS)
- Ewing Sarcoma

AND

2 - Disease is ONE of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second-line therapy

Product Name:Stivarga	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or progressive glioblastoma

Product Name:Stivarga

Diagnosis	Colorectal Cancer (CRC), Soft Tissue Sarcoma (STS), Gastrointestinal Stromal Tumor (GIST), Hepatobiliary Cancer, Bone Cancer, Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name:Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stivarga therapy

2 . Revision History

Date	Notes
8/22/2024	Added examples to anti-EGFR therapy. Removed “criteria” from all re authorization sections. Separated gastrointestinal stromal tumor crite ria from soft tissue sarcoma criteria and updated criteria per NCCN g uideline. Added disease subtype criteria to hepatobiliary cancer secti on. Changed osteosarcoma section to bone cancer and added Ewing Sarcoma to criteria per NCCN guideline.

Stivarga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152502
Guideline Name	Stivarga
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Stivarga	
Diagnosis	Colorectal Cancer (CRC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic colorectal cancer

AND

2 - History of failure, contraindication, or intolerance to treatment with ALL of the following:

- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy
- Fluoropyrimidine-based chemotherapy
- Anti-VEGF therapy-based chemotherapy

AND

3 - ONE of the following:

3.1 Tumor is RAS mutant-type

OR

3.2 BOTH of the following:

3.2.1 Tumor is RAS wild-type

AND

3.2.2 History of failure, contraindication, or intolerance to anti-EGFR therapy [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]

Product Name:Stivarga	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of soft tissue sarcoma (STS)

AND

2 - ONE of the following:

2.1 Extremity/superficial trunk or head/neck that is non-adipocytic with advanced/metastatic disease with disseminated metastases

OR

2.2 Retroperitoneal/intra-abdominal that is non-adipocytic with recurrent unresectable or stage IV disease

OR

2.3 Advanced/metastatic pleomorphic rhabdomyosarcoma

OR

2.4 Angiosarcoma

Product Name:Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Disease is one of the following:

- Gross residual (R2 resection)
- Unresectable primary
- Tumor rupture
- Recurrent/metastatic

AND

3 - One of the following:

3.1 SDH-deficient GIST

OR

3.2 One of the following

3.2.1 Failure to both of the following as confirmed by claims history or submission of medical records:

- imatinib mesylate (generic Gleevec)
- sunitinib malate) (generic Sutent)

OR

3.2.2 History of contraindication or intolerance to both of the following (please specify intolerance or contraindication):

- imatinib mesylate (generic Gleevec)
- sunitinib malate) (generic Sutent)

Product Name:Stivarga

Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic cholangiocarcinoma
- Intrahepatic cholangiocarcinoma

AND

1.2 Disease is ONE of the following:

- Unresectable
- Resected gross residual (R2)
- Metastatic

OR

2 - BOTH of the following:

2.1 Diagnosis of hepatocellular carcinoma

AND

2.2 Used as subsequent-line therapy for disease progression

Product Name:Stivarga	
Diagnosis	Bone Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Osteosarcoma
- Dedifferentiated chondrosarcoma
- High grade undifferentiated pleomorphic sarcoma (UPS)
- Ewing Sarcoma

AND

2 - Disease is ONE of the following:

- Relapsed/refractory
- Metastatic

AND

3 - Used as second-line therapy

Product Name:Stivarga	
Diagnosis	Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or progressive glioblastoma

Product Name:Stivarga

Diagnosis	Colorectal Cancer (CRC), Soft Tissue Sarcoma (STS), Gastrointestinal Stromal Tumor (GIST), Hepatobiliary Cancer, Bone Cancer, Glioblastoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Stivarga therapy

Product Name:Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Stivarga	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Stivarga therapy

2 . Revision History

Date	Notes
8/22/2024	Added examples to anti-EGFR therapy. Removed “criteria” from all re authorization sections. Separated gastrointestinal stromal tumor crite ria from soft tissue sarcoma criteria and updated criteria per NCCN g uideline. Added disease subtype criteria to hepatobiliary cancer secti on. Changed osteosarcoma section to bone cancer and added Ewing Sarcoma to criteria per NCCN guideline.

Strensiq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136412
Guideline Name	Strensiq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Strensiq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on ALL of the following:

1.1 ONE of the following:

1.1.1 Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)

OR

1.1.2 Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

AND

1.2.1.2 Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

OR

1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA (deoxyribonucleic acid) testing*

AND

2 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

3.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

3.2 BOTH of the following:

3.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

3.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

4 - ONE of the following:

4.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

4.2 BOTH of the following:

4.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vial

AND

4.2.2 Patient's weight is greater than or equal to 40 kg

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering.

Product Name:Strensiq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)

AND

2 - Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

4.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

4.2 BOTH of the following:

4.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

4.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

5 - ONE of the following:

5.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

5.2 BOTH of the following:

5.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vials

AND

5.2.2 Patient's weight is greater than or equal to 40 kg

2 . Revision History

Date	Notes
11/16/2023	removal of routine audit language

Strensiq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136412
Guideline Name	Strensiq
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Strensiq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on ALL of the following:

1.1 ONE of the following:

1.1.1 Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)

OR

1.1.2 Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 years (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

AND

1.2 ONE of the following:

1.2.1 BOTH of the following:

1.2.1.1 Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

AND

1.2.1.2 Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

OR

1.2.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA (deoxyribonucleic acid) testing*

AND

2 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone disorders

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

3.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

3.2 BOTH of the following:

3.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

3.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

4 - ONE of the following:

4.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

4.2 BOTH of the following:

4.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vial

AND

4.2.2 Patient's weight is greater than or equal to 40 kg

Notes	*Results of prior genetic testing can be submitted as confirmation of di agnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's United Healthcare plan prior to ordering.

Product Name:Strensiq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)

AND

2 - Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., serum pyridoxal 5'-phosphate (PLP) level, serum or urine phosphoethanolamine (PEA) level, urinary inorganic pyrophosphate (PPi level)]

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- A specialist experienced in the treatment of metabolic bone diseases

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Diagnosis of perinatal/infantile-onset hypophosphatasia

AND

4.1.2 Request does not exceed a maximum supply limit of 9 mg/kg/week (milligrams/kilogram/week)

OR

4.2 BOTH of the following:

4.2.1 Diagnosis of juvenile-onset hypophosphatasia

AND

4.2.2 Request does not exceed a maximum supply limit of 6 mg/kg/week

AND

5 - ONE of the following:

5.1 Patient is prescribed Strensiq 18 mg/0.45 mL (milliliter), Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

OR

5.2 BOTH of the following:

5.2.1 Patient is prescribed Strensiq 80 mg/0.8 mL vials

AND

5.2.2 Patient's weight is greater than or equal to 40 kg

2 . Revision History

Date	Notes
11/16/2023	removal of routine audit language

Stribild

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-204213
Guideline Name	Stribild
Formulary	• Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Stribild	
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of post-exposure prophylaxis (PEP)

OR

1.2 BOTH of the following: **1.2.1** Diagnosis of HIV (human immunodeficiency virus) **AND** **1.2.2** ONE of the following: **1.2.2.1** Provider gives a reason or special circumstance as to why the patient is not an appropriate candidate for three preferred* products, one of which must be Genvoya (please specify why the patient is not a candidate) **OR** **1.2.2.2** Continuation of current therapy	
Notes	Approval Duration: 12 months for HIV; 4 weeks for PEP. *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

2 . Revision History

Date	Notes
3/5/2025	Removed CO, NY, and NY EPP from markets in scope. For CO, Genvoya/Stribild are moving to the HIV guideline. For NY/NY EPP, Genvoya/Stribild are moving to open access. For RI, Genvoya is moving to open access, therefore removed Genvoya as a target from this guideline. Updated criteria and notes section for Stribild. Updated guideline name.

Stromectol

Prior Authorization Guideline

Guideline ID	GL-120273
Guideline Name	Stromectol
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:Brand Stromectol, generic ivermectin tabs	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of ONE of the following:

- Onchocerciasis due to nematode parasite
- Pediculosis
- Strongyloidiasis
- Ascariasis
- Scabies (including crusted scabies)
- Cutaneous larva migrans (hook worm disease)
- Enterobiasis
- Filariasis
- Trichuriasis
- Gnathostomiasis

2 . Revision History

Date	Notes
1/19/2023	Updated guideline name.

Sublingual Immunotherapy (SLIT)

Prior Authorization Guideline

Guideline ID	GL-124648
Guideline Name	Sublingual Immunotherapy (SLIT)
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Grastek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

2.1 Positive skin test to Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

OR

2.2 In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky blue/June grass, Meadow Fescue, or Redtop)

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the grass pollen season

AND

4 - ONE of the following:

4.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

OR

4.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Oralair)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Grastek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Grastek therapy

Product Name:Oralair	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe grass pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

2.1 Positive skin test to any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

OR

2.2 In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for any of the five grass species contained in Oralair [(i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens) or cross-reactive grass pollens (e.g., Cocksfoot, Meadow Fescue, or Redtop)]

AND

3 - Treatment is started or will be started at least 4 months before the beginning of the grass pollen season

AND

4 - ONE of the following:

4.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]

- leukotriene inhibitor [e.g., montelukast (Singulair)]

OR

4.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Not received in combination with similar cross-reactive grass pollen immunotherapy (e.g., Grastek)

AND

6 - Patient does not have unstable and/or uncontrolled asthma

AND

7 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Oralair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Oralair therapy

Product Name:Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe short ragweed pollen-induced allergic rhinitis defined by symptoms severe enough to interfere with quality of life (e.g., sleep disturbances; impairment of daily, sport, or leisure activities; impairment of school or work performance)

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to short ragweed pollen
- In vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen

AND

3 - Treatment is started or will be started at least 12 weeks before the beginning of the short ragweed pollen season

AND

4 - ONE of the following:

4.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

OR

4.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

5 - Patient does not have unstable and/or uncontrolled asthma

AND

6 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Ragwitek therapy

Product Name:Odactra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis

AND

2 - Diagnosis confirmed by ONE of the following:

- Positive skin test to licensed house dust mite allergen extracts
- In vitro testing for IgE (immunoglobulin E) antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites

AND

3 - ONE of the following:

3.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

OR

3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

- oral antihistamine [e.g., cetirizine (Zyrtec)]
- intranasal antihistamine [e.g., azelastine (Astelin)]
- intranasal corticosteroid [e.g., fluticasone (Flonase)]
- leukotriene inhibitor [e.g., montelukast (Singulair)]

AND

4 - Patient does not have unstable and/or uncontrolled asthma

AND

5 - Prescribed by or in consultation with a specialist in allergy and immunology

Product Name:Odactra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Odactra therapy	

2 . Revision History

Date	Notes
4/13/2023	Updated T/F criteria.

Sucraid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206584
Guideline Name	Sucraid
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State Nebraska • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Sucraid	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting a diagnosis of congenital sucrase-isomaltase deficiency (CSID)

AND

2 - Submission of medical records documenting diagnosis has been confirmed by one of the following:

2.1 Endoscopic biopsy of the small bowel indicating ALL of the following:

2.1.1 Normal small bowel morphology

AND

2.1.2 Absent or markedly reduced sucrase activity

AND

2.1.3 Isomaltase activity varying from 0 to full activity

AND

2.1.4 Reduced maltase activity

AND

2.1.5 ONE of the following:

2.1.5.1 Normal lactase activity

OR

2.1.5.2 BOTH of the following:

- Reduced lactase
- Sucrase:lactase ratio of less than 1.0

OR

2.2 Molecular genetic testing of the sucrase-isomaltase (SI) gene indicating a pathogenic isomaltase gene variant

OR

2.3 Carbon-13 sucrose breath test (13C SBT) indicating a cumulative [13C] CO2 exhalation over 90 minutes below 10th percentile (i.e., less than 3.9% for men and less than 5.2% for women)

AND

3 - Prescribed by or in consultation with a gastroenterologist or rare disease specialist

AND

4 - Will be used with a sucrose-free, low starch diet

Product Name:Sucraid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Sucraid therapy [e.g., reduced symptoms (e.g., abdominal pain, bloating, gas, vomiting), reduced number of stools per day, reduced number of symptomatic days]

AND **2** - Prescribed by or in consultation with a gastroenterologist or rare disease specialist **AND** **3** - Will be used with a sucrose-free, low starch diet

2 . Revision History

Date	Notes
3/5/2025	Updated formularies. Added requirement for submission of medical r ecords documenting diagnosis and confirmation of diagnosis

Sunosi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138902
Guideline Name	Sunosi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

AND

2 - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - ONE of the following:

3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

3.1.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.1.2 ONE of the following:

- Modafinil (generic Provigil)

- Armodafinil (generic Nuvigil)

OR

3.2 History of contraindication or intolerance to ALL of the following drugs or classes (please specify contraindication or intolerance):

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant
- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

AND

1.2.2 ONE or more of the following signs/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction [e.g., continuous positive airway pressure (CPAP), bi-level positive airway pressure (BiPAP)] have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - ONE of the following:

3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

2 . Revision History

Date	Notes
1/11/2024	Updated and cleaned up criteria.

Sunosi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138902
Guideline Name	Sunosi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a multiple sleep latency test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

AND

2 - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - ONE of the following:

3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

3.1.1 ONE of the following:

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant

AND

3.1.2 ONE of the following:

- Modafinil (generic Provigil)

- Armodafinil (generic Nuvigil)

OR

3.2 History of contraindication or intolerance to ALL of the following drugs or classes (please specify contraindication or intolerance):

- Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
- Methylphenidate based stimulant
- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

Product Name:Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with ONE of the following:

1.1 Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

OR

1.2 BOTH of the following:

1.2.1 Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

AND

1.2.2 ONE or more of the following signs/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by bed partner or other observer
- Observed apnea

AND

2 - BOTH of the following:

2.1 Standard treatments for the underlying airway obstruction [e.g., continuous positive airway pressure (CPAP), bi-level positive airway pressure (BiPAP)] have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - ONE of the following:

3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

OR

3.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

- Modafinil (generic Provigil)
- Armodafinil (generic Nuvigil)

AND

4 - Prescribed by ONE of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist
- Pulmonologist

Product Name:Sunosi	
Diagnosis	Obstructive Sleep Apnea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

AND

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

2 . Revision History

Date	Notes
1/11/2024	Updated and cleaned up criteria.

Sutent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147415
Guideline Name	Sutent
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

2.1 Disease progression on ONE of the following as confirmed by claims history or submission of medical records:

- imatinib (generic Gleevec)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)*

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- imatinib (generic Gleevec)
- Stivarga (regorafenib)

OR

2.3 SDH (succinate dehydrogenase)-deficient GIST

Notes	*Qinlock is non-preferred and should not be included in denial to provider.

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Disease is advanced

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Progressive pancreatic neuroendocrine tumors (pNET)

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor/hemangiopericytoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 Disease is refractory to radioactive iodine treatment

OR

2 - ALL of the following:

2.1 Diagnosis of medullary thyroid carcinoma

AND

2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

2.3 ONE of the following:

2.3.1 Clinical trials or preferred systemic therapy options are not available or appropriate [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

OR

2.3.2 There is progression on preferred systemic therapy options [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic or blast phase

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	GIST, RCC, Neuroendocrine and Adrenal Tumors, Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
5/28/2024	Updated criteria for GIST, neuroendocrine/adrenal tumors, and thyroid carcinoma per NCCN recommendations.

Sutent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147415
Guideline Name	Sutent
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

2.1 Disease progression on ONE of the following as confirmed by claims history or submission of medical records:

- imatinib (generic Gleevec)
- Stivarga (regorafenib)
- Standard dose Qinlock (ripretinib)*

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

- imatinib (generic Gleevec)
- Stivarga (regorafenib)

OR

2.3 SDH (succinate dehydrogenase)-deficient GIST

Notes	*Qinlock is non-preferred and should not be included in denial to provider.

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - ONE of the following:

2.1 Disease has relapsed

OR

2.2 Disease is advanced

OR

2.3 BOTH of the following:

2.3.1 Used in adjuvant setting

AND

2.3.2 Patient has a high risk of recurrence following nephrectomy

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Progressive pancreatic neuroendocrine tumors (pNET)

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Alveolar soft part sarcoma (ASPS)
- Angiosarcoma
- Solitary fibrous tumor/hemangiopericytoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of ONE of the following:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

1.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

1.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

1.4 Disease is refractory to radioactive iodine treatment

OR

2 - ALL of the following:

2.1 Diagnosis of medullary thyroid carcinoma

AND

2.2 ONE of the following:

- Patient has progressive disease
- Patient has symptomatic metastatic disease

AND

2.3 ONE of the following:

2.3.1 Clinical trials or preferred systemic therapy options are not available or appropriate [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

OR

2.3.2 There is progression on preferred systemic therapy options [e.g., Caprelsa (vandetanib), Cometriq (cabozantinib)]

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent chordoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Central Nervous System Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of surgically inaccessible meningiomas

AND

2 - ONE of the following:

- Disease is recurrent
- Disease is progressive

AND

3 - Further radiation is not possible

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Thymic Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thymic carcinoma

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic or blast phase

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	GIST, RCC, Neuroendocrine and Adrenal Tumors, Soft Tissue Sarcoma, Thyroid Carcinoma, Chordoma, Central Nervous System Cancer, Thymic Carcinoma, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Sutent, generic sunitinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
5/28/2024	Updated criteria for GIST, neuroendocrine/adrenal tumors, and thyroid carcinoma per NCCN recommendations.

Symdeko

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151413
Guideline Name	Symdeko
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Symdeko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory result documenting ONE of the following:

2.1 The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

OR

2.2 The patient has at least ONE mutation in the CFTR gene that is responsive to Symdeko (See Table in Background Section)

AND

3 - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

Product Name:Symdeko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Symdeko therapy (e.g., improved lung function, stable lung function)

2 . Background

Benefit/Coverage/Program Information

Table 1 CFTR Gene Mutations

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G*	E116K	G576A;R668C †	L967S	R117H	S737F
2789+5G→A*	E193K	G622D	L997F	R117L	S912L
3272-26A→G*	E403D	G970D	L1324P	R117P	S945L *
3849+10kbC→T *	E588V	G1069R	L1335P	R170H	S977F*
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E *	F311del	H939R	M952I	R347H *	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N †	I148T	P67L *	R352Q *	T1053I
D110E	F508del ‡	I175V	P205S	R352W	V201M
D110H *	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M

D443Y; G576A; R668C †	F1074L	I807M	Q359R	R792G	V1153E
D579G *	F1099L	I980K	Q1291R	R933G	V1240G
D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W *	Y109N
D979V	G194R	I1366N	R74W; D1270N †	R1162L	Y161S
D1152H *	G194V	K1060T	R74W; V201M †	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N †	R1283S	Y1032C
E56K	G551D	L206W *	R75Q	S549N	
E60K	G551S	L320V	R117C *	S549R	

* Clinical data for these mutations in Clinical Studies.

^ A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in the table to be indicated.

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
8/13/2024	Simplified reauthorization criteria

Synagis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156915
Guideline Name	Synagis
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Synagis*	
Diagnosis	Prematurity
Guideline Type	Prior Authorization
Approval Criteria	

1 - BOTH of the following:

1.1 Patient is an infant born before 29 weeks, 0 days gestation

AND

1.2 Patient is less than 12 months of age at the start of RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV "season"***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV "season"

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV “season.” **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name:Synagis*	
Diagnosis	Chronic Lung Disease (CLD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ALL of the following for patients age 0 to less than 12 months:

1.1.1 The patient is a preterm infant defined as gestational age less than 32 weeks, 0 days

AND

1.1.2 Patient has developed chronic lung disease (CLD) of prematurity

AND

1.1.3 There was a requirement for greater than 21% oxygen for at least the first 28 days after birth

OR

1.2 ALL of the following for patients age greater than or equal to 12 months to less than 24 months:

1.2.1 The patient was born at less than 32 weeks, 0 days gestation

AND

1.2.2 The patient required at least 28 days of oxygen after birth

AND

1.2.3 The patient continues to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV “season”

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV "season"***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV "season"

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV “season.” **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name:Synagis*	
Diagnosis	Congenital Heart Disease (CHD)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following for patients age 0 to less than 12 months:

1.1.1 Patient has hemodynamically significant congenital heart disease (CHD) including ONE of the following:

- Acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Moderate to severe pulmonary hypertension
- Documentation that decisions regarding prophylaxis for infants with cyanotic heart defects were made in consultation with a pediatric cardiologist

OR

1.1.2 The patient is undergoing cardiac transplantation during the RSV “season”

OR

1.2 BOTH of the following:

1.2.1 The patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 ONE of the following:

- After cardiac bypass
- At the conclusion of extracorporeal membrane oxygenation
- The patient is undergoing cardiac transplantation during the RSV "season"

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV "season"***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV "season"

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure

- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV “season.” **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name:Synagis*	
Diagnosis	Congenital abnormalities of the airway or neuromuscular disease
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Patient is age 0 to less than 12 months

AND

1.2 Patient has ONE of the following:

- Neuromuscular disease
- A congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV “season”

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV “season.” **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name:Synagis*	
Diagnosis	Immunocompromised children less than 24 months of age
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is less than 24 months of age

AND

1.2 The patient is immunocompromised (e.g. receiving cancer chemotherapy, undergoing hematopoietic stem cell transplantation, or solid organ transplantation)

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV "season"***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV "season"

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]

- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV “season.” **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. Any subsequent doses received in the hospital setting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses may be needed.

Product Name:Synagis*	
Diagnosis	Cystic fibrosis (CF)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following for patients age 0 to less than 12 months:

1.1.1 Patient has cystic fibrosis

AND

1.1.2 Patient has clinical evidence of at least ONE of the following:

- Chronic lung disease (CLD)
- Nutritional compromise
- Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart

OR

1.2 BOTH of the following:

1.2.1 Patient is greater than or equal to 12 months to less than 24 months of age

AND

1.2.2 Patient has manifestations of severe lung disease including ONE of the following:

- Previous hospitalization for pulmonary exacerbation in the first year of life
- Abnormalities on chest radiography or chest computed tomography that persists when stable
- Weight for length less than the 10th percentile on a pediatric growth chart

AND

2 - Administered during RSV season**

AND

3 - Monthly dose of Synagis does not exceed 15 milligram per kilogram per dose

AND

4 - Dosage of Synagis does not exceed 5 monthly doses per single RSV “season”***

AND

5 - Patient has not previously received treatment with Beyfortus (nirsevimab-alip) during or entering the current RSV "season"

AND

6 - Synagis is not being requested for any of the following situations alone:

- Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with congenital heart disease and cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy
- Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (less than 29 weeks, 0 days gestation) is present]
- Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
- Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children
- Synagis prophylaxis for prevention of nosocomial disease

AND

7 - The request is NOT for one of the following:

- Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
- Treatment of symptomatic RSV disease

Notes	*Approval for up to 5 doses per single RSV "season." **Information regarding RSV season may be found at: • Centers for Disease and Prevention (CDC) surveillance reports: https://www.cdc.gov/nrevss/php/dashboard/index.html ***Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose s

	eries for the season. Any subsequent doses received in the hospital s etting, are also considered as part of the maximum 5 dose series. For infants born during the RSV “season,” fewer than 5 monthly doses ma y be needed.

2 . Background

Benefit/Coverage/Program Information
Additional Information In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV “season” in the state of Florida that could affect the timing of Synagis administration. • Despite varied onsets, the RSV “season” is of the same duration (5 months) in the different regions of Florida. • On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants. • Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% or the mean percentage of specimens testing positive for RSV by PCR is ≥ 3%, whichever occurs first. RSV “season” offset is defined as the last week during which the mean percentage of positive specimens is ≥ 10%, or the mean percentage of positive specimens by PCR is ≥ 3%, whichever occurs last. Use of specimens to determine the start of the RSV “season” requires that the number of specimens tested be statistically significant.

3 . Revision History

Date	Notes
10/3/2024	Updated CDC website. Removed old sharepoint link.

Tabrecta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129175
Guideline Name	Tabrecta
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

2.1 Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors

OR

2.2 High level MET amplification in lung cancer

Product Name:Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tabrecta therapy

Product Name:Tabrecta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tabrecta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tabrecta therapy

2 . Revision History

Date	Notes
8/1/2023	Updated formularies, cleaned up criteria.

Tafinlar

Prior Authorization Guideline

Guideline ID	GL-151106
Guideline Name	Tafinlar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Tafinlar	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.3.2 Used in combination with Mekinist (trametinib)

AND

2 - Cancer is positive for BRAF V600 mutation

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Tafinlar is active against primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar

Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - ONE of the following:

- Used in combination with Mekinist (trametinib)
- Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar

Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.2 Cancer is positive for BRAF V600E mutation

AND

1.3 Used in combination with Mekinist (trametinib)

AND

1.4 ONE of the following:

1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.4.2 Prescribed as adjuvant therapy following resection

AND

1.5 If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

AND

2.5 Cancer is positive for BRAF V600 mutation

AND

2.6 If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

AND

6 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

AND

6 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease
- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Mekinist (trametinib)

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Used in combination with Mekinist (trametinib)

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable

- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Mekinist (trametinib)

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent

- Metastatic

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	All Indications except NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name:Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tafinlar therapy

2 . Revision History

Date	Notes
8/6/2024	Added new criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Tafinlar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151106
Guideline Name	Tafinlar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Tafinlar	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Unresectable melanoma

OR

1.2 Metastatic melanoma

OR

1.3 BOTH of the following:

1.3.1 Prescribed as adjuvant therapy for melanoma involving the lymph node(s)

AND

1.3.2 Used in combination with Mekinist (trametinib)

AND

2 - Cancer is positive for BRAF V600 mutation

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

1.1.1 Patient has metastatic brain lesions

AND

1.1.2 Tafinlar is active against primary tumor (melanoma)

OR

1.2 Patient has a glioma

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar

Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Advanced
- Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - ONE of the following:

- Used in combination with Mekinist (trametinib)
- Used as a single agent if the combination of Mekinist and Tafinlar is not tolerated

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar

Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of anaplastic thyroid cancer (ATC)

AND

1.2 Cancer is positive for BRAF V600E mutation

AND

1.3 Used in combination with Mekinist (trametinib)

AND

1.4 ONE of the following:

1.4.1 Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

OR

1.4.2 Prescribed as adjuvant therapy following resection

AND

1.5 If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

OR

2 - ALL of the following:

2.1 ONE of the following diagnoses:

- Follicular carcinoma
- Oncocytic carcinoma
- Papillary carcinoma

AND

2.2 ONE of the following:

- Unresectable locoregional recurrent disease
- Persistent disease
- Metastatic disease

AND

2.3 ONE of the following:

- Patient has symptomatic disease
- Patient has progressive disease

AND

2.4 Disease is refractory to radioactive iodine treatment

AND

2.5 Cancer is positive for BRAF V600 mutation

AND

2.6 If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Hepatobiliary Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Gallbladder cancer
- Extrahepatic Cholangiocarcinoma
- Intrahepatic Cholangiocarcinoma

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

AND

6 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Langerhans Cell Histiocytosis
- Erdheim-Chester Disease

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of solid tumor

AND

2 - Used as subsequent treatment after progression on or after systemic treatment

AND

3 - Disease is unresectable or metastatic

AND

4 - Cancer is positive for BRAF V600E mutation

AND

5 - Used in combination with Mekinist (trametinib)

AND

6 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Epithelial Ovarian Cancer
- Fallopian Tube Cancer
- Primary Peritoneal Cancer

AND

2 - ONE of the following:

- Persistent disease
- Recurrence in BRAF V600E positive tumors
- Recurrence of low-grade serous carcinoma

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Pancreatic Cancer / Ampullary Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Pancreatic adenocarcinoma
- Ampullary adenocarcinoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced
- Unresectable

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Mekinist (trametinib)

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Used in combination with Mekinist (trametinib)

AND

3 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Disease is ONE of the following:

- Recurrent and unresectable

- Metastatic

AND

3 - Cancer is positive for BRAF V600E mutation

AND

4 - Used in combination with Mekinist (trametinib)

AND

5 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRAF V600E-mutated gastrointestinal stromal tumor (GIST)

AND

2 - Disease is ONE of the following:

- Gross residual disease (R2 resection)
- Unresectable primary disease
- Tumor rupture
- Progressive
- Recurrent

- Metastatic

AND

3 - Used in combination with Mekinist (trametinib)

AND

4 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	All Indications except NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tafinlar therapy

Product Name:Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for Tafinlar tablets for oral solution, there is a reason or special circumstance why the patient is unable to use Tafinlar capsules (document reason or special circumstance)

Product Name:Tafinlar	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tafinlar therapy

2 . Revision History

Date	Notes
8/6/2024	Added new criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Tagrisso

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164118
Guideline Name	Tagrisso
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastases from EGFR mutation-positive non-small cell lung cancer (NSCLC)

OR

2 - Diagnosis of leptomeningeal metastases from EGFR mutation-positive NSCLC

Product Name:Tagrisso	
Diagnosis	Central Nervous System (CNS) Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

Product Name:Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is positive for at least ONE of the following EGFR mutations:

- Exon 19
- Exon 21 L858R
- S767I
- L861Q
- G719X
- T790M

AND

3 - One of the following:

3.1 All of the following:

- disease is stage IB, II, IIIA, or IIIB (T3, N2)
- Patient has undergone complete resection
- Patient has received previous adjuvant chemotherapy or ineligible to receive platinum-based chemotherapy

OR

3.2 All of the following:

- Disease is stage II-III
- Disease is locally advanced or unresectable
- No disease progression during or following concurrent or sequential chemoradiation

OR

3.3 Disease is recurrent, advanced, or metastatic

Product Name:Tagrisso	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tagrisso therapy

Product Name:Tagrisso	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tagrisso	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tagrisso therapy

2 . Revision History

Date	Notes
1/22/2025	Updated clinical criteria.

Takhzyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147193
Guideline Name	Takhzyro
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Takhzyro	
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hereditary angioedema (HAE) as confirmed by ONE of the following:

1.1 C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following (per laboratory standard):

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

1.2 HAE with normal C1 inhibitor levels and ONE of the following:

1.2.1 Confirmed presence variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6

OR

1.2.2 Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

OR

1.2.3 Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

AND

2 - BOTH of the following:

2.1 For prophylaxis against HAE attacks

AND

2.2 Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

AND

3 - BOTH of the following:

3.1 Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Takhzyro

AND

3.2 Documentation of baseline HAE attack rate is greater than or equal to one attack per 4 weeks

AND

4 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

5 - ONE of the following:

5.1 Failure to Haegarda confirmed by claims history or submitted medical records

OR

5.2 History of contraindication or intolerance to Haegarda (please specify intolerance or contraindication)

OR

5.3 Patient is currently on Takhzyro therapy confirmed by claims history or submitted medical records

AND

6 - ONE of the following:

6.1 For adult and pediatric patients 12 years and older, Takhzyro 300 mg (milligrams) is given every 2 weeks*

OR

6.2 For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 2 weeks*

OR

6.3 For pediatric patients less than 6 years of age, Takhzyro 150 mg is given every 4 weeks**

Notes	*Adult and pediatric patients 6 years of age and older approval length: 8 months. **Pediatric patients less than 6 years of age approval length: 12 months.

Product Name:Takhzyro	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response while on Takhzyro therapy

AND

2 - Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Ruconest, Firazyr, Kalbitor) as determined by claims information, while on Takhzyro therapy

AND

3 - Prescribed by ONE of the following:

- Immunologist
- Allergist

AND

4 - BOTH of the following:

4.1 For prophylaxis against hereditary angioedema (HAE) attacks

AND

4.2 Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo)

AND

5 - ONE of the following:

5.1 Patient is less than 6 years of age and Takhzyro 150 mg (milligrams) is given every 4 weeks*

OR

5.2 Patient is at least 6 years of age, and BOTH of the following:

5.2.1 Documentation of the number of acute HAE attacks in the previous 6 months, while on Takhzyro therapy

AND

5.2.2 ONE of the following:

5.2.2.1 If the patient experienced no (zero) acute HAE attacks in the previous 6 months, ONE of the following*:

- For adult and pediatric patients 12 years of age and older, Takhzyro 300 mg is given every 4 weeks**
- For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 4 weeks**

OR

5.2.2.2 If the patient experienced one or more HAE attacks in the previous 6 months, ONE of the following***:

- For adult and pediatric patients 12 years of age and older, Takhzyro 300 mg is given every 2 weeks
- For pediatric patients 6 to less than 12 years of age, Takhzyro 150 mg is given every 2 weeks

Notes	*Patient experienced no acute HAE attacks in the previous 6 months, or is less than 6 years of age approval length: 12 months. **Patients experiencing unexpected breakthrough HAE attacks once s witched to every 4 week dosing will require additional review to allow f or 2 weeks dosing. ***Patient experienced 1 or more HAE attacks in the previous 6 month s approval length: 6 months.

2 . Revision History

Date	Notes
5/9/2024	Update to diagnostic criteria for HAE with normal C1 inhibitor levels. Updated and simplified reauthorization criteria.

Taltz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206586
Guideline Name	Taltz
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2 ONE of the following:

1.2.1 ALL of the following:

1.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.2.1.2 One of the following:

1.2.1.2.1 Failure to ONE of the following topical therapy classes as confirmed by claims history or submission of medical records:

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication)

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin

- Coal tar

AND

1.2.1.3 ONE of the following:

- Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records
- History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab, Tremfya (guselkumab)]

AND

1.3 One of the following:

1.3.1 Failure to TWO of the following preferred products, as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

OR

1.3.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

AND

1.4 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

AND

1.5 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.6 Prescribed by or in consultation with a dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

2.3 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

Notes	^See Table 1 for PDL Links

Product Name:Taltz	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical

records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab)]

AND

1.3 One of the following:

1.3.1 Failure to TWO of the following preferred products as confirmed by claims history or submission of medical records

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

OR

1.3.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication)

- One of the preferred adalimumab products^
- Enbrel (etanercept)
- One of the preferred ustekinumab products^

AND

1.4 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

AND

1.5 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.6 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with one of the following:

- Rheumatologist
- Dermatologist

Notes	^See Table 1 for PDL Links

Product Name:Taltz

Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 ONE of the following:

1.2.1 Failure to TWO NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab)].

AND

1.3 One of the following:

1.3.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

- One of the preferred adalimumab products^
- Enbrel (etanercept)

OR

1.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication)

- One of the preferred adalimumab products^
- Enbrel (etanercept)

AND

1.4 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

AND

1.5 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.6 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	^See Table 1 for PDL Links

Product Name:Taltz	
Diagnosis	Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active non-radiographic axial spondyloarthritis

AND

1.2 ONE of the following:

1.2.1 Failure to two NSAIDs (non-steroidal anti-inflammatory drugs) (e.g., ibuprofen,

naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as confirmed by claims history or submission of medical records [e.g. Cimzia (certolizumab), Cosentyx (secukinumab)]

AND

1.3 ONE of the following:

- Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records
- History of contraindication or intolerance to Cosentyx (secukinumab) (please specify contraindication or intolerance)

AND

1.4 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Taltz therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active non-radiographic axial spondyloarthritis

AND

2.3 Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 Prescribed by or in consultation with a rheumatologist

Product Name:Taltz	
Diagnosis	Plaque Psoriasis, Psoriatic Arthritis (PsA), Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Taltz therapy

AND

2 - Patient is NOT receiving Taltz in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx

(secukinumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*	
Notes	*Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
Table 1: PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Added NM to formulary. Criteria updates. Changed "Stelara" to "uste kinumab" .

Talzenna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134170
Guideline Name	Talzenna
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

3 - Presence of a germline BRCA (breast cancer)-mutation

AND

4 - ONE of the following:

4.1 Patient is currently on Talzenna therapy as confirmed by claims history or submitted medical records

OR

4.2 History of intolerance or contraindication to Lynparza (please specify intolerance or contraindication)

OR

4.3 Provider attests that the patient is not an appropriate candidate for Lynparza

Product Name:Talzenna	
Diagnosis	Prostate Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer

AND

2 - Presence of homologous recombination repair (HRR) gene mutations

AND

3 - Used in combination with Xtandi (enzalutamide)

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

Product Name:Talzenna	
Diagnosis	Breast Cancer, Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Talzenna therapy

Product Name:Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Talzenna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Talzenna therapy

2 . Revision History

Date	Notes

10/3/2023	Added new Talzenna 0.1 mg and 0.35 mg strengths. Added criteria fo r HRR gene-mutated mCRPC per label.

Tarceva

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164096
Guideline Name	Tarceva
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pancreatic cancer

AND

2 - Disease is ONE of the following:

- Locally advanced
- Unresectable
- Metastatic

AND

3 - Used in combination with gemcitabine

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

- Metastatic
- Recurrent

- Advanced

AND

3 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR)exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., S768I, L861Q, G719X)

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chordoma

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of kidney cancer

AND

2 - Disease is stage IV or relapsed

AND

3 - Disease is of non-clear cell histology

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain, leptomeningeal, or spine metastases from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

- Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions
- Tumors are positive for exon 21 (L858R) substitution mutations
- Tumors are positive for a known sensitizing EGFR mutation (e.g., S768I, L861Q, G719X)

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Vulvar cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vulvar cancer

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	Pancreatic Cancer, Non-Small Cell Lung Cancer (NSCLC), Chordoma, Kidney Cancer, Central Nervous System (CNS) Cancers, Vulvar Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tarceva therapy

Product Name:Brand Tarceva, generic erlotinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Tarceva, generic erlotinib

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tarceva therapy

2 . Revision History

Date	Notes
1/22/2025	Updated GPI list.

Targretin (bexarotene)

Prior Authorization Guideline

Guideline ID	GL-138782
Guideline Name	Targretin (bexarotene)
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Brand Targretin, generic bexarotene	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - ONE of the following:

2.1 Failure to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g., interferons]) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids (clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate), phototherapy, or systemic therapies [e.g., interferons]) (please specify contraindication or intolerance)

Product Name:Brand Targretin, generic bexarotene	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has not had disease progression while on therapy

Product Name:Brand Targretin, generic bexarotene	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Brand Targretin, generic bexarotene	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
1/10/2024	Updated guideline name; Removed Colorado SP (RMHCAID, RMHC HP, RMHWRP) from benefit coverage; Minor cosmetic/formatting cle anup of criteria; Removed reference to "Targretin" in reauthorization criterion for NCCN Recommended Regimens section. No changes to clinical intent.

Tarpeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145027
Guideline Name	Tarpeyo
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • •

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

AND

2 - Patient is at risk for disease progression

AND

3 - Used to reduce the loss of kidney function

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m^2 (milliliters/minute/1.73 square meters)

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with ONE of the following, as confirmed by claims history or submitted medical records:

- Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

OR

5.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARBs (please specify allergy, contraindication, or intolerance)

AND

6 - ONE of the following:

6.1 Failure of ONE 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone) confirmed by claims history or submitted medical records

OR

6.2 History of intolerance or contraindication to ONE glucocorticoid (please specify intolerance or contraindication)

AND

7 - Prescribed by or in consultation with a nephrologist

2 . Revision History

Date	Notes
3/28/2024	Updated indication requirements and removed example of disease pr ogression.

Tasigna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138778
Guideline Name	Tasigna
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Tasigna	
Diagnosis	Chronic Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myeloid leukemia

AND

2 - ONE of the following:

2.1 Patient is not a candidate for imatinib (Gleevec) as attested by physician

OR

2.2 Patient is currently on Tasigna therapy

Product Name:Tasigna	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive gastrointestinal stromal tumor (GIST)

AND

2 - ONE of the following:

2.1 Failure to ALL of the following, as confirmed by claims history or submission of medical records:

- Imatinib (generic Gleevec)
- Sunitinib (generic Sutent)

- Stivarga (regorafenib)
- Qinlock (ripretinib)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

- Imatinib (generic Gleevec)
- Sunitinib (generic Sutent)
- Stivarga (regorafenib)
- Qinlock (ripretinib)

Product Name:Tasigna	
Diagnosis	Acute Lymphoblastic Leukemia (Ph+B-ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive B-cell acute lymphoblastic leukemia (Ph+B-ALL)

Product Name:Tasigna	
Diagnosis	Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and ABL1 (gene) rearrangement

AND

2 - Neoplasm is in blast or chronic phase

Product Name:Tasigna	
Diagnosis	Melanoma: Cutaneous
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic or unresectable melanoma cutaneous tumors with activating mutations of KIT

AND

2 - Used as second-line or subsequent therapy for disease progression, intolerance, and or projected risk of progression with BRAF-targeted therapy

Product Name:Tasigna	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pigmented villonodular synovitis/tenosynovial giant cell tumor

Product Name:Tasigna	
Diagnosis	Chronic Myeloid Leukemia, Gastrointestinal Stromal Tumor (GIST), Acute Lymphoblastic Leukemia (Ph+B-ALL), Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes, Melanoma: Cutaneous, Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on Tasigna therapy	

Product Name:Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Tasigna will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium	

Product Name:Tasigna	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Tasigna therapy

2 . Revision History

Date	Notes
1/11/2024	Updated criteria for GIST. Updated criteria for Myeloid/Lymphoid Neo plasms with Eosinophilia and Tyrosine Kinase Gene Fusions. Added Melanoma Cutaneous and Soft Tissue Sarcoma as indications for crit eria per NCCN recommendations.

Tasmar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124758
Guideline Name	Tasmar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:generic tolcapone, Brand Tasmar	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is currently on a stable dose of a carbidopa/levodopa-containing medication and will continue receiving treatment with a carbidopa/levodopa-containing medication while on therapy

AND

3 - ONE of the following:

3.1 Failure to TWO of the following anti-Parkinson's disease adjunctive pharmacotherapy classes (trial must be from TWO different classes) as confirmed by claims history or submission of medical records:

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

OR

3.2 History of intolerance or contraindication to ALL of the following anti-Parkinson's disease adjunctive pharmacotherapy classes (please specify intolerance or contraindication):

- Dopamine agonists (e.g., pramipexole, ropinirole)
- Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
- Monoamine oxidase (MAO) B inhibitors (e.g., selegiline)

AND

4 - Patient has received baseline liver function tests to rule out the presence of underlying liver disease

AND

5 - Prescribed by or in consultation with a neurologist or specialist in the treatment of Parkinson's disease

AND

6 - Prescriber attests they have had complete discussion with the patient about the risks and benefits of Tasmar (tolcapone) use, including the risk of liver failure

Product Name:generic tolcapone, Brand Tasmar	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tasmar (tolcapone) therapy

AND

2 - Patient will continue to receive treatment with a carbidopa/levodopa-containing medication

AND

3 - Patient has received periodic evaluation of liver function tests to rule out liver failure associated with Tasmar (tolcapone) use

2 . Revision History

Date	Notes
4/17/2023	Updated T/F criteria language.

Tavalisse

Prior Authorization Guideline

Guideline ID	GL-208220
Guideline Name	Tavalisse
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic immune thrombocytopenia (ITP)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to at least ONE of the following classes confirmed by claims history or submitted medical records:

- Corticosteroids
- Immunoglobulins

OR

2.1.1.2 History of contraindication or intolerance to BOTH of the following classes (please specify intolerance or contraindication):

- Corticosteroids
- Immunoglobulins

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to Promacta (eltrombopag) confirmed by claims history or submitted medical records

OR

2.1.2.2 History of contraindication or intolerance to Promacta (eltrombopag) (please specify intolerance or contraindication)

OR **2.2** Patient is currently on Tavalisse therapy

Product Name:Tavalisse	
Diagnosis	Chronic immune thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tavalisse therapy	

2 . Revision History

Date	Notes
3/6/2025	Updated formularies

Tavneos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-183190
Guideline Name	Tavneos
Formulary	• Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) • Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Tavneos	
Diagnosis	ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe active ANCA (anti-neutrophil cytoplasmic autoantibody)-associated vasculitis

AND

2 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the disease is ONE of the following types:

2.1 Granulomatosis with polyangiitis (GPA)

OR

2.2 Microscopic polyangiitis (MPA)

AND

3 - Patient is being treated with an initial immunosuppressive regimen to induce remission (i.e., rituximab, cyclophosphamide)

AND

4 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

5 - Prescribed by ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist

- Vascular Medicine Specialist

Product Name:Tavneos	
Diagnosis	ANCA (Anti-Neutrophil Cytoplasmic Autoantibody)-Associated Vasculitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tavneos therapy

AND

2 - Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g., prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

AND

3 - Prescribed by or in consultation with ONE of the following:

- Rheumatologist
- Nephrologist
- Pulmonologist
- Vascular Medicine Specialist

2 . Revision History

Date	Notes
2/20/2025	Combined formularies. No changes to clinical criteria.

Tazverik

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147164
Guideline Name	Tazverik
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of epithelioid sarcoma

AND

2 - Disease is ONE of the following:

- Metastatic
- Locally advanced

AND

3 - Disease is not eligible for complete resection

Product Name:Tazverik	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or refractory follicular lymphoma

AND

2 - ONE of the following:

2.1 Subsequent therapy in EZH2 (gene) mutation positive disease after 2 prior therapies

OR

2.2 Second-line therapy irrespective of EZH2 mutation status for older or infirm patients with indications for treatment (i.e., other therapy options are not expected to be tolerable)

OR

2.3 Third-line and/or subsequent therapy (if not previously given) irrespective of EZH2 mutation status in patients with indications for treatment

Product Name:Tazverik	
Diagnosis	Epithelioid Sarcoma, Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tazverik therapy

Product Name:Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tazverik	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tazverik therapy

2 . Revision History

Date	Notes
5/8/2024	Added criteria to relapsed/refractory follicular lymphoma based on N CCN recommendations

Tegsedi

Prior Authorization Guideline

Guideline ID	GL-138803
Guideline Name	Tegsedi
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2024

1 . Criteria

Product Name:Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

- Diagnosis of Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
- Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has not had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name:Tegsedi	
Diagnosis	Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

2 - Patient is not receiving Tegsedi in combination with ONE of the following:

- Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]
- Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
1/10/2024	Update to simplify reauthorization criteria.

Temodar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165047
Guideline Name	Temodar
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New Mexico • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island • Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of central nervous system tumors:

- Intracranial and Spinal Ependymoma (excluding Subependymoma)
- World Health Organization (WHO) Grade 2, 3, or 4 isocitrate dehydrogenase (IDH)-mutation Astrocytoma
- WHO Grade 2 or 3 IDH-mutant, 1p19q Codeleted Oligodendroglioma
- Medulloblastoma
- Circumscribed Gliomas
- Glioblastoma
- Limited or extensive brain metastases
- Primary CNS (central nervous system) lymphoma

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of melanoma:

- Metastatic or unresectable cutaneous melanoma
- Metastatic or unresectable uveal melanoma
- Mucosal melanoma

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Neuroendocrine and Adrenal Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of neuroendocrine tumors:

- Bronchopulmonary/thymic disease
- Poorly controlled carcinoid syndrome in gastrointestinal tract, lung or thymus
- Pancreas
- Pheochromocytoma/paraganglioma
- Poorly differentiated (High Grade)/ large or small cell
- Well differentiated grade 3 neuroendocrine tumors

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following types of primary cutaneous lymphomas:

- Mycosis fungoides (MF)
- Sézary syndrome (SS)

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of recurrent unresectable or stage IV retroperitoneal/intra-abdominal soft tissue sarcoma
- Diagnosis of rhabdomyosarcoma
- Undifferentiated pleomorphic sarcoma
- Diagnosis of solitary fibrous tumor/hemangiopericytoma

OR

2 - BOTH of the following:

2.1 Diagnosis of soft tissue sarcoma of the extremity/body wall, head/neck

AND

2.2 ONE of the following:

- Disease is stage IV
- Disease has disseminated metastases

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Ewing's sarcoma family of tumors
- Mesenchymal chondrosarcoma

AND

2 - ONE of the following:

- Disease has relapsed
- Disease is progressive following primary treatment
- Used as second-line therapy for metastatic disease

AND

3 - Used in combination with Camptosar (irinotecan)

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic uterine sarcoma

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - ONE of the following:

2.1 Relapse following complete or partial response or stable disease with primary treatment

OR

2.2 Primary progressive disease

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	Central Nervous Systems (CNS) Tumor, Melanoma, Neuroendocrine and Adrenal Tumors, Primary Cutaneous Lymphomas, Soft Tissue Sarcoma, Bone Cancer, Uterine Sarcoma, Small Cell Lung Cancer (SCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Temodar therapy

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Temodar will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Temodar, generic temozolomide	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Temodar therapy	

2 . Revision History

Date	Notes
2/12/2025	Combined formularies. Corrected spelling of Camptosar.

Tepmetko

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125881
Guideline Name	Tepmetko
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York EPP • Medicaid - Community & State New York • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Tepmetko	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer

AND

2 - Disease is recurrent, advanced, or metastatic

AND

3 - Tumor is MET exon 14 skipping mutation positive

Product Name:Tepmetko	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tepmetko therapy

Product Name:Tepmetko	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tepmetko	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Tepmetko therapy	

2 . Revision History

Date	Notes
5/19/2023	Updated Formularies. Removed RMH, added ACUCO

Test Strips

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127185
Guideline Name	Test Strips
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Hawaii • Medicaid - Community & State Maryland • Medicaid - Community & State New Jersey • Medicaid - Community & State New York • Medicaid - Community & State New York EPP • Medicaid - Community & State Pennsylvania CHIP • Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Non-preferred Test Strips	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Failure of both of the following confirmed by claims history or submitted medical records:

- OneTouch Ultra Test Strips
- OneTouch Verio Test Strips

OR

1.2 History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

- OneTouch Ultra Test Strips
- OneTouch Verio Test Strips

OR

2 - Patient is on an insulin pump

Product Name:All Test Strips	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - If the patient is insulin dependent or pregnant, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

2 - If the patient is not insulin dependent nor pregnant, ONE the following:

2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR **2.2** The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time **OR** **2.3** The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time **OR** **2.4** The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise **OR** **2.5** Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)

Notes	The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 2 test strips/day.

2 . Revision History

Date	Notes
6/27/2023	Added new GPIs to market since last update. No changes to clinical criteria.

Test Strips

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127185
Guideline Name	Test Strips
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Non-preferred Test Strips	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Failure of both of the following confirmed by claims history or submitted medical records:

OneTouch Ultra Test Strips

OneTouch Verio Test Strips

OR

1.2 History of intolerance or contraindication to both of the following (please specify intolerance or contraindication):

OneTouch Ultra Test Strips

OneTouch Verio Test Strips

OR

2 - Patient is on an insulin pump

Product Name:All Test Strips	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - If the patient is insulin dependent or pregnant, the physician must confirm the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions)

OR

2 - If the patient is not insulin dependent nor pregnant, ONE the following:

2.1 The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control

OR **2.2** The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time **OR** **2.3** The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time **OR** **2.4** The patient requires additional testing due to fluctuations in blood glucose due to physical activity/exercise **OR** **2.5** Other circumstances where prescribing physician confirms that the patient requires a greater quantity because of more frequent blood glucose testing (clinical review required by UnitedHealthcare reviewing pharmacist and/or medical director)	
Notes	The quantity limit for insulin-dependent and pregnant patients is 6 test strips/day. The quantity limit for non-insulin dependent and non-pregnant patients is 2 test strips/day.

2 . Revision History

Date	Notes
6/27/2023	Added new GPIs to market since last update. No changes to clinical criteria.

Testosterone

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163815
Guideline Name	Testosterone
Formulary	Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex	
Diagnosis	Hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 TWO pre-treatment serum total testosterone levels less than 300 ng/dL (nanograms/deciliter) [less than 10.4 nmol/L (nanomoles/liter)] or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

OR

1.2 BOTH of the following:

1.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) [e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

AND

1.2.2 ONE pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (picograms/milliliter) (< 5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

OR

1.3 Patient has a history of ONE of the following:

Bilateral orchiectomy

Panhypopituitarism

A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

2 - Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

Genotropin

Humatrope

Norditropin FlexPro

Nutropin AQ

Omnitrope

Saizen

AND

3 - Patient is NOT taking any aromatase inhibitor [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

AND

4 - Patient was male at birth

AND

5 - Diagnosis of hypogonadism

AND

6 - ONE of the following:

Significant reduction in weight (less than 90% ideal body weight) [e.g., AIDS (acquired immunodeficiency syndrome) wasting syndrome]

Osteopenia

Osteoporosis

Decreased bone density

Decreased libido

Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

AND

7 - ONE of the following:

7.1 If the request is for a non-preferred** topical testosterone (gel, solution) or testosterone transdermal systems (patches), ONE of the following:

7.1.1 Failure to ONE of the following, confirmed by claims history or submitted medical records:

generic testosterone 1% topical gel

testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

7.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

generic testosterone 1% topical gel

testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

7.2 If the request is for Xyosted, BOTH of the following:

7.2.1 ONE of the following:

7.2.1.1 Failure to testosterone cypionate injection (generic Depo-Testosterone), confirmed by claims history or submitted medical records

OR

7.2.1.2 History of intolerance or contraindication to testosterone cypionate injection (generic Depo-Testosterone) (please specify intolerance or contraindication)

AND

7.2.2 ONE of the following:

7.2.2.1 Failure to intramuscular testosterone enanthate injection, confirmed by claims history or submitted medical records

OR

7.2.2.2 History of intolerance or contraindication to intramuscular testosterone enanthate injection (please specify intolerance or contraindication)

OR

7.3 If the request is for Jatenzo, Kyzatrex, Tlando, or Undecatrex, ONE of the following:

7.3.1 Failure to ALL of the following:

testosterone cypionate vials

testosterone enanthate vials

testosterone gel - tube, pack, or pump bottle, or testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

7.3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

testosterone cypionate vials

testosterone enanthate vials

testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

Notes	*Patients that have previously received injectable testosterone open access should be reviewed using reauthorization criteria **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex	
Diagnosis	Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

AND

2 - ONE of the following:

2.1 If the request is for a non-preferred** topical testosterone (gel, solution) or testosterone transdermal systems (patches), ONE of the following:

2.1.1 Failure to ONE of the following, confirmed by claims history or submitted medical records:

generic testosterone 1% topical gel

testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

2.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

generic testosterone 1% topical gel

testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

2.2 If the request is for Xyosted, BOTH of the following:

2.2.1 ONE of the following:

2.2.1.1 Failure to testosterone cypionate injection (generic Depo-Testosterone), confirmed by claims history or submitted medical records

OR

2.2.1.2 History of intolerance or contraindication to testosterone cypionate injection (generic Depo-Testosterone) (please specify intolerance or contraindication)

AND

2.2.2 ONE of the following:

2.2.2.1 Failure to intramuscular testosterone enanthate injection, confirmed by claims history or submitted medical records

OR

2.2.2.2 History of intolerance or contraindication to intramuscular testosterone enanthate injection (please specify intolerance or contraindication)

OR

2.3 If the request is for Jatenzo, Kyzatrex, Tlando, or Undecatrex, ONE of the following:

2.3.1 Failure to ALL of the following:

testosterone cypionate vials

testosterone enanthate vials

testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

OR

2.3.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

testosterone cypionate vials

testosterone enanthate vials

testosterone gel - tube, pack, or pump bottle or testosterone 1.62% pump (generic Androgel 1.62% pump)

Notes	*Patients that have previously received injectable testosterone open a ccess should be reviewed using reauthorization criteria **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

Product Name:Androderm, generic testosterone gel, Brand Androgel, generic testosterone gel pump, Brand Androgel Pump, testosterone soln, Brand Fortesta, generic testosterone TD gel, Natesto, Brand Testim, Brand Vogelxo, Brand Vogelxo Pump, Xyosted, Jatenzo, Kyzatrex, Tlando, Brand Depo-Testosterone, generic testosterone cypionate, testosterone enanthate, Undecatrex	
Diagnosis	Hypogonadism, Gender Dysphoria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has a diagnosis of Gender Dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

OR

1.2 ALL of the following:

1.2.1 Patient has a history of ONE of the following:

Bilateral orchiectomy

Panhypopituitarism

A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

AND

1.2.2 Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

Genotropin

Humatrope

Norditropin FlexPro

Nutropin AQ

Omnitrope

Saizen

AND

1.2.3 Patient is NOT taking any aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

OR

1.3 ALL of the following:

1.3.1 Patient has a diagnosis of Hypogonadism

AND

1.3.2 ONE of the following:

1.3.2.1 Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

OR

1.3.2.2 Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

OR

1.3.2.3 BOTH of the following:

1.3.2.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) [e.g., thyroid disorder, HIV (human immunodeficiency virus) disease, liver disorder, diabetes, obesity]

AND

1.3.2.3.2 ONE of the following:

Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

AND

1.3.3 Patient is NOT taking any of the following growth hormones, unless diagnosed with panhypopituitarism:

Genotropin

Humatrope

Norditropin FlexPro Nutropin AQ Omnitrope Saizen **AND** **1.3.4** Patient is NOT taking any aromatase inhibitors [e.g., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]

2 . Revision History

Date	Notes
1/15/2025	Updated GPIs. Added Undecatrex

Tezspire

Prior Authorization Guideline

Guideline ID	GL-155264
Guideline Name	Tezspire
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

2 - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

2.1 Reduction in the frequency of exacerbations

OR

2.2 Decreased utilization of rescue medications

OR

2.3 Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

OR

2.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

3 - Tezspire is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

4 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE-therapy [e.g., Xolair (omalizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

AND

5 - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Tezspire will be used in combination with ONE of the following:

3.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

3.2 Combination therapy including BOTH of the following:

3.2.1 ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

3.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Tezspire will be used to treat eosinophilic asthma

AND

4.1.2 BOTH of the following:

4.1.2.1 ONE of the following

Failure to a 4-month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] as confirmed by claims history or submission of medical records

History of contraindication or intolerance to an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] (please specify contraindication or intolerance)

AND

4.1.2.2 ONE of the following:

Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records

History of contraindication or intolerance to Dupixent (dupilumab) (please specify contraindication or intolerance)

OR

4.2 BOTH of the following:

4.2.1 Tezspire will be used to treat persistent allergic asthma

AND

4.2.2 ONE of the following:

Failure to a 4-month trial of Xolair (omalizumab) as confirmed by claims history or submission of medical records

History of intolerance or contraindication to Xolair (omalizumab) (please specify contraindication or intolerance)

OR

4.3 BOTH of the following:

4.3.1 Tezspire will be used to treat oral corticosteroid dependent asthma

AND

4.3.2 ONE of the following:

Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records

History of intolerance or contraindication to Dupixent (dupilumab) (please specify contraindication or intolerance)

OR

4.4 Patient's asthma is not of the eosinophilic, allergic, or oral corticosteroid dependent phenotype

AND

5 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE therapy [e.g., Xolair (omalizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

6 - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

Reduction in the frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

2 - Tezspire is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

3 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE therapy [e.g., Xolair (omalizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

2 . Revision History

Date	Notes
9/19/2024	Modified wording for existing prior authorization for under the medical benefit.

Tezspire

Prior Authorization Guideline

Guideline ID	GL-155264
Guideline Name	Tezspire
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Tezspire under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

AND

2 - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

2.1 Reduction in the frequency of exacerbations

OR

2.2 Decreased utilization of rescue medications

OR

2.3 Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

OR

2.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

3 - Tezspire is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

4 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE-therapy [e.g., Xolair (omalizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

AND

5 - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

2.1 Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control test [ACT] score consistently less than 20)

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Tezspire will be used in combination with ONE of the following:

3.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

OR

3.2 Combination therapy including BOTH of the following:

3.2.1 ONE maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

3.2.2 ONE additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Tezspire will be used to treat eosinophilic asthma

AND

4.1.2 BOTH of the following:

4.1.2.1 ONE of the following

Failure to a 4-month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] as confirmed by claims history or submission of medical records

History of contraindication or intolerance to an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] (please specify contraindication or intolerance)

AND

4.1.2.2 ONE of the following:

Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records

History of contraindication or intolerance to Dupixent (dupilumab) (please specify contraindication or intolerance)

OR

4.2 BOTH of the following:

4.2.1 Tezspire will be used to treat persistent allergic asthma

AND

4.2.2 ONE of the following:

Failure to a 4-month trial of Xolair (omalizumab) as confirmed by claims history or submission of medical records

History of intolerance or contraindication to Xolair (omalizumab) (please specify contraindication or intolerance)

OR

4.3 BOTH of the following:

4.3.1 Tezspire will be used to treat oral corticosteroid dependent asthma

AND

4.3.2 ONE of the following:

Failure to a 4-month trial of Dupixent (dupilumab) as confirmed by claims history or submission of medical records

History of intolerance or contraindication to Dupixent (dupilumab) (please specify contraindication or intolerance)

OR

4.4 Patient's asthma is not of the eosinophilic, allergic, or oral corticosteroid dependent phenotype

AND

5 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE therapy [e.g., Xolair (omalizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

AND

6 - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Product Name:Tezspire auto-injector pen	
Diagnosis	Severe Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tezspire therapy as demonstrated by at least ONE of the following:

Reduction in the frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

2 - Tezspire is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

AND

3 - Patient is NOT receiving Tezspire in combination with any of the following:

Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-IgE therapy [e.g., Xolair (omalizumab)]

Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]

2 . Revision History

Date	Notes
9/19/2024	Modified wording for existing prior authorization for under the medical benefit.

Thalomid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150975
Guideline Name	Thalomid
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/5/2024

1 . Criteria

Product Name:Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name:Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

AND

2 - ONE of the following:

2.1 Used for acute treatment

OR

2.2 Used as maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence

Product Name:Thalomid	
Diagnosis	Castleman Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Castleman Disease (CD)

AND

2 - ONE of the following:

2.1 NOT used as first line therapy

OR

2.2 ALL of the following:

2.2.1 Therapy is for active idiopathic multicentric CD with no evidence of organ failure

AND

2.2.2 Used in combination with cyclophosphamide and prednisone

AND

2.2.3 Patient is human immunodeficiency virus (HIV)-negative

AND

2.2.4 Patient is human herpesvirus-8 (HHV8)-negative

Product Name:Thalomid	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of HIV (human immunodeficiency virus)-negative Kaposi Sarcoma

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of AIDS-related Kaposi Sarcoma

AND

1.2.2 Patient is currently being treated with antiretroviral therapy (ART) as confirmed by claims history or submission of medical records

AND

2 - NOT used as first line therapy

AND

3 - Patient has immune reconstitution inflammatory syndrome (IRIS)

Product Name:Thalomid	
Diagnosis	Langerhans Cell Histiocytosis, Rosai-Dorfman Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans cell histiocytosis

OR

2 - Diagnosis of Rosai-Dorfman Disease

Product Name:Thalomid	
Diagnosis	Multiple Myeloma, Castleman Disease (CD), Kaposi Sarcoma, Langerhans Cell Histiocytosis, Rosai-Dorfman Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Thalomid therapy

Product Name:Thalomid	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL), NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Thalomid therapy

2 . Revision History

Date	Notes
8/5/2024	Removed criteria for myelofibrosis-associated anemia. Renamed dia gnosis header from B-Cell Lymphomas to Castleman Disease (CD). Updated criteria for Kaposi sarcoma per NCCN guidance.

Therapeutic Duplication (Subtype A)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-216248
Guideline Name	Therapeutic Duplication (Subtype A)
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Nebraska Medicaid - Community & State Kansas Medicaid - Community & State New Mexico Medicaid - Community & State North Carolina (ACUNC) Medicaid - Community & State Virginia Medicaid - Community & State Texas

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Generic arformoterol nebulizer solution, Brand Brovana nebulizer, generic formoterol nebulizer solution, Brand Perforomist nebulizer, Striverdi Respimat, Serevent Diskus, Incruse Ellipta, Brand Spiriva Handihaler, generic tiotropium, Spiriva Respimat, Tudorza Pressair, generic ipratropium inhalation solution, Atrovent HFA, Anoro Ellipta, Stiolto Respimat, Bevespi Aerosphere, Duaklir Pressair, Breztri Aerosphere, Glyxambi, Steglujan,

Qtern, Trijardy XR, Brand Pulmicort suspension, generic budesonide suspension, Victoza, Adlyxin, Trulicity, Bydureon BCise, Byetta, Ozempic, Rybelsus, Januvia, Janumet, Janumet XR, Brand Onglyza, generic saxagliptin, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Tradjenta, Jentadueto, Jentadueto XR, Nesina, alogliptin, Kazano, alogliptin/metformin, Oseni, alogliptin/pioglitazone, Mounjaro, Xultophy, Soliqua, Invokana, brand Farxiga, generic dapagliflozin, Jardiance, Invokamet, Invokamet XR, brand Xigduo XR, generic dapagliflozin/metformin ER, Synjardy, Synjardy XR, Steglatro, Segluromet, Zituvio, Brand Flovent HFA, Fluticasone propionate HFA, Flovent Diskus, Brand Fluticasone propionate Diskus, Brand Pulmicort Flexhaler, Alvesco, ArmonAir Digihaler, Asmanex Twisthaler, Asmanex HFA, Arnuity Ellipta, Qvar RediHaler, Lonhala Magnair, Trelegy Ellipta, Brand Advair Diskus, generic fluticasone propionate/salmeterol diskus (generic Advair Diskus), generic Wixela Inhub (generic Advair Diskus), AirDuo Respiclick, fluticasone/salmeterol (authorized generic of AirDuo), Brand Advair HFA, Brand Fluticasone/salmeterol HFA, Brand Symbicort, generic budesonide/formoterol, Breyna, AirDuo Digihaler, Dulera, Breo Ellipta, Brand fluticasone/vilanterol Ellipta, Basaglar Tempo pen, Basaglar Kwikpen, Insulin Glargine Solostar, Lantus Solostar, Toujeo Solostar, Toujeo Max Solostar, Semglee Pen Injector, Insulin Glargine-YFGN pen, Lantus vial, Insulin Glargine vial, Semglee vial, Insulin Glargine-YFGN vial, Levemir vial, Levemir Flextouch, Levemir Flexpen, Tresiba vial, Insulin Degludec vial, Tresiba Flextouch, Insulin Degludec Flextouch, Rezvoglar, Baclofen tabs, generic baclofen suspension, Brand Fleqsuvy, Brand Ozobax DS, brand Ozobax, Brand Baclofen solution, brand Lioresal intrathecal, generic baclofen intrathecal, brand Gablofen intrathecal, baclofen intrathecal solution, Lyvispah, generic carisoprodol tab, brand Soma, brand Vanadom tab, generic chlorzoxazone, brand Lorzone, generic cyclobenzaprine, brand Fexmid, generic cyclobenzaprine ER, brand Amrix, metaxalone, methocarbamol, orphenadrine CR/ER, generic tizanidine caps/tabs, brand Zanaflex caps/tabs, brand Dantrium, generic dantrolene, brand Norgesic, generic orphenadrine/aspirin/caffeine, norgesic forte, orphengesic forte, Brand Neurontin caps/tabs/soln, generic gabapentin caps/tabs/soln, gabapentin tinytabs, brand Lyrica caps/soln, generic pregabalin caps/soln, brand Gralise, brand Lyrica CR, generic pregabalin ER, Horizant, Zorvolex, brand Zipsor, generic diclofenac caps, brand Lofena, generic diclofenac tabs, diclofenac DR/ER, brand Cambia, generic diclofenac packet (migraine), etodolac cap, brand Lodine, generic etodolac tab, etodolac ER, brand Nalfon caps/tabs, generic fenoprofen caps/tabs, flurbiprofen, ibuprofen caps/tabs/chewable (includes All Manufactures), Brand Advil, ibuprofen suspension (40 mg/ml & 100 mg/5ml), indomethacin caps, indomethacin ER/SR caps, indocin susp, indocin suppository, indomethacin suppository, ketoprofen cap, ketoprofen ER cap, ketorolac tabs, meclofenamate cap, mefenamic acid, meloxicam cap/tab, brand Relafen DS, generic nabumetone, generic naproxen tab/susp/caps (includes All Manufactures), brand naprosyn tab/susp, brand Aleve, brand Anaprox DS, brand EC-Naprosyn, generic naproxen DR, generic EC-naproxen, brand Naprelan, generic naproxen CR/ER, Brand Daypro, generic oxaprozin, brand Feldene, generic piroxicam, sulindac, tolmetin, brand Celebrex, generic celecoxib, Elyxyb, brand Arthrotec, generic diclofenac sodium/misoprostol, brand Duexis, generic ibuprofen/famotidine, brand Vimovo, generic naproxen/esomeprazole, brand Advil PM, generic ibuprofen/diphenhydramine, brand Aleve PM, generic naproxen/diphenhydramine, hydrocodone/ibuprofen, brand Treximet, generic sumatriptan/naproxen, Motrin Dual Action/Tylenol, Advil Dual Action/acetaminophen, acetaminophen/ibuprofen, Naproxen/capsaicin cream (Naprotin), Inpefa, Saxenda, Wegovy, Brand Brenzavvy, Brand Bexagliflozin, Zepbound, Coxanto, Jantoven, warfarin tabs, Pradaxa, generic dabigatran, Eliquis, Savaysa, Xarelto, Brand Lunesta, generic eszopiclone, zaleplon, Zolpidem, Brand Ambien, generic zolpidem, Brand Ambien CR, generic zolpidem CR. Edluar, Zolpimist, Brand Rozerem, generic ramelteon, Brand Silenor, generic doxepin (sleep) 3mg

and 6 mg tabs, Belsomra, Dayvigo, Quviviq, Brand Precedex, generic dexmedetomidine, Dexmedetomidine, Igalmi, Brand Hetlioz, generic tasimelteon, Hetlioz LQ, Brand Restoril, generic temazepam, Brand Halcion, generic triazolam, Brand Doral, generic quazepam, flurazepam, estazolam, Zituvimet, Sitagliptin/metformin, Brand Tanlor, Dolobid, generic diflunisal, Zituvimet XR, Tresni, Fenopron, Gabarone, Addaprin	
Diagnosis	DUR: Therapeutic Duplication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued

OR

2 - All of the following:

2.1 The requested medication combination is supported by information from ONE of the following appropriate compendia of current literature:

American Hospital Formulary Service Drug Information

National Comprehensive Cancer Network Drugs and Biologics Compendium

Thomson Micromedex DrugDex

Clinical pharmacology

United States Pharmacopoeia-National Formulary (USP-NF)

AND

2.2 The drug combination is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plan’s program

AND

2.3 The provider attests that they are aware that the patient is using duplicate therapy

AND

2.4 Special clinical circumstances exist that necessitate the need for duplicate therapy (document special circumstances)

AND

2.5 Provider attests that the necessity for continued concomitant therapy and safety will be periodically assessed

2 . Revision History

Date	Notes
3/18/2025	Updated product list. Combined formularies. Changed to Admin GL ty pe. Removed GPIs.

Therapeutic Duplication (Subtype B)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-216246
Guideline Name	Therapeutic Duplication (Subtype B)
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) Medicaid - Community & State Indiana Medicaid - Community & State Michigan Medicaid - Community & State Nebraska Medicaid - Community & State Washington Medicaid - Community & State Kansas Medicaid - Community & State New Mexico Medicaid - Community & State North Carolina (ACUNC) Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:(All formulations/packaging, except for Entyvio) Entyvio Pen, Stelara, Cimzia, Abrilada, Humira, Amjevita, Idacio, Hulio, Cyltezo, Yusimry, Yuflyma, Hadlima, Hyrimoz, adalimumab (adalimumab-AATY, adalimumab-RYVK, adalimumab-ADBM, adalimumab-AACF, adalimumab-ADAZ, adalimumab-FKJP), Simponi, Enbrel, Actemra, Cosentyx, Ilaris, Kineret, Kevzara, Taltz, Tremfya, Orencia, Xeljanz, Xeljanz XR, Xeljanz Solution, Siliq, Otezla, Olumiant, Ilumya, Skyrizi, Rinvoq, Sotyktu, Cibinqo, Adbry, Dupixent, brand Copaxone, generic glatiramer acetate, generic glatopa, Mavenclad, Rebif, Avonex, Betaseron, Extavia, brand Aubagio, generic teriflunomide, Plegridy, Lemtrada, Tysabri, Ocrevus, brand Tecfidera, generic dimethyl fumarate, Vumerity, brand Gilenya, generic fingolimod, Tascenso ODT, Zeposia, Mayzent, Bafiertam, Kesimpta, Ponvory, Xolair, Fasenra, Nucala, Cinqair, Tezspire, Velsipity, Bimzelx, Omvoh, Zymfentra, Simlandi, Spevigo, Tyenne, Rinvoq LQ, Nemluvio, Ebglyss, Wezlana, Steqeyma, Yesintek, Pyzchiva, Otulfi, Selarsdi	
Diagnosis	DUR: Therapeutic Duplication
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - The requested medication will be used exclusively, and the previously prescribed medication will be discontinued	

2 . Revision History

Date	Notes
3/17/2025	Updated to Admin GL type.

Tibsovo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208199
Guideline Name	Tibsovo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - ONE of the following:

3.1 Disease is relapsed or refractory

OR

3.2 BOTH of the following:

3.2.1 New diagnosis of AML

AND

3.2.2 ONE of the following:

Patient is 75 years of age or older

Patient has comorbidities that preclude the use of intensive induction chemotherapy

Patient is 60 years of age or older AND not a candidate for or declines intensive induction therapy

Patient is 60 years of age or older AND receiving post-induction therapy following response to previous lower intensity therapy

Product Name:Tibsovo

Diagnosis	Bone Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chondrosarcoma

AND

2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - Disease is ONE of the following:

Conventional (grades 1-3)

Dedifferentiated

Product Name:Tibsovo	
Diagnosis	Biliary Tract Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cholangiocarcinoma

AND

2 - Susceptible IDH1 (isocitrate dehydrogenase 1) mutation-positive

AND

3 - Disease is ONE of the following:

Locally advanced

Unresectable

Metastatic

AND

4 - Disease has progressed on or after systemic treatment

Product Name:Tibsovo	
Diagnosis	Oligodendroglioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of oligodendroglioma

AND

2 - Disease is recurrent or progressive

AND

3 - Presence of BOTH of the following:

IDH1 mutation

1p19q codeletion

AND

4 - Disease is WHO grade 2 or 3

Product Name:Tibsovo	
Diagnosis	Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of astrocytoma

AND

2 - Disease is recurrent or progressive

AND

3 - Presence of IDH1 mutation

AND

4 - Disease is WHO grade 2, 3, or 4

Product Name:Tibsovo	
Diagnosis	Myelodysplastic Syndrome (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome (MDS)

AND

2 - Disease is relapsed or refractory

AND

3 - Presence of IDH1 mutation

Product Name:Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML), Bone Cancer, Biliary Tract Cancer, Oligodendroglioma, Astrocytoma, Myelodysplastic syndrome (MDS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tibsovo therapy

Product Name:Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tibsovo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tibsovo therapy

2 . Revision History

Date	Notes
3/5/2025	Updated formularies. Updated criteria for oligodendroglioma and astr ocytoma

Tobramycin Inhalation

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134476
Guideline Name	Tobramycin Inhalation
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:generic tobramycin 300 mg/4mL nebu soln (generic Bethkis)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cystic fibrosis (CF)

OR

2 - BOTH of the following:

2.1 Diagnosis of noncystic fibrosis bronchiectasis

AND

2.2 ONE of the following:

2.2.1 Three or more exacerbations per year

OR

2.2.2 Two or more exacerbations requiring hospitalization per year

Product Name:Kitabis Pak, Brand Tobi nebu soln, generic tobramycin 300 mg/5mL nebu soln, Brand Tobramycin 300mg/5mL nebu soln, Tobi Podhaler, Brand Bethkis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of cystic fibrosis (CF)

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of noncystic fibrosis bronchiectasis

AND

1.2.2 ONE of the following:

1.2.2.1 Three or more exacerbations per year

OR

1.2.2.2 Two or more exacerbations requiring hospitalization per year

AND

2 - Lung infection with positive culture demonstrating Pseudomonas aeruginosa infection

AND

3 - ONE of the following:

3.1 Failure to generic tobramycin 300 mg/4mL (milligrams/milliliter) solution for inhalation (generic Bethkis) as confirmed by claims history or submission of medical records

OR

3.2 History of contraindication or intolerance to generic tobramycin 300 mg/4mL solution for inhalation (generic Bethkis) (please specify contraindication or intolerance)

Product Name:Kitabis Pak, Brand Tobi nebu soln, generic tobramycin 300 mg/5mL nebu soln, Brand Tobramycin 300mg/5mL nebu soln, Tobi Podhaler, Brand Bethkis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/10/2023	Updated product name lists, added criteria for noncystic fibrosis bron chiectasis with recurrent exacerbations.

Tocilizumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155273
Guideline Name	Tocilizumab
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State New York EPP

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Actemra subcutaneous, Tyenne subcutaneous	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of ONE non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses confirmed by claims history or submitted medical records

OR

1.2.2 History of intolerance or contraindication to ONE non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a biologic or targeted synthetic DMARD FDA (Food and Drug Administration)-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

AND

1.3 ONE of the following:

1.3.1 Failure of ONE of the preferred adalimumab products* confirmed by claims history or submitted medical records

OR

1.3.2 History of intolerance or contraindication to ALL preferred adalimumab products* (please specify intolerance or contraindication)

AND

1.4 If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)**

AND

1.5 Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.6 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records

AND

2.2 Diagnosis of moderately to severely active RA

AND

2.3 Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

2.4 If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)**

AND

2.5 Prescribed by or in consultation with a rheumatologist

Notes	*For a list of preferred adalimumab products please reference drug coverage tools. **For a list of preferred tocilizumab products please reference drug coverage tools.

Product Name:Actemra subcutaneous, Tyenne subcutaneous	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - ONE of the following:

2.1 Failure to ONE glucocorticoid (e.g., prednisone) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to ALL glucocorticoids (e.g., prednisone) (please specify intolerance or contraindication)

OR

2.3 Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records

AND

3 - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products (please document reason/special circumstances)**

AND

4 - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	**For a list of preferred tocilizumab products please reference drug co verage tools.

Product Name:Actemra subcutaneous, Tyenne subcutaneous	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - ONE of the following:

2.1 Failure to ONE of the preferred adalimumab products* confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to ALL of the preferred adalimumab products* (please specify intolerance or contraindication)

OR

2.3 Patient is currently on tocilizumab therapy as confirmed by claims history or submitted medical records

AND

3 - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products** (please document reason/special circumstances)

AND

4 - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*For a list of preferred adalimumab products please reference drug coverage tools. **For a list of preferred tocilizumab products please reference drug coverage tools.

Product Name:Actemra subcutaneous, Tyenne subcutaneous	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products** (please document reason/special circumstances)

AND

4 - Prescribed by or in consultation with a rheumatologist

Notes	**For a list of preferred tocilizumab products please reference drug coverage tools.

Product Name:Actemra subcutaneous, Tyenne subcutaneous

Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by ALL of the following:

1.1 ONE of the following:

1.1.1 Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

OR

1.1.2 At least TWO of the following:

Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)

Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)

Telangiectasia

Abnormal nailfold capillaries

Pulmonary arterial hypertension

Raynaud's phenomenon

SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

AND

1.2 Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT (high-resolution computed tomography), involving at least 10% of the lungs

AND

2 - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

3 - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products** (please document reason/special circumstances)

AND

4 - Prescribed by or in consultation with a pulmonologist

Notes	**For a list of preferred tocilizumab products please reference drug co verage tools.

Product Name:Actemra subcutaneous, Tyenne subcutaneous	
Diagnosis	RA, GCA, PJIA, SJIA, SSc-ILD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to tocilizumab therapy

AND

2 - Patient is NOT receiving tocilizumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab),

Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]* **AND** **3** - If the request is for a non-preferred tocilizumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred tocilizumab products** (please document reason/special circumstances)	
Notes	* Examples of drug(s) may not be applicable based on the requested i ndication. **For a list of preferred tocilizumab products please reference drug co verage tools.

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
9/19/2024	Updated safety language. Added Tyenne and renamed policy to Tocilizumab. Updated step through agents where appropriate.

Topical NSAIDs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134133
Guideline Name	Topical NSAIDs
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Brand diclofenac epolamine patch, Brand Flector	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute pain due to minor strains, sprains, or contusions

AND

2 - The patient did not receive adequate pain relief when treated with at least TWO preferred* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy

AND

3 - ONE of the following:

3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

diclofenac topical gel 1% [Rx (prescription) formulation]

diclofenac topical gel 1% [OTC (over-the-counter) formulation]

OR

3.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

diclofenac topical gel 1% (Rx formulation)

diclofenac topical gel 1% (OTC formulation)

Notes	*PDL links are listed in Background.

Product Name:Brand Pennsaid, generic diclofenac sodium soln 2%, diclofenac sodium soln 1.5%	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of pain due to osteoarthritis of the knee(s)

AND

2 - The patient did not receive adequate pain relief when treated with at least TWO preferred* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy

AND

3 - ONE of the following:

3.1 If the request is for Pennsaid (diclofenac sodium soln 2%), ONE of the following:

3.1.1 Failure of BOTH of the following, as confirmed by claims history or submitted medical records:

diclofenac topical gel 1% [Rx (prescription) or OTC (over the counter) formulation] (generic for Voltaren)

diclofenac 1.5% topical solution

OR

3.1.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

diclofenac topical gel 1% (Rx or OTC formulation) (generic for Voltaren)

diclofenac 1.5% topical solution

OR

3.2 If the request is for diclofenac topical solution 1.5%, ONE of the following:

3.2.1 Failure of ONE of the following, as confirmed by claims history or submitted medical records:

diclofenac topical gel 1% (Rx formulation) (generic for Voltaren)

diclofenac topical gel 1% (OTC formulation) (generic for Voltaren)

OR

3.2.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

diclofenac topical gel 1% (Rx formulation) (generic for Voltaren)

diclofenac topical gel 1% (OTC formulation) (generic for Voltaren)

Notes	*PDL links are listed in Background.

Product Name:Voltaren (Rx and OTC formulations)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of pain due to osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists

AND

2 - ONE of the following:

2.1 If the request is for the Rx (prescription) formulation, BOTH of the following:

2.1.1 The patient did not receive adequate pain relief when treated with at least TWO preferred* non-steroidal anti-inflammatory drugs (NSAIDs), one of which must be celecoxib (generic for Celebrex), as confirmed by claims history or submitted medical records. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy

AND

2.1.2 ONE of the following:

2.1.2.1 Failure to BOTH of the following, as confirmed by claims history or submission of medical records:

diclofenac topical gel 1% [Rx or OTC (over-the-counter) formulation] (generic Voltaren)

Brand Voltaren topical gel 1% (OTC formulation)

OR

2.1.2.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

diclofenac topical gel 1% (Rx or OTC formulation) (generic Voltaren)

Brand Voltaren topical gel 1% (OTC formulation)

OR

2.2 If the request is for the OTC formulation, ONE of the following:

2.2.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

diclofenac topical gel 1% (Rx formulation) (generic Voltaren)

diclofenac topical gel 1% (OTC formulation) (generic Voltaren)

OR

2.2.2 History of intolerance or contraindication to BOTH of the following (please provide intolerance or contraindication):

diclofenac topical gel 1% (Rx formulation) (generic Voltaren)

diclofenac topical gel 1% (OTC formulation) (generic Voltaren)	
Notes	*PDL links are listed in Background.

2 . Background

Benefit/Coverage/Program Information
PDL links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
10/3/2023	Updated GPI name for Voltaren Gel. Removed RMHCAID from formulary and revised CO PDL Link.

Topical Retinoid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161604
Guideline Name	Topical Retinoid Products
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic tretinoin microsphere, Retin-A Micro, Brand Differin cream, generic adapalene cream, Differin gel (Rx only)/lotion, adapalene gel/soln/pads, Fabior, tazarotene foam, Tazorac, generic tazarotene, adapalene/benzoyl peroxide, Brand Epiduo, Brand Epiduo Forte, Brand Atralin, generic tretinoin gel, Avita, Brand Retin-A, Altreno, Aklief, Arazlo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

2 - Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Patient has a diagnosis of acne vulgaris

AND

3.1.2 ONE of the following:

3.1.2.1 Failure to a trial of BOTH of the following as confirmed by claims history or submission of medical records:

Differin OTC (over the counter)

Tretinoin cream (generic Retin-A cream)

OR

3.1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Differin OTC

Tretinoin cream (generic Retin-A cream)

OR

3.2 BOTH of the following:

3.2.1 Patient does NOT have a diagnosis of acne vulgaris

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to a trial of at least THREE preferred* products as confirmed by claims history or submission of medical records

OR

3.2.2.2 History of intolerance or contraindication to ALL preferred* products (please specify intolerance or contraindication)

Notes	*Step therapy is not limited to topical retinoids. In instances where the re are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferre d products. *See Table 2 in Background for PDL links.

Product Name:generic tretinoin cream	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is less than 18 years old

OR

2 - ALL of the following:

2.1 Patient is 18 years of age or older

AND

2.2 Patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

2.3 Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

2 . Background

Benefit/Coverage/Program Information

Table 1: Examples of non-cosmetic medical conditions include, but are not limited to, the following:

Acanthosis nigricans	Keratoderma
Acne	Keratoderma palmaris et plantaris
Acne keloidalis nuchae	Keratosis rubra figurata
Acne rosacea	Kyrle's disease
Acne vulgaris	Lamellar ichthyosis
Actinic cheilitis	Leukoplakia
Actinic dermatitis	Lichen planus
Actinic keratosis	Mal de Meleda
	Malignancy

Basal cell carcinoma	Mendes da Costa syndrome
Bowen's disease	Molluscum contagiosum
Cystic acne	Non-bullous congenital ichthyosis
Darier's disease	Papillon-Lefevre syndrome
Darier-White Disease	Porokeratosis
Dermal mucinosis	Pseudofollicular barbae
Discoid lupus erythematosus	Pseudoacanthosis nigricans
Epidermoid cysts	Psoriasis
Epidermolytic hyperkeratosis	Psoriasis erythrodermic, palmoplantar
Erythrokeratoderma variabilis	Psoriasis pustular
Favre Racouchot disease	Psoriatic arthritis
Flat warts	Rosacea
Folliculitis	Sebaceous cysts
Fox Fordyce disease	Senile keratosis
Grover's disease	Solar keratosis
Hidradenitis suppurativa	Squamous cell carcinoma
Hyperkeratosis	Systematized epidermal nevus
Hyperkeratosis follicularis	Transient acantholytic dermatosis
Hyperkeratotic eczema	Tylotic eczema
Ichthyoses	X-linked ichthyosis
Ichthyosis vulgaris	Verruca planae
Keloid scar	Von Zumbusch pustular
Keratoacanthoma	Warts

Keratosis follicularis	Wound healing (mild)

Table 2: PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
12/3/2024	Updated GPIs

Topical Retinoid Products

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161604
Guideline Name	Topical Retinoid Products
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:generic tretinoin microsphere, Retin-A Micro, Brand Differin cream, generic adapalene cream, Differin gel (Rx only)/lotion, adapalene gel/soln/pads, Fabior, tazarotene foam, Tazorac, generic tazarotene, adapalene/benzoyl peroxide, Brand Epiduo, Brand Epiduo Forte, Brand Atralin, generic tretinoin gel, Avita, Brand Retin-A, Altreno, Aklief, Arazlo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

2 - Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Patient has a diagnosis of acne vulgaris

AND

3.1.2 ONE of the following:

3.1.2.1 Failure to a trial of BOTH of the following as confirmed by claims history or submission of medical records:

Differin OTC (over the counter)

Tretinoin cream (generic Retin-A cream)

OR

3.1.2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Differin OTC

Tretinoin cream (generic Retin-A cream)

OR

3.2 BOTH of the following:

3.2.1 Patient does NOT have a diagnosis of acne vulgaris

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to a trial of at least THREE preferred* products as confirmed by claims history or submission of medical records

OR

3.2.2.2 History of intolerance or contraindication to ALL preferred* products (please specify intolerance or contraindication)

Notes	*Step therapy is not limited to topical retinoids. In instances where the re are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferre d products. *See Table 2 in Background for PDL links.

Product Name:generic tretinoin cream	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is less than 18 years old

OR

2 - ALL of the following:

2.1 Patient is 18 years of age or older

AND

2.2 Patient has a non-cosmetic medical condition (e.g., acne vulgaris, psoriasis, precancerous skin lesions) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

AND

2.3 Medication is not being requested solely for cosmetic purposes (e.g., photo-aging, wrinkling, hyperpigmentation, sun damage, melasma) (See Table 1 in Background for additional list of non-cosmetic medical conditions)

2 . Background

Benefit/Coverage/Program Information

Table 1: Examples of non-cosmetic medical conditions include, but are not limited to, the following:

Acanthosis nigricans	Keratoderma
Acne	Keratoderma palmaris et plantaris
Acne keloidalis nuchae	Keratosis rubra figurata
Acne rosacea	Kyrle's disease
Acne vulgaris	Lamellar ichthyosis
Actinic cheilitis	Leukoplakia
Actinic dermatitis	Lichen planus
Actinic keratosis	Mal de Meleda
	Malignancy

Basal cell carcinoma	Mendes da Costa syndrome
Bowen's disease	Molluscum contagiosum
Cystic acne	Non-bullous congenital ichthyosis
Darier's disease	Papillon-Lefevre syndrome
Darier-White Disease	Porokeratosis
Dermal mucinosis	Pseudofollicular barbae
Discoid lupus erythematosus	Pseudoacanthosis nigricans
Epidermoid cysts	Psoriasis
Epidermolytic hyperkeratosis	Psoriasis erythrodermic, palmoplantar
Erythrokeratoderma variabilis	Psoriasis pustular
Favre Racouchot disease	Psoriatic arthritis
Flat warts	Rosacea
Folliculitis	Sebaceous cysts
Fox Fordyce disease	Senile keratosis
Grover's disease	Solar keratosis
Hidradenitis suppurativa	Squamous cell carcinoma
Hyperkeratosis	Systematized epidermal nevus
Hyperkeratosis follicularis	Transient acantholytic dermatosis
Hyperkeratotic eczema	Tylotic eczema
Ichthyoses	X-linked ichthyosis
Ichthyosis vulgaris	Verruca planae
Keloid scar	Von Zumbusch pustular
Keratoacanthoma	Warts

Keratosis follicularis	Wound healing (mild)

Table 2: PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY/NY EPP: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
12/3/2024	Updated GPIs

Trelegy Ellipta, Breztri

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147215
Guideline Name	Trelegy Ellipta, Breztri
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Trelegy Ellipta, Breztri Aerosphere	
Diagnosis	Chronic Obstructive Pulmonary Disease (COPD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

AND

2 - ONE of the following:

2.1 Failure to a 30 day trial of ONE of the following combinations as confirmed by claims history or submission of medical records:

2.1.1 ONE of the following long-acting muscarinic antagonist (LAMA) plus long-acting beta2-agonist (LABA)

Anoro Ellipta (umeclidinium/vilanterol)

Stiolto Respimat (tiotropium/olodaterol)

OR

2.1.2 ONE of the following inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA)

fluticasone/salmeterol (authorized generic of AirDuo)

fluticasone propionate/salmeterol diskus (generic Advair Diskus)

Wixela Inhub (generic Advair Diskus)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

Anoro Ellipta (umeclidinium/vilanterol)

Stiolto Respimat (tiotropium/olodaterol)

fluticasone/salmeterol (authorized generic of AirDuo)

fluticasone propionate/salmeterol diskus (generic Advair Diskus)

Wixela Inhub (generic Advair Diskus)

OR

2.3 Eosinophil count greater than or equal to 300 cells/microliter as confirmed by submission of medical records

Product Name:Trelegy Ellipta, Breztri Aerosphere	
Diagnosis	Asthma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - ONE of the following:

2.1 Failure to treatment with at least a 30-day trial of ONE of the following, confirmed by claims history or submission of medical records:

fluticasone/salmeterol (authorized generic of AirDuo)

fluticasone propionate/salmeterol diskus (generic Advair Diskus)

Wixela Inhub (generic Advair Diskus)

OR

2.2 History of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

fluticasone/salmeterol (authorized generic of AirDuo)

fluticasone propionate/salmeterol diskus (generic Advair Diskus) Wixela Inhub (generic Advair Diskus)

2 . Revision History

Date	Notes
5/9/2024	Updated formularies. No clinical changes to guideline.

Tremfya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-206588
Guideline Name	Tremfya
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State New Mexico

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic moderate to severe plaque psoriasis

AND

2 - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Tremfya therapy as confirmed by claims history or submission of medical records

OR

4.2 All of the following:

4.2.1 One of the following:

4.2.1.1 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), ustekinumab]

OR

4.2.1.2 All of the following:

4.2.1.2.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

4.2.1.2.2 One of the following:

Failure to ONE of the following topical therapy classes confirmed by claims history or submission of medical records: Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication): Corticosteroids (e.g., betamethasone, clobetasol, desonide), Vitamin D analogs (e.g., calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus), Anthralin, Coal tar

AND

4.2.1.2.3 One of the following:

Failure to a 3 month trial of methotrexate at maximally indicated dose confirmed by claims history or submitted medical records

History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

AND

4.2.2 One of the following:

4.2.2.1 Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following preferred products (please specify intolerance or contraindication):

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

AND

4.2.3 One of the following:

Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator

[e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

3 - Prescribed by or in consultation with one of the following:

Rheumatologist

Dermatologist

AND

4 - One of the following:

4.1 Patient is currently on Tremfya therapy as confirmed by claims history or submission of medical records

OR

4.2 ALL of the following:

4.2.1 One of the following:

Failure to a 3 month trial of methotrexate at the maximally indicated dose, confirmed by claims history or submitted medical records

History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), ustekinumab, Xeljanz/XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

AND

4.2.2 One of the following:

4.2.2.1 Failure to TWO of the following preferred products as confirmed by claims history or submitted medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

OR

4.2.2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication)

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

AND

4.2.3 One of the following:

Failure to Cosentyx (secukinumab) as confirmed by claims history or submitted medical records

History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

Notes	*See PDL links in Background

Product Name:Tremfya	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Patient has been established on therapy with Tremfya under an active UnitedHealthcare medical benefit prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

2.2 Patient is currently on Tremfya therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, adalimumab, Skyrizi (risankizumab)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Tremfya	
Diagnosis	Plaque Psoriasis, Psoriatic Arthritis (PsA), Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tremfya therapy

AND

2 - Patient is NOT receiving Tremfya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

Notes	*Examples of drug(s) may not be applicable based on the requested i ndication.

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

3 . Revision History

Date	Notes
3/6/2025	Added NM to formulary. Changed "Stelara" to "ustekinumab". Criteria updates for PsO and PsA dx.

Trikafta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151752
Guideline Name	Trikafta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results documenting that the patient has at least ONE of the following mutations in the CFTR gene:

F508del mutation

A mutation that is responsive based on in vitro data (see chart in Table 1 of background section)

AND

3 - The patient is greater than or equal to 2 years of age

AND

4 - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

Product Name:Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Trikafta therapy (e.g., improved lung function, stable lung function)

2 . Background

Benefit/Coverage/Program Information

Table 1

List of *CFTR* gene mutations that are responsive to Trikafta

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N* †	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del* *	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C †	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*

D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N* †	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M* †	*S364P*	*Y161S*
E116K	*G576A;R668C* †	*L165S*	*R74W;V201M; D1270N* †	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
8/14/2024	Removed prescriber requirement from reauthorization criteria. Increa sed initial authorization approval duration to 12 months.

Trikafta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151752
Guideline Name	Trikafta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Submission of laboratory results documenting that the patient has at least ONE of the following mutations in the CFTR gene:

F508del mutation

A mutation that is responsive based on in vitro data (see chart in Table 1 of background section)

AND

3 - The patient is greater than or equal to 2 years of age

AND

4 - Prescribed by, or in consultation with, a provider who specializes in the treatment of CF

Product Name:Trikafta	
Diagnosis	Cystic Fibrosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Trikafta therapy (e.g., improved lung function, stable lung function)

2 . Background

Benefit/Coverage/Program Information

Table 1

List of *CFTR* gene mutations that are responsive to Trikafta

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N* †	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del* *	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C †	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*

D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N* †	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M* †	*S364P*	*Y161S*
E116K	*G576A;R668C* †	*L165S*	*R74W;V201M; D1270N* †	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

3 . Revision History

Date	Notes
8/14/2024	Removed prescriber requirement from reauthorization criteria. Increa sed initial authorization approval duration to 12 months.

Triptans

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208201
Guideline Name	Triptans
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:almotriptan, generic eletriptan, Brand Relpax, generic frovatriptan, Brand Frova, Onzetra XSail, generic rizatriptan, Brand Maxalt, generic rizatriptan ODT, Brand Maxalt-MLT, Imitrex Statdose System, sumatriptan auto-inj, Brand Imitrex nasal spr/tabs, generic sumatriptan nasal spr/tabs/inj, Brand Imitrex Statdose Refill, generic sumatriptan refill, generic sumatriptan/naproxen, Brand Treximet, Zembrace Symtouch, generic zolmitriptan tabs/nasal spr, Brand Zomig tabs/nasal spr, Brand Zolmitriptan nasal spr, zolmitriptan ODT, Tosymra	
Diagnosis	Non-Preferred Products*
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - If the requested medication is non-preferred*, BOTH of the following:

1.1 Diagnosis of migraine headaches with or without aura

AND

1.2 ONE of the following:

1.2.1 Patient has failure to THREE of the following as confirmed by claims history or submission of medical records:

Eletriptan (generic Relpax)

Naratriptan

Rizatriptan

One of the following sumatriptan formulations: tablets, nasal spray, 4 mg injection, or 6 mg injection

Zolmitriptan (generic Zomig)

OR

1.2.2 Patient has a history of contraindication or intolerance to ALL of the following (please specify intolerance or contraindication):

Eletriptan (generic Relpax)

Naratriptan

Rizatriptan

One of the following sumatriptan formulations: tablets, nasal spray, 4 mg injection, or 6 mg injection

Zolmitriptan (generic Zomig)

Notes	*PDL links in Background.

Product Name:Imitrex Statdose System, sumatriptan auto-inj, sumatriptan inj, Brand Imitrex Statdose Refill, generic sumatriptan refill	
Diagnosis	Migraine Headaches
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Currently receiving prophylactic therapy with at least ONE of the following as confirmed by claims history or submission of medical records:

A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)

Candesartan* (generic Atacand)

A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine*** [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**]

Divalproex sodium (generic Depakote/Depakote ER)

OnabotulinumtoxinA (generic Botox)**

A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]

Topiramate (generic Topamax)

A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND

3 - ONE of the following:

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of the following compendia:

American Hospital Formulary Service Drug Information

Thomson Micromedex DrugDex

Clinical pharmacology

United States Pharmacopoeia-National Formulary (USP-NF)

OR

3.3 Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated

AND

4 - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	See Table 1 in Background. *This is non-preferred and should not be included in denial to provider . **This is a medical benefit and should not be included in denial to prov ider. ***Requires prior authorization

Product Name:Imitrex Statdose System, sumatriptan auto-inj, sumatriptan inj, Brand Imitrex Statdose Refill, generic sumatriptan refill	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of cluster headaches

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months

AND

3 - ONE of the following:

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of the following compendia:

American Hospital Formulary Service Drug Information

Thomson Micromedex DrugDex

Clinical pharmacology

United States Pharmacopoeia-National Formulary (USP-NF)

OR

3.3 Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated

AND

4 - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity	
Notes	See Table 1 in Background.

Product Name:almotriptan, generic eletriptan, Brand Relpax, generic frovatriptan, Brand Frova, Onzetra XSail, generic rizatriptan, Brand Maxalt, generic rizatriptan ODT, Brand Maxalt-MLT, Brand Imitrex nasal spr/tabs, generic sumatriptan nasal spr/tabs, generic sumatriptan/naproxen, Brand Treximet, Zembrace Symtouch, generic zolmitriptan tabs/nasal spr, Brand Zomig tabs/nasal spr, Brand Zolmitriptan nasal spr, zolmitriptan ODT, Tosymra, generic naratriptan	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of migraine headaches with or without aura

AND

2 - Currently receiving prophylactic therapy with at least ONE of the following as confirmed by claims history or submission of medical records:

A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol*)

Candesartan* (generic Atacand)

A calcitonin gene-related peptide receptor (CGRP) antagonist or inhibitor for preventive treatment of migraine*** [i.e., Aimovig, Ajovy*, Emgality, Qulipta*, Vyepti**]

Divalproex sodium (generic Depakote/Depakote ER)

OnabotulinumtoxinA (generic Botox)**

A serotonin-norepinephrine reuptake inhibitor [i.e., duloxetine (Cymbalta), venlafaxine (Effexor/Effexor XR)]

Topiramate (generic Topamax)

A tricyclic antidepressant [i.e., amitriptyline (Elavil), nortriptyline (Pamelor)]

AND **3** - ONE of the following: **3.1** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information **OR** **3.2** Higher dose or quantity is supported by one of the following compendia: American Hospital Formulary Service Drug Information Thomson Micromedex DrugDex Clinical pharmacology United States Pharmacopoeia-National Formulary (USP-NF) **OR** **3.3** Provider provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated **AND** **4** - Provider acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Notes	See Table 1 in Background. *This is non-preferred and should not be included in denial to provider . **This is a medical benefit and should not be included in denial to prov ider. ***Requires prior authorization

2 . Background

Benefit/Coverage/Program Information

Table 1. Quantity Limits

Drug Name	Strength	Quantity Limit
Brand Amerge generic naratriptan	1mg, 2.5mg	9 tabs/month
Brand Frova Generic frovatriptan	2.5mg	9 tabs/month
Brand Imitrex tablets Generic sumatriptan tablets	25mg, 50mg, 100mg	9 tabs/month
Brand Maxalt Generic rizatriptan	5mg, 10mg	9 tabs/month
Brand Maxalt MLT Generic rizatriptan ODT	5mg, 10mg	9 tabs/month
Generic almotriptan	6.25mg, 12.5mg	6 tabs/month
Relpax Generic eletriptan	20mg, 40mg	6 tabs/month
Brand Zomig Generic zolmitriptan	2.5mg, 5mg	6 tabs/month
Brand Zomig ZMT Generic zolmitriptan ODT	2.5mg, 5mg	6 tabs/month

Brand Imitrex nasal spray Generic sumatriptan nasal spray	5mg, 20mg	6 spray devices/month
Zomig nasal spray	2.5mg, 5mg	6 spray devices/month
Treximet Generic sumatriptan/naproxen	85mg/500 mg, 10mg/60mg	9 tabs/month
Onzetra Xsail	11mg	1 box (8 units)/month
Zembrace SymTouch	3mg/0.5mL	2 boxes (8 units)/month
Brand Imitrex Generic Sumatriptan Autoinjector/Cartridge Refills	4mg/0.5mL 6mg/0.5mL	8 autoinjectors or cartridge refills/month (4 boxes/month)
Brand Imitrex Generic Sumatriptan Vials	6mg/0.5mL	10 vials/month (2 boxes/month)
Generic Sumatriptan Pre-filled Syringe	6mg/0.5mL	8 prefilled syringes (4 boxes/month)
Tosymra nasal spray	10mg	6 units per month

PDL links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Updated formularies. Removed naratriptan step therapy section. Add ed eletriptan and zolmitriptan as options in the non-preferred section. Updated prophylactic therapies list and notes

Truqap

Prior Authorization Guideline

Guideline ID	GL-202194
Guideline Name	Truqap
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Truqap	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

Locally advanced

Recurrent unresectable (local or regional)

Metastatic

AND

3 - Disease is hormone receptor (HR)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of one or more PIK3CA/AKT1/PTEN-alterations

AND

6 - ONE of the following:

6.1 Has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen)

OR

6.2 Recurrence on or within 12 months of completing adjuvant therapy

AND

7 - Used in combination with fulvestrant

Product Name:Truqap	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Truqap therapy

AND

2 - Used in combination with fulvestrant

Product Name:Truqap	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Truqap	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Truqap therapy	

2 . Revision History

Date	Notes
2/25/2025	Combined formularies. Added new GPIs for Truqap therapy packs. For BC initial auth section, added "recurrent unresectable (local or regional)" as an option for disease type.

Tryvio

Prior Authorization Guideline

Guideline ID	GL-154407
Guideline Name	Tryvio
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/5/2024

1 . Criteria

Product Name:Tryvio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of resistant hypertension

AND

2 - One of the following:

2.1 Systolic blood pressure greater than or equal to 130 mm Hg (millimeters of mercury) on two consecutive measurements

OR

2.2 Diastolic blood pressure greater than or equal to 80 mm Hg on two consecutive measurements

AND

3 - Patient is receiving concomitant therapy with all of the following confirmed by claims history or submitted medical records:

3.1 Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]

AND

3.2 Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)

AND

3.3 Maximally tolerated diuretics (e.g., hydrochlorothiazide)

AND

4 - One of the following:

4.1 Patient is receiving concomitant therapy with a mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] confirmed by claims history or submitted medical records

OR

4.2 Patient has a contraindication, or intolerance to mineralocorticoid receptor antagonist [MRA (e.g., spironolactone, eplerenone)] (please specify intolerance or contraindication)

AND

5 - One of the following:

5.1 Patient is receiving concomitant therapy with a beta-blocker (e.g., labetalol, carvedilol) confirmed by claims history or submitted medical records

OR

5.2 Patient has a contraindication, or intolerance to beta-blockers (e.g., labetalol, carvedilol) (please specify intolerance or contraindication)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name:Tryvio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation the patient is receiving clinical benefit to Tryvio therapy

AND

2 - Patient is receiving concomitant therapy with all of the following confirmed by claims history or submitted medical records:

2.1 Maximally tolerated blocker of the renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor (e.g., enalapril, lisinopril) or angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)]

AND

2.2 Maximally tolerated calcium channel blocker (e.g., amlodipine, diltiazem, verapamil)

AND

2.3 Maximally tolerated diuretics (e.g., hydrochlorothiazide)

2 . Revision History

Date	Notes
9/5/2024	New guideline

Tukysa

Prior Authorization Guideline

Guideline ID	GL-124509
Guideline Name	Tukysa
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is ONE of the following:

Advanced unresectable

Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting [e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)]

AND

5 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Product Name:Tukysa	
Diagnosis	CNS Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of brain metastases with HER2 (human epidermal growth factor receptor 2) positive breast cancer

AND

2 - Patient has been previously treated with an anti-HER2-based regimen [e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)]

AND

3 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Product Name:Tukysa	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable, advanced, or metastatic colorectal cancer [HER2-amplified and RAS (gene) and BRAF (gene) wild-type]

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - ONE of the following:

3.1 Patient has previously been treated with ONE of the following regimens:

Fluoropyrimidine-based chemotherapy

Oxaliplatin-based chemotherapy

Irinotecan-based chemotherapy

OR

3.2 Patient is not appropriate for intensive therapy

AND

4 - Used in combination with trastuzumab (e.g., Herceptin, Kanjinti)

Product Name:Tukysa	
Diagnosis	Breast Cancer, CNS Cancers, Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tukysa therapy

Product Name:Tukysa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Tukysa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tukysa therapy

2 . Revision History

Date	Notes
4/11/2023	Added criteria section for colorectal cancer.

Turalio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161269
Guideline Name	Turalio
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis (PVNS)

Product Name:Turalio	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Langerhans Cell Histiocytosis

Erdheim-Chester Disease

Rosai-Dorfman Disease

AND

2 - Colony stimulating factor 1 receptor (CSF1R) mutation positive

Product Name:Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS), Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Turalio therapy

Product Name:Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Turalio therapy

2 . Revision History

Date	Notes
11/25/2024	Updated GPIs

Turalio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161269
Guideline Name	Turalio
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a diagnosis of tenosynovial giant cell tumor (TGCT)/pigmented villonodular synovitis (PVNS)

Product Name:Turalio	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Langerhans Cell Histiocytosis

Erdheim-Chester Disease

Rosai-Dorfman Disease

AND

2 - Colony stimulating factor 1 receptor (CSF1R) mutation positive

Product Name:Turalio	
Diagnosis	Tenosynovial Giant Cell Tumor (TGCT)/Pigmented Villonodular Synovitis (PVNS), Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Turalio therapy

Product Name:Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Turalio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Turalio therapy

2 . Revision History

Date	Notes
11/25/2024	Updated GPIs

Tykerb

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161408
Guideline Name	Tykerb
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer

AND

1.2 Disease is hormone receptor positive and human epidermal growth factor receptor 2-positive (HER2+)

AND

1.3 Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

2 - ALL of the following:

2.1 ONE of the following:

Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer

Breast cancer that is unresponsive to preoperative systemic therapy

AND

2.2 Disease is HER2+

AND

2.3 Used as fourth line therapy and beyond in combination with ONE of the following:

Herceptin (trastuzumab)

Xeloda (capecitabine)

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

AND

1.2 Tykerb is active against primary (breast) tumor

AND

1.3 Used in combination with Xeloda (capecitabine)

OR

2 - ALL of the following:

2.1 Diagnosis of progressive or recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

2.2 Patient has received previous radiation therapy

AND

2.3 ONE of the following:

Patient has received gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology

Patient has received subtotal resection and evidence of metastasis (brain, spine, or CSF)

Patient has unresectable disease

AND

2.4 Used in combination with Temodar (temozolomide)

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent conventional or chondroid chordoma

AND

2 - Disease is epidermal growth factor receptor (EGFR)-positive

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Colon Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type

AND

3 - ONE of the following:

3.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.2 BOTH of the following:

3.2.1 Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation

AND

3.2.2 ONE of the following:

Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

Patient has a contraindication to checkpoint inhibitor immunotherapy

AND

4 - ONE of the following:

4.1 BOTH of the following:

Used as initial therapy for unresectable metachronous metastases

Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

4.2 Intensive chemotherapy with one of the following is not recommended:

Oxaliplatin

Irinotecan

Capecitabine

OR

4.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Rectal Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rectal cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type

AND

3 - ONE of the following:

3.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.2 BOTH of the following:

3.2.1 Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation

AND

3.2.2 ONE of the following:

Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

Patient has a contraindication to checkpoint inhibitor immunotherapy

AND

4 - ONE of the following:

4.1 BOTH of the following:

Used as initial therapy for unresectable metachronous metastases

Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

4.2 Intensive chemotherapy with one of the following is not recommended:

Oxaliplatin

Irinotecan

Capecitabine

OR

4.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Product Name:Brand Tykerb, generic lapatinib

Diagnosis	Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tykerb therapy

2 . Revision History

Date	Notes
11/28/2024	Updated coverage criteria for breast cancer, central nervous system cancers, chordoma, colon cancer, and rectal cancer

Tykerb

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161408
Guideline Name	Tykerb
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer

AND

1.2 Disease is hormone receptor positive and human epidermal growth factor receptor 2-positive (HER2+)

AND

1.3 Used in combination with an aromatase inhibitor [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

OR

2 - ALL of the following:

2.1 ONE of the following:

Diagnosis of recurrent unresectable (local or regional) or stage IV breast cancer

Breast cancer that is unresponsive to preoperative systemic therapy

AND

2.2 Disease is HER2+

AND

2.3 Used as fourth line therapy and beyond in combination with ONE of the following:

Herceptin (trastuzumab)

Xeloda (capecitabine)

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of recurrent, central nervous system (CNS) cancer with metastatic lesions

AND

1.2 Tykerb is active against primary (breast) tumor

AND

1.3 Used in combination with Xeloda (capecitabine)

OR

2 - ALL of the following:

2.1 Diagnosis of progressive or recurrent intracranial or spinal ependymoma (excluding subependymoma)

AND

2.2 Patient has received previous radiation therapy

AND

2.3 ONE of the following:

Patient has received gross total or subtotal resection with negative cerebrospinal fluid (CSF) cytology

Patient has received subtotal resection and evidence of metastasis (brain, spine, or CSF)

Patient has unresectable disease

AND

2.4 Used in combination with Temodar (temozolomide)

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Chordoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent conventional or chondroid chordoma

AND

2 - Disease is epidermal growth factor receptor (EGFR)-positive

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Colon Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colon cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type

AND

3 - ONE of the following:

3.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.2 BOTH of the following:

3.2.1 Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation

AND

3.2.2 ONE of the following:

Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

Patient has a contraindication to checkpoint inhibitor immunotherapy

AND

4 - ONE of the following:

4.1 BOTH of the following:

Used as initial therapy for unresectable metachronous metastases

Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

4.2 Intensive chemotherapy with one of the following is not recommended:

Oxaliplatin

Irinotecan

Capecitabine

OR

4.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	Rectal Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of rectal cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-amplified and RAS and BRAF wild type

AND

3 - ONE of the following:

3.1 Disease is proficient mismatch repair/microsatellite-stable (pMMR/MSS)

OR

3.2 BOTH of the following:

3.2.1 Disease is positive for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation

AND

3.2.2 ONE of the following:

Patient is ineligible for or progressed on checkpoint inhibitor immunotherapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Jemperli (dostarlimab-gxly)]

Patient has a contraindication to checkpoint inhibitor immunotherapy

AND

4 - ONE of the following:

4.1 BOTH of the following:

Used as initial therapy for unresectable metachronous metastases

Previous therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months

OR

4.2 Intensive chemotherapy with one of the following is not recommended:

Oxaliplatin

Irinotecan

Capecitabine

OR

4.3 Used as second-line and subsequent therapy for progression of advanced or metastatic disease

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has not previously been treated with a HER2 inhibitor [e.g., trastuzumab, Perjeta (pertuzumab), Nerlynx (neratinib)]

Product Name:Brand Tykerb, generic lapatinib

Diagnosis	Breast Cancer, Central Nervous System (CNS) Cancers, Chordoma, Colon Cancer, Rectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Tykerb therapy

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Tykerb, generic lapatinib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Tykerb therapy

2 . Revision History

Date	Notes
11/28/2024	Updated coverage criteria for breast cancer, central nervous system cancers, chordoma, colon cancer, and rectal cancer

Tymlos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136548
Guideline Name	Tymlos
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Tymlos	
Approval Length	24 Months*
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 BOTH of the following:

Patient is female

Diagnosis of postmenopausal osteoporosis

OR

1.2 BOTH of the following:

Patient is male

Diagnosis of osteoporosis

AND

2 - ONE of the following:

2.1 Patient is at high risk of fracture [e.g., recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%)]

OR

2.2 Patient has a history of failure, intolerance, or contraindication to other available osteoporosis therapy (e.g., alendronate, denosumab, risedronate, zoledronate)

AND

3 - Treatment duration has not exceeded a total of 24 months* of cumulative use of parathyroid hormone analogs (e.g., Teriparatide Injection, Forteo, Tymlos) during the patient's lifetime

Notes	*Duration of coverage will be limited to 24 months of cumulative parat hyroid hormone analog therapy (e.g., Teriparatide Injection, Forteo, T ymlos) in the patient's lifetime.

2 . Revision History

Date	Notes
11/20/2023	Updated criteria to align with label and treatment guidelines, remove d routine audit language from criteria.

Upneeq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208217
Guideline Name	Upneeq
Formulary	Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State Nebraska Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Upneeq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired blepharoptosis

AND

2 - Patient has a functional impairment related to the position of the eyelid

AND

3 - ONE of the following:

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 millimeters (mm) in primary gaze

Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze

Superior visual field loss of at least 12 degrees or 24 percent

AND

4 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injections, myasthenia gravis)

Product Name:Upneeq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy

2 . Revision History

Date	Notes
3/5/2025	Added PA-CAID for 4/1 go-live. No change to criteria.

Ustekinumab

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-207324
Guideline Name	Ustekinumab
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/5/2025

1 . Criteria

Product Name:All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chronic moderate to severe plaque psoriasis

AND

1.2 ONE of the following:

1.2.1 ALL of the following:

1.2.1.1 Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

AND

1.2.1.2 ONE of the following:

1.2.1.2.1 Failure to ONE of the following topical therapy classes, confirmed by claims history or submitted medical records:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

OR

1.2.1.2.2 History of intolerance or contraindication to ALL of the following topical therapy classes (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

AND

1.2.1.3 ONE of the following:

Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records

History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)]

AND

1.3 ONE of the following:

Failure to one of the preferred adalimumab products confirmed by claims history or submitted medical records

History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

AND

1.4 Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.5 ONE of the following:

1.5.1 Requested medication is ustekinumab 45 mg (milligrams)/0.5 mL (milliliters)

OR

1.5.2 BOTH of the following:

Requested medication is ustekinumab 90 mg/1 mL

Patient's weight is greater than 100 kilograms (220 pounds)

AND

1.6 Prescribed by or in consultation with a dermatologist

AND

1.7 If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

1.8 If the request is for Brand Stelara, ONE of the following:

1.8.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

1.8.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*

OR

2 - ALL of the following:

2.1 Patient is currently on ustekinumab therapy as confirmed by claims history or submitted medical records

AND

2.2 Diagnosis of chronic moderate to severe plaque psoriasis

AND

2.3 Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with a dermatologist

AND

2.5 If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

2.6 If the request is for Brand Stelara, ONE of the following:

2.6.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

2.6.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*

Notes	*See PDL links in Background

Product Name:All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

1.1.1 BOTH of the following:

Requested medication is ustekinumab 45 mg (milligrams)/0.5 mL (milliliters)

Diagnosis of active psoriatic arthritis

OR

1.1.2 ALL of the following:

Requested medication is ustekinumab 90 mg/1 mL

Patient's weight is greater than 100 kilograms (220 pounds)

Diagnosis of active psoriatic arthritis

Diagnosis of co-existent moderate to severe plaque psoriasis

AND

1.2 Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.3 ONE of the following:

Failure to a 3 month trial of methotrexate at maximally indicated dose, confirmed by claims history or submitted medical records

History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Tremfya (guselkumab) Xeljanz (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

AND

1.4 ONE of the following:

Failure to one of the preferred adalimumab products confirmed by claims history or submitted medical records

History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

AND

1.5 Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

AND

1.6 If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

1.7 If the request is for Brand Stelara, ONE of the following:

1.7.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

1.7.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*

OR

2 - ALL of the following:

2.1 Patient is currently on ustekinumab therapy as confirmed by claims history or submitted medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

2.4 Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

AND

2.5 If the request is for a non-preferred ustekinumab product, the prescriber has given a

clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

2.6 If the request is for Brand Stelara, ONE of the following:

2.6.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

2.6.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*

Notes	*See PDL links in Background

Product Name:All subcutaneous formulations of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek	
Diagnosis	Plaque Psoriasis, Psoriatic Arthritis
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to ustekinumab therapy

AND

2 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]*

AND

3 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)**

AND

4 - If the request is for Brand Stelara, ONE of the following:

4.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients**

OR

4.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness**

Notes	*Examples of drug(s) may not be applicable based on the requested i ndication. **See PDL links in Background

Product Name:90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek

Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

2.1.1.1 Failure to ONE of the following conventional therapy drugs or classes at maximally indicated dose, confirmed by claims history or submitted medical records:

Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)

6-mercaptopurine (Purinethol)

Azathioprine (Imuran)

Methotrexate (Rheumatrex, Trexall)

OR

2.1.1.2 History of intolerance or contraindication to ALL of the following conventional therapy drugs or classes (please specify intolerance or contraindication):

Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)

6-mercaptopurine (Purinethol)

Azathioprine (Imuran)

Methotrexate (Rheumatrex, Trexall)

OR

2.1.1.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as confirmed by claims history or submission of medical records [e.g., Cimzia (certolizumab), adalimumab]

AND

2.1.2 ONE of the following:

Failure to one of the preferred adalimumab products, as confirmed by claims history or submitted medical records

History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

OR

2.2 Patient is currently on ustekinumab therapy for moderately to severely active Crohn's disease as confirmed by claims history or submitted medical records

OR

2.3 Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active Crohn's disease

AND

3 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

6 - If the request is for Brand Stelara, ONE of the following:

6.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

6.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara

Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*

Notes	*See PDL links in Background

Product Name:90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 ONE of the following:

Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine), as confirmed by claims history or submitted medical records

Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), Xeljanz (tofacitinib)]

AND

2.1.2 ONE of the following:

Failure to one of the preferred adalimumab products, confirmed by claims history or submitted medical records

History of intolerance or contraindication to one of the preferred adalimumab products (please specify intolerance or contraindication)

OR

2.2 Patient is currently on ustekinumab therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submitted medical records

OR

2.3 Patient has been established on therapy with ustekinumab under an active UnitedHealthcare medical benefit prior authorization for treatment of moderately to severely active ulcerative colitis

AND

3 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND

6 - If the request is for Brand Stelara, ONE of the following:

6.1 Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients*

OR

6.2 BOTH of the following:

Submission of medical records confirming patient has previously been successfully treated with brand Stelara Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*	
Notes	*See PDL links in Background

Product Name:90 mg/mL subcutaneous formulation of the following: Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, Yesintek	
Diagnosis	Crohn's Disease (CD), Ulcerative Colitis
Approval Length	12 month(s) NOTE: If approving a non-preferred ustekinumab, please enter: 1) The group authorization CSPREFUSTE and 2) An authorization for the non-preferred ustekinumab at GPI-12 level
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to ustekinumab therapy

AND

2 - Patient is NOT receiving ustekinumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Skyrizi (risankizumab)]

AND

3 - If the request is for a non-preferred ustekinumab product, the prescriber has given a clinical reason or special circumstance why the patient is unable to use the preferred ustekinumab products (please document reason/special circumstances)*

AND **4** - If the request is for Brand Stelara, ONE of the following: **4.1** Submission of medical records confirming patient allergy or intolerance to at least two preferred ustekinumab biosimilars' inactive ingredients* **OR** **4.2** BOTH of the following: Submission of medical records confirming patient has previously been successfully treated with brand Stelara Submission of medical records confirming patient has tried at least two preferred ustekinumab biosimilars for 6-8 weeks per product and saw a decrease in effectiveness*	
Notes	*See PDL links in Background

2 . Background

Benefit/Coverage/Program Information
PDL Links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Changed effective date to 3/5/2025.

Vafseo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158184
Guideline Name	Vafseo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least three months

AND

3 - Both of the following:

Ferritin greater than 100 mcg/L

Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - One of the following:

5.1 Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records

OR

5.2 History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] (please specify contraindication or intolerance)

AND

6 - Prescribed by or in consultation with one of the following:

Hematologist

Nephrologist

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vafseo therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by both of the following:

Ferritin greater than 100 mcg/L

Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 12 g/dL

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with one of the following: Hematologist Nephrologist

2 . Revision History

Date	Notes
10/29/2024	New

Vafseo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158184
Guideline Name	Vafseo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease (CKD)

AND

2 - Patient has been receiving dialysis for at least three months

AND

3 - Both of the following:

Ferritin greater than 100 mcg/L

Transferrin saturation (TSAT) greater than 20%

AND

4 - Hemoglobin level less than 11 g/dL

AND

5 - One of the following:

5.1 Failure to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] as confirmed by claims history or submission of medical records

OR

5.2 History of contraindication or intolerance to an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)] (please specify contraindication or intolerance)

AND

6 - Prescribed by or in consultation with one of the following:

Hematologist

Nephrologist

Product Name:Vafseo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vafseo therapy (e.g., clinically meaningful increase in hemoglobin level)

AND

2 - Adequate iron stores confirmed by both of the following:

Ferritin greater than 100 mcg/L

Transferrin saturation (TSAT) greater than 20%

AND

3 - Hemoglobin level does not exceed 12 g/dL

AND

4 - Patient is not on concurrent treatment with an erythropoietin stimulating agent (ESA) [e.g., Aranesp (darbepoetin), Epogen (epoetin alfa), Procrit (epoetin alfa), Retacrit (epoetin alfa-epbx)]

AND

5 - Prescribed by or in consultation with one of the following: Hematologist Nephrologist

2 . Revision History

Date	Notes
10/29/2024	New

Valchlor

Prior Authorization Guideline

Guideline ID	GL-117472
Guideline Name	Valchlor
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Chronic or smoldering T-cell leukemia/lymphoma

Primary cutaneous marginal zone or follicle center B-cell lymphoma

Lymphomatoid papulosis (LyP) with extensive lesions

Mycosis fungoides (MF)/Sezary syndrome (SS)

Product Name:Valchlor	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans Cell Histiocytosis (LCH)

AND

2 - Skin disease is unifocal and isolated

Product Name:Valchlor	
Diagnosis	Primary Cutaneous Lymphomas, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name:Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

2 . Revision History

Date	Notes
11/30/2022	Updated Markets in Scope. No changes to clinical criteria

Valchlor

Prior Authorization Guideline

Guideline ID	GL-117472
Guideline Name	Valchlor
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Valchlor	
Diagnosis	Primary Cutaneous Lymphomas
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Chronic or smoldering T-cell leukemia/lymphoma

Primary cutaneous marginal zone or follicle center B-cell lymphoma

Lymphomatoid papulosis (LyP) with extensive lesions

Mycosis fungoides (MF)/Sezary syndrome (SS)

Product Name:Valchlor	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Langerhans Cell Histiocytosis (LCH)

AND

2 - Skin disease is unifocal and isolated

Product Name:Valchlor	
Diagnosis	Primary Cutaneous Lymphomas, Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Valchlor

Product Name:Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Valchlor	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Valchlor therapy

2 . Revision History

Date	Notes
11/30/2022	Updated Markets in Scope. No changes to clinical criteria

Vanflyta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158185
Guideline Name	Vanflyta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Vanflyta	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is FLT3 internal tandem duplication (ITD) positive

AND

3 - ONE of the following:

3.1 Vanflyta will be used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy

OR

3.2 Vanflyta will be used for patients with relapsed/refractory disease as a component of repeating the initial successful induction regimen or as a single agent

Product Name:Vanflyta	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vanflyta therapy

Product Name:Vanflyta

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Vanflyta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vanflyta therapy

2 . Revision History

Date	Notes
10/29/2024	For AML, added "Initial Authorization" therapy stage and added allow ance for relapsed/refractory disease per NCCN recommendations.

Vecamyl

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135290
Guideline Name	Vecamyl
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

Note:

Effective Date: 11/15/2019

1 . Criteria

Product Name:Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately severe to severe essential hypertension

OR

2 - Diagnosis of uncomplicated malignant hypertension

Product Name:Vecamyl	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Vecamyl therapy

2 . Revision History

Date	Notes
10/23/2023	Combined all Core formularies into one guideline.

Velsipity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208196
Guideline Name	Velsipity
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Velsipity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

2 - ONE of the following:

2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

OR

2.2 Patient has been previously treated with a targeted immunomodulator FDA (Food and Drug Administration)-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

3 - ONE of the following:

3.1 Patient is currently on Velsipity therapy as confirmed by claims history or submission of medical records

OR

3.2 Failure to ONE of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

One of the preferred ustekinumab products*

OR

3.3 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products*

One of the preferred ustekinumab products*

AND

4 - Patient is NOT receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	*For a list of preferred adalimumab products please reference drug co verage tools.

Product Name:Velsipity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Velsipity therapy

AND

2 - Patient is NOT receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

2 . Background

Benefit/Coverage/Program Information
PDL links: CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Updated formularies. Updated safety check language. Replaced Stel ara with ustekinumab throughout. Added ustekinumab as a step optio n in UC. Added NM PDL link to background.

Vemlidy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118680
Guideline Name	Vemlidy
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name:Vemlidy	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - ONE of the following:

1.1 Failure to entecavir (generic Baraclude) as confirmed by claims history or submission of medical records

OR

1.2 History of contraindication or intolerance to entecavir (generic Baraclude) (please specify contraindication or intolerance)

OR

1.3 Patient is not a suitable candidate for entecavir (generic Baraclude)

AND

2 - ONE of the following:

2.1 Failure to tenofovir disoproxil fumarate (generic Viread) as confirmed by claims history or submission of medical records

OR

2.2 History of contraindication or intolerance to tenofovir disoproxil fumarate (generic Viread) (please specify contraindication or intolerance)

OR

2.3 Patient has an estimated glomerular filtration rate below 90 mL/min (milliliters/minute)

OR

2.4 Patient has a diagnosis of osteopenia as defined by a BMD (bone mineral density) T-score between -1 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1) based on BMD measurements from one of the following with evidence of progressive bone loss on

serial DEXA (dual-energy X-ray absorptiometry) scan [Provider must submit patient specific BMD T-scores]:

Lumbar spine (at least two vertebral bodies)

Hip (femoral neck, total hip)

Radius (one-third radius site)

OR

2.5 Patient has a diagnosis of osteoporosis as defined by a BMD T-score less than or equal to -2.5 based on BMD measurements from one of the following [Provider must submit patient specific BMD T-score]:

Lumbar spine (at least two vertebral bodies)

Hip (femoral neck, total hip)

Radius (one-third radius site)

OR

2.6 Patient has a prior low-trauma or non-traumatic fracture

OR

2.7 Patient is less than 20 years of age

2 . Revision History

Date	Notes
12/23/2022	Updated language for bone loss, no change to intent.

Venclexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149567
Guideline Name	Venclexta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/5/2024

1 . Criteria

Product Name:Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Product Name:Venclexta	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Not used as first line therapy

Product Name:Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

1.2 ONE of the following:

1.2.1 Used as treatment induction in candidates for intensive induction therapy

OR

1.2.2 Used as treatment induction in candidates for lower-intensity induction therapy

OR

1.2.3 Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen

OR

1.2.4 Used as consolidation therapy as continuation of lower-intensity regimen used for induction

AND

1.3 Used in combination with decitabine, azacitidine, or low-dose cytarabine

OR

2 - ALL of the following:

2.1 Diagnosis of relapsed/refractory acute myeloid leukemia (AML)

AND

2.2 Used as a component of repeating the initial successful induction regimen

AND

2.3 Greater than or equal to 12 months since induction regimen if not administered continuously

AND

2.4 Therapy was not stopped due to development of clinical resistance

OR

3 - ALL of the following:

3.1 Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) - acute myeloid leukemia (AML)

AND

3.2 Considered systemic disease and therapy is given as palliative intent

AND

3.3 Patient has low performance and/or nutritional status (i.e., serum albumin less than 3.2 g/dL [grams/deciliter]; not a candidate for intensive remission therapy or Elzonris)

AND

3.4 Venclexta therapy to be given in combination with azacitidine, decitabine, or low-dose cytarabine

Product Name:Venclexta	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or progressive multiple myeloma which has been previously treated

AND

2 - Patient has t(11;14) translocation

AND

3 - Venclexta therapy to be given in combination with dexamethasone

Product Name:Venclexta	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL)

AND

2 - Venclexta therapy to be given in combination with ONE of the following:

Decitabine

Hyper-CVAD

Nelarabine Mini hyper-CVD

Product Name:Venclexta	
Diagnosis	Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelomonocytic leukemia (CMML)

AND

2 - Classified as CMML-2 (less than 20% bone marrow blasts or blast equivalents)

AND

3 - Venclexta therapy to be given in combination with azacitidine or decitabine

Product Name:Venclexta	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Disease is progressive after relapsed/refractory therapy

AND

3 - Disease is resistant to BRAF inhibitor therapy (i.e., Zelboraf, Tafinlar)

Product Name:Venclexta	
Diagnosis	Accelerated/Blast Phase Myeloproliferative Neoplasm
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

2 - Used for management of disease progression of myeloproliferative neoplasm

AND

3 - Venclexta therapy to be given in combination with azacitidine or decitabine

Product Name:Venclexta	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory systemic light chain amyloidosis

AND

2 - Patient has t(11;14) translocation

Product Name:Venclexta	
Diagnosis	Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma which has been previously treated

Product Name:Venclexta	
Diagnosis	All Indications except NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Product Name:Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Venclexta therapy

2 . Revision History

Date	Notes
7/5/2024	Updated criteria for ALL and AML based on NCCN recommendations . Updated verbiage for MM and NCCN Recommended Regimens. Ad ded criteria for CMML, hairy cell leukemia, and accelerated/blast pha se myeloproliferative neoplasms based on NCCN recommendations.

Venclexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149567
Guideline Name	Venclexta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/5/2024

1 . Criteria

Product Name:Venclexta	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Product Name:Venclexta	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Not used as first line therapy

Product Name:Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

1.2 ONE of the following:

1.2.1 Used as treatment induction in candidates for intensive induction therapy

OR

1.2.2 Used as treatment induction in candidates for lower-intensity induction therapy

OR

1.2.3 Used as follow-up after induction therapy following response to previous lower intensity therapy with the same regimen

OR

1.2.4 Used as consolidation therapy as continuation of lower-intensity regimen used for induction

AND

1.3 Used in combination with decitabine, azacitidine, or low-dose cytarabine

OR

2 - ALL of the following:

2.1 Diagnosis of relapsed/refractory acute myeloid leukemia (AML)

AND

2.2 Used as a component of repeating the initial successful induction regimen

AND

2.3 Greater than or equal to 12 months since induction regimen if not administered continuously

AND

2.4 Therapy was not stopped due to development of clinical resistance

OR

3 - ALL of the following:

3.1 Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) - acute myeloid leukemia (AML)

AND

3.2 Considered systemic disease and therapy is given as palliative intent

AND

3.3 Patient has low performance and/or nutritional status (i.e., serum albumin less than 3.2 g/dL [grams/deciliter]; not a candidate for intensive remission therapy or Elzonris)

AND

3.4 Venclexta therapy to be given in combination with azacitidine, decitabine, or low-dose cytarabine

Product Name:Venclexta	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed or progressive multiple myeloma which has been previously treated

AND

2 - Patient has t(11;14) translocation

AND

3 - Venclexta therapy to be given in combination with dexamethasone

Product Name:Venclexta	
Diagnosis	Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL)

AND

2 - Venclexta therapy to be given in combination with ONE of the following:

Decitabine

Hyper-CVAD

Nelarabine Mini hyper-CVD

Product Name:Venclexta	
Diagnosis	Chronic Myelomonocytic Leukemia (CMML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic myelomonocytic leukemia (CMML)

AND

2 - Classified as CMML-2 (less than 20% bone marrow blasts or blast equivalents)

AND

3 - Venclexta therapy to be given in combination with azacitidine or decitabine

Product Name:Venclexta	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

AND

2 - Disease is progressive after relapsed/refractory therapy

AND

3 - Disease is resistant to BRAF inhibitor therapy (i.e., Zelboraf, Tafinlar)

Product Name:Venclexta	
Diagnosis	Accelerated/Blast Phase Myeloproliferative Neoplasm
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of accelerated/blast phase myeloproliferative neoplasm

AND

2 - Used for management of disease progression of myeloproliferative neoplasm

AND

3 - Venclexta therapy to be given in combination with azacitidine or decitabine

Product Name:Venclexta	
Diagnosis	Systemic Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory systemic light chain amyloidosis

AND

2 - Patient has t(11;14) translocation

Product Name:Venclexta	
Diagnosis	Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma which has been previously treated

Product Name:Venclexta	
Diagnosis	All Indications except NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Venclexta therapy

Product Name:Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Venclexta	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Venclexta therapy

2 . Revision History

Date	Notes
7/5/2024	Updated criteria for ALL and AML based on NCCN recommendations . Updated verbiage for MM and NCCN Recommended Regimens. Ad ded criteria for CMML, hairy cell leukemia, and accelerated/blast pha se myeloproliferative neoplasms based on NCCN recommendations.

Veozah

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163756
Guideline Name	Veozah
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Veozah	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2 - One of the following:

2.1 Failure (after a 30-day trial) to ONE of the following as confirmed by claims history or submission of medical records:

Hormonal therapy (e.g., estradiol, Premarin, Prempro)

Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine)]

OR

2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

Hormonal therapy (e.g., estradiol, Premarin, Prempro)

Non-hormonal therapy [e.g., clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine reuptake inhibitors (e.g., venlafaxine)]

AND

3 - Patient has received baseline hepatic laboratory tests to rule out the presence of underlying liver disease

Product Name:Veozah	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline) **AND** **2** - Patient has received periodic evaluation of hepatic laboratory tests to rule out liver injury associated with Veozah use

2 . Revision History

Date	Notes
1/14/2025	Added criteria for hepatic laboratory tests

Verkazia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127288
Guideline Name	Verkazia
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Verkazia, Cyclosporine in Klarity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe vernal keratoconjunctivitis

AND

2 - ONE of the following:

2.1 Failure to TWO of the following categories as confirmed by claims history or submission of medical records:

Ophthalmic antihistamines (e.g., azelastine, olopatadine)

Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)

Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

OR

2.2 History of intolerance or contraindication to ALL of the following categories (please specify intolerance or contraindication):

Ophthalmic antihistamines (e.g., azelastine, olopatadine)

Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)

Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

Product Name:Verkazia, Cyclosporine in Klarity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response

2 . Revision History

Date	Notes
6/29/2023	Updated formularies, cleaned up criteria.

Verquvo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145896
Guideline Name	Verquvo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Verquvo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure

AND

2 - Ejection fraction is less than 45 percent

AND

3 - Heart failure is classified as ONE of the following:

New York Heart Association Class II

New York Heart Association Class III

New York Heart Association Class IV

AND

4 - ONE of the following:

4.1 Hospitalization for heart failure within the past six months

OR

4.2 Outpatient IV (intravenous) diuretics for heart failure within the past three months

AND

5 - ONE of the following:

5.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated beta-blocker (e.g., bisoprolol, carvedilol, metoprolol) confirmed by claims history or submission of medical records

OR

5.2 Patient has a contraindication or intolerance to beta-blocker therapy (please specify intolerance or contraindication)

AND

6 - ONE of the following:

6.1 Patient is on a stabilized dose and receiving concomitant therapy with one of the following confirmed by claims history or submission of medical records:

Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

Angiotensin II receptor blocker (ARB) (e.g., losartan)

Angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto)

OR

6.2 Patient has an allergy, contraindication, or intolerance to ACE inhibitors, ARBs, and ARNIs (please specify intolerance or contraindication)

AND

7 - ONE of the following:

7.1 Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated aldosterone antagonist (e.g., spironolactone) confirmed by claims history or submission of medical records

OR

7.2 Patient has a contraindication or intolerance to aldosterone antagonist therapy (please specify intolerance or contraindication)

AND

8 - ONE of the following:

8.1 Patient is on a stabilized dose and receiving concomitant therapy with a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated for heart failure (e.g., Farxiga) confirmed by claims history or submission of medical records

OR

8.2 Patient has a contraindication or intolerance to SGLT2 inhibitor therapy (please specify intolerance or contraindication)

AND

9 - Verquvo is prescribed by or in consultation with a cardiologist

Product Name:Verquvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
4/18/2024	Updated criteria for SGLT2 trial requirements.

Verzenio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150983
Guideline Name	Verzenio
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/7/2024

1 . Criteria

Product Name:Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is hormone-receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - ONE of the following:

4.1 BOTH of the following:

4.1.1 Disease is advanced, recurrent, or metastatic

AND

4.1.2 ONE of the following:

4.1.2.1 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or Faslodex (fulvestrant)

OR

4.1.2.2 ALL of the following:

Used as monotherapy

Patient has disease progression following endocrine therapy

Patient has already received at least one prior chemotherapy regimen

OR

4.2 BOTH of the following:

4.2.1 Disease is early breast cancer at high risk of recurrence (i.e., greater than or equal to 4 positive lymph nodes, or 1-3 positive lymph nodes with one or both of the following: Grade 3 disease, tumor size greater than or equal to 5 centimeters)

AND

4.2.2 Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or tamoxifen

Product Name:Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Verzenio therapy

Product Name:Verzenio	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic endometrial cancer

AND

2 - Tumor is estrogen receptor (ER)-positive

AND

3 - Used in combination with letrozole

Product Name:Verzenio	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Verzenio therapy

Product Name:Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verzenio will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Verzenio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Verzenio therapy

2 . Revision History

Date	Notes
8/5/2024	Annual review. Updated background and added clinical criteria for en dometrial carcinoma per NCCN. Updated references.

Vijoice

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152470
Guideline Name	Vijoice
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Rhode Island Medicaid - Community & State Pennsylvania CHIP

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Vijoice tablets, Vijoice granules	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - ONE of the following:

2.1 Confirmed presence of a mutation in the PIK3CA gene

OR

2.2 ONE of the following:

2.2.1 TWO or more of the following spectrum features:

Overgrowth: adipose, muscle, nerve, skeletal

Vascular malformations: capillary, venous, arteriovenous, lymphatic

Epidermal nevus

OR

2.2.2 ONE or more of the following isolated features:

Large isolated lymphatic malformation

Isolated macrodactyly or overgrown splayed feet/ hands with overgrown limbs

Truncal adipose overgrowth

Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia

Epidermal nevus

Seborrheic keratoses

Benign lichenoid keratoses

AND

3 - Patient is 2 years of age or older

AND

4 - Patient has severe manifestations of PROS requiring systemic therapy

AND

5 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Product Name:Vijoice tablets, Vijoice granules	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vijoice therapy

AND

2 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PIK3CA-Related Overgrowth Spectrum (PROS) manifestations

2 . Revision History

Date	Notes

8/23/2024	Added new GPI for Vijoice granules formulation. Updated product na me list and GPI table accordingly. Updated initial authorization criteri a. Updated initial authorization duration to 12 months.

Vijoice

Prior Authorization Guideline

Guideline ID	GL-152470
Guideline Name	Vijoice
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Rhode Island Medicaid - Community & State Pennsylvania CHIP

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Vijoice tablets, Vijoice granules	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - ONE of the following:

2.1 Confirmed presence of a mutation in the PIK3CA gene

OR

2.2 ONE of the following:

2.2.1 TWO or more of the following spectrum features:

Overgrowth: adipose, muscle, nerve, skeletal

Vascular malformations: capillary, venous, arteriovenous, lymphatic

Epidermal nevus

OR

2.2.2 ONE or more of the following isolated features:

Large isolated lymphatic malformation

Isolated macrodactyly or overgrown splayed feet/ hands with overgrown limbs

Truncal adipose overgrowth

Hemimegalencephaly (bilateral) / dysplastic megalencephaly / focal cortical dysplasia

Epidermal nevus

Seborrheic keratoses

Benign lichenoid keratoses

AND

3 - Patient is 2 years of age or older

AND

4 - Patient has severe manifestations of PROS requiring systemic therapy

AND

5 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PROS manifestations

Product Name:Vijoice tablets, Vijoice granules	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vijoice therapy

AND

2 - Prescribed by, or in consultation with, a clinical geneticist or a practitioner who has specialized expertise in the management of PIK3CA-Related Overgrowth Spectrum (PROS) manifestations

2 . Revision History

Date	Notes

8/23/2024	Added new GPI for Vijoice granules formulation. Updated product na me list and GPI table accordingly. Updated initial authorization criteri a. Updated initial authorization duration to 12 months.

Vitrakvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208221
Guideline Name	Vitrakvi
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Vitrakvi	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Presence of a solid tumor

AND

2 - Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.)

AND

3 - Disease is without a known acquired resistance mutation (e.g., TRKA G595R, G623R, G696A, F617L)

AND

4 - Disease is ONE of the following:

Metastatic

Unresectable

Product Name:Vitrakvi	
Diagnosis	Solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

Product Name:Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Vitrakvi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vitrakvi therapy

2 . Revision History

Date	Notes
3/6/2025	Updated formularies

Vivjoa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134118
Guideline Name	Vivjoa
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2023

1 . Criteria

Product Name:Vivjoa	
Approval Length	4 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of recurrent vulvovaginal candidiasis

AND

2 - Patient is not of reproductive potential (i.e., persons who are biological females who are postmenopausal or have another reason for permanent infertility [(e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)]

AND

3 - BOTH of the following:

3.1 Other causes (including but not limited to bacterial vaginosis or trichomoniasis) have been ruled out

AND

3.2 Failure of a maintenance course of oral fluconazole defined as 100-mg, 150-mg, or 200-mg taken weekly for 6 months confirmed by claims history or submission of medical records.

AND

4 - Prescribed by, or in consultation with, one of the following:

Infectious disease physician

Obstetrician/Gynecologist

2 . Revision History

Date	Notes
10/2/2023	Removed RMHP formulary

Vizimpro

Prior Authorization Guideline

Guideline ID	GL-118462
Guideline Name	Vizimpro
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2023

1 . Criteria

Product Name:Vizimpro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is recurrent, advanced, or metastatic

AND

3 - Disease is positive for ONE of the following EGFR (epidermal growth factor receptor) mutations:

Exon 19 deletion

Exon 21 L858R substitution

S768I

L861Q

G719X

Product Name:Vizimpro	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vizimpro therapy

Product Name:Vizimpro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Vizimpro	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vizimpro therapy

2 . Revision History

Date	Notes
12/16/2022	Updated criteria to add EGFR mutations, cleaned up indications and criteria.

Vonjo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154893
Guideline Name	Vonjo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Vonjo	
Diagnosis	Myelofibrosis (MF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

Primary myelofibrosis

Post-polycythemia vera myelofibrosis

Post-essential thrombocythemia myelofibrosis

Accelerated/blast phase myeloproliferative neoplasm

AND

2 - One of the following:

2.1 BOTH of the following:

2.1.1 Patient has symptomatic lower-risk myelofibrosis

AND

2.1.2 Patient has a platelet count less than 50 x 10^9/L

OR

2.2 All of the following:

2.2.1 Patient has higher-risk myelofibrosis

AND

2.2.2 Patient is not a transplant candidate or transplant not currently feasible

AND

2.2.3 One of the following:

2.2.3.1 Patient has a platelet count less than 50 x 10^9/L

OR

2.2.3.2 Both of the following:

2.2.3.2.1 Patient has symptomatic splenomegaly and/or constitutional symptoms

AND

2.2.3.2.2 Patient has a platelet count greater than or equal to 50 x 10^9/L

OR

2.3 Used for treatment of myelofibrosis-associated anemia

OR

2.4 Used for splenomegaly and other disease-related symptoms in one of the following:

2.4.1 Continued near the start of conditioning therapy of transplant candidates

OR

2.4.2 Palliation in combination with hypomethylating agents (azacitidine or decitabine) as bridging therapy prior to transplant, or if not a candidate for transplant

Product Name:Vonjo	
Diagnosis	Myelofibrosis (MF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that patient has evidence of symptom improvement or reduction in spleen volume while on Vonjo

Product Name:Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Vonjo will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Vonjo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vonjo therapy

2 . Revision History

Date	Notes

9/13/2024	Added accelerated/blast phase myeloproliferative neoplasm to list of MF subtypes. Updated criteria for low- and high-risk MF, MF-associated anemia, and splenomegaly and other disease-related symptoms per NCCN guidelines. Updated approval durations to 12 months.

Voranigo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164769
Guideline Name	Voranigo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Voranigo	
Diagnosis	Astrocytoma/Oligodendroglioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

Astrocytoma

Oligodendroglioma

AND

2 - Presence of IDH1 or IDH2 mutation

AND

3 - History of one of the following:

Biopsy

Sub-total resection

Gross total resection

Product Name:Voranigo	
Diagnosis	Astrocytoma/Oligodendroglioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Voranigo therapy

Product Name:Voranigo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Voranigo	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Voranigo therapy

2 . Revision History

Date	Notes
2/5/2025	Updated formularies. Removed Grade 2 disease requirement

Votrient

Prior Authorization Guideline

Guideline ID	GL-163948
Guideline Name	Votrient
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of renal cell carcinoma (RCC)

AND

1.2 ONE of the following:

Disease has relapsed

Stage IV disease

Disease is advanced

OR

2 - Diagnosis of von Hippel-Lindau (VHL)-associated renal cell carcinoma

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

Angiosarcoma

Alveolar soft part sarcoma

Pleomorphic rhabdomyosarcoma

Retroperitoneal/intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease

Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases

Solitary fibrous tumor/hemangiopericytoma

Desmoid tumors (aggressive fibromatosis)

Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation

Dedifferentiated Chordoma

Epithelioid hemangioendothelioma

Extraskeletal myxoid chondrosarcoma

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of one of the following:

Follicular carcinoma

Oncocytic carcinoma

Papillary carcinoma

AND

1.2 One of the following:

Unresectable locoregional recurrent disease

Persistent disease

Metastatic disease

AND

1.3 One of the following:

Patient has symptomatic disease

Patient has progressive disease

AND

1.4 One of the following:

Disease is refractory to radioactive iodine treatment

Distant metastatic disease not amenable to radioactive iodine treatment

OR

2 - All of the following:

2.1 Diagnosis of medullary carcinoma

AND

2.2 One of the following:

Disease is progressive

Disease is symptomatic with distant metastases

AND

2.3 One of the following:

2.3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

Caprelsa (vandetanib)

Cometriq (cabozantinib)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Caprelsa (vandetanib)

Cometriq (cabozantinib)

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - One of the following:

Disease is advanced

Disease is recurrent/metastatic

Disease is inoperable

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - ONE of the following:

Disease is persistent

Disease is recurrent

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chondrosarcoma

AND

2 - Disease is metastatic and widespread

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumors (GIST)

AND

2 - Disease is unresectable, progressive, or metastatic

AND

3 - One of the following:

3.1 Used as first-line therapy in SDH-deficient GIST

OR

3.2 Used after progression on ALL of the following:

Imatinib (generic Gleevac)

Sunitinib (generic Sutent)

Stivarga (regorafenib)

Standard dose Qinlock (ripretinib)

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel Cell Carcinoma

AND

2 - Disease is M1 disseminated

AND

3 - One of the following:

3.1 Anti-PD-L1 or anti-PD-1 therapy is contraindicated

OR

3.2 Disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer, Chondrosarcoma, Gastrointestinal Stromal Tumors (GIST), Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Votrient therapy

2 . Revision History

Date	Notes
1/16/2025	Updated criteria for Sarcoma

Votrient

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163948
Guideline Name	Votrient
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following

1.1 Diagnosis of renal cell carcinoma (RCC)

AND

1.2 ONE of the following:

Disease has relapsed

Stage IV disease

Disease is advanced

OR

2 - Diagnosis of von Hippel-Lindau (VHL)-associated renal cell carcinoma

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Soft Tissue Sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

Angiosarcoma

Alveolar soft part sarcoma

Pleomorphic rhabdomyosarcoma

Retroperitoneal/intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease

Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases

Solitary fibrous tumor/hemangiopericytoma

Desmoid tumors (aggressive fibromatosis)

Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation

Dedifferentiated Chordoma

Epithelioid hemangioendothelioma

Extraskeletal myxoid chondrosarcoma

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of one of the following:

Follicular carcinoma

Oncocytic carcinoma

Papillary carcinoma

AND

1.2 One of the following:

Unresectable locoregional recurrent disease

Persistent disease

Metastatic disease

AND

1.3 One of the following:

Patient has symptomatic disease

Patient has progressive disease

AND

1.4 One of the following:

Disease is refractory to radioactive iodine treatment

Distant metastatic disease not amenable to radioactive iodine treatment

OR

2 - All of the following:

2.1 Diagnosis of medullary carcinoma

AND

2.2 One of the following:

Disease is progressive

Disease is symptomatic with distant metastases

AND

2.3 One of the following:

2.3.1 Failure to ONE of the following, as confirmed by claims history or submission of medical records:

Caprelsa (vandetanib)

Cometriq (cabozantinib)

OR

2.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Caprelsa (vandetanib)

Cometriq (cabozantinib)

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of uterine sarcoma

AND

2 - One of the following:

Disease is advanced

Disease is recurrent/metastatic

Disease is inoperable

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - ONE of the following:

Disease is persistent

Disease is recurrent

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Chondrosarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chondrosarcoma

AND

2 - Disease is metastatic and widespread

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Gastrointestinal Stromal Tumors (GIST)

AND

2 - Disease is unresectable, progressive, or metastatic

AND

3 - One of the following:

3.1 Used as first-line therapy in SDH-deficient GIST

OR

3.2 Used after progression on ALL of the following:

Imatinib (generic Gleevac)

Sunitinib (generic Sutent)

Stivarga (regorafenib)

Standard dose Qinlock (ripretinib)

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Merkel Cell Carcinoma

AND

2 - Disease is M1 disseminated

AND

3 - One of the following:

3.1 Anti-PD-L1 or anti-PD-1 therapy is contraindicated

OR

3.2 Disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	Renal Cell Carcinoma (RCC)/Kidney Cancer, Soft Tissue Sarcoma (STS), Thyroid Carcinoma, Uterine Sarcoma, Ovarian Cancer, Chondrosarcoma, Gastrointestinal Stromal Tumors (GIST), Merkel Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Votrient therapy

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Votrient will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Brand Votrient, generic pazopanib	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Votrient therapy

2 . Revision History

Date	Notes
1/16/2025	Updated criteria for Sarcoma

Vowst

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164987
Guideline Name	Vowst
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State Michigan Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Vowst	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent Clostridioides difficile infection (rCDI) as defined by BOTH of the following:

1.1 Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days

AND

1.2 A positive stool test for Clostridioides difficile toxin

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has had one or more recurrences of CDI following an initial episode of CDI

AND

4 - Patient has completed at least 10 days of ONE of the following antibiotic therapies for rCDI 2 to 4 days prior to initiating Vowst as confirmed by claims history or submission of medical records:

Oral vancomycin

Dificid (fidaxomicin)

AND

5 - Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days]

AND

6 - Patient will drink magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst

AND

7 - Prescribed by or in consultation with one of the following:

Gastroenterologist

Infectious disease specialist

2 . Revision History

Date	Notes
2/11/2025	Updated formularies. No changes to clinical criteria.

Voxzogo

Prior Authorization Guideline

Guideline ID	GL-210193
Guideline Name	Voxzogo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State Nebraska Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is less than 18 years of age

AND

2 - Diagnosis of achondroplasia as confirmed by ONE of the following:

2.1 Submission of medical records documenting BOTH of the following:

2.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

2.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

2.2 Submission of medical records documenting molecular genetic testing confirmed c.1138G > A or c.1138G > C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

3 - Patient has open epiphyses

AND

4 - BOTH of the following:

4.1 Patient has not had limb-lengthening surgery in the previous 18 months

AND

4.2 Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

5 - Prescribed by ONE of the following:

Clinical geneticist

Endocrinologist

A practitioner who has specialized expertise in the management of achondroplasia

Product Name:Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Voxzogo therapy [e.g., improvement in annualized growth velocity (AGV) compared to baseline]

AND

2 - Patient has open epiphyses

AND

3 - Patient does not plan to have limb-lengthening surgery while on Voxzogo

AND

4 - Prescribed by or in consultation with ONE of the following:

Clinical geneticist

Endocrinologist

A practitioner who has specialized expertise in the management of achondroplasia

2 . Revision History

Date	Notes
3/6/2025	Added PA-CAID for 4/1 go-live. No change to criteria.

Voydeya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150918
Guideline Name	Voydeya
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/5/2024

1 . Criteria

Product Name:Voydeya	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by both of the following:

1.1 Flow cytometry analysis confirming presence of PNH clones

AND

1.2 Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unexplained/unusual thrombosis, hemolysis/hemoglobinuria, kidney disease, pulmonary hypertension, etc.)

AND

2 - All of the following:

2.1 Patient is currently receiving complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

AND

2.2 Patient is experiencing extravascular hemolysis (EVH) while on complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

AND

2.3 Patient will continue to receive complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab)

AND

3 - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

AND

4 - Prescribed by, or in consultation with one of the following:

Hematologist

Oncologist

Product Name:Voydeya	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Voydeya therapy [e.g., decrease in extravascular hemolysis (EVH), increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, etc.)]

AND

2 - Patient continues to receive Voydeya in combination with complement protein C5 inhibitor Soliris (eculizumab) or Ultomiris (ravulizumab) for PNH

AND

3 - Patient is not receiving Voydeya in combination with a complement protein C3 inhibitor [e.g., Empaveli (Pegcetacoplan)] or a complement factor B inhibitor [e.g., Fabhalta (iptacopan)] used for the treatment of PNH

AND

4 - Prescribed by, or in consultation with one of the following:

Hematologist Oncologist

2 . Revision History

Date	Notes
8/5/2024	New guideline

Vtama

Prior Authorization Guideline

Guideline ID	GL-207211
Guideline Name	Vtama
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Vtama	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - ONE of the following:

2.1 Failure to a minimum duration of a 4-week trial to TWO of the following topical therapies as confirmed by claims history or submission of medical records:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

OR

2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

OR

2.3 Patient is currently on Vtama therapy as confirmed by claims history or submission of medical records

AND

3 - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Product Name:Vtama	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is NOT receiving Vtama in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

2 . Revision History

Date	Notes

2/28/2025	Added ST bypass for current users in initial auth section. Removed r eference to Stelara in examples of targeted immunomodulators due t o ustekinumab biosimilar availability. Minor cosmetic updates.

Vyalev

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164784
Guideline Name	Vyalev
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State Michigan Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's disease

AND

2 - Patient has inadequately controlled motor fluctuations despite being treated with optimized oral therapies (e.g. levodopa)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vyalev therapy demonstrated by an increase in “on” time without troublesome dyskinesia

2 . Revision History

Date	Notes
2/5/2025	New guideline

Vyalev

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164784
Guideline Name	Vyalev
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State Michigan Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced Parkinson's disease

AND

2 - Patient has inadequately controlled motor fluctuations despite being treated with optimized oral therapies (e.g. levodopa)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Vyalev	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Vyalev therapy demonstrated by an increase in “on” time without troublesome dyskinesia

2 . Revision History

Date	Notes
2/5/2025	New guideline

Vyndaqel and Vyndamax

Prior Authorization Guideline

Guideline ID	GL-208204
Guideline Name	Vyndaqel and Vyndamax
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State Michigan Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - ONE of the following:

2.1 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits

OR

2.3 ALL of the following

2.3.1 Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis

AND

2.3.2 Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake*

AND

2.3.3 Absence of light chain amyloidosis

AND

3 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

4 - Physician attests that the patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level that, when combined with signs and symptoms, is considered definitive for a diagnosis of ATTR-CM

AND

5 - ONE of the following:

History of heart failure, with at least one prior hospitalization for heart failure

Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

6 - Prescribed by, or in consultation, with a cardiologist

AND

7 - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

Notes	*May require prior authorization and notification

Product Name:Vyndaqel, Vyndamax	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Vyndaqel or

Vyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.) **AND** **2** - Documentation that patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure **AND** **3** - Prescribed by or in consultation with a cardiologist **AND** **4** - Patient is not receiving Vyndaqel/Vyndamax in combination with an RNA-targeted therapy for ATTR amyloidosis [i.e., Amvuttra (vutrisiran), Attruby (acoramadis), Onpattro (patisiran), Tegsedi (inotersen), or Wainua (eplontersen)]

2 . Revision History

Date	Notes
3/5/2025	Updated formularies. Updated initial auth criteria. Removed criteria al lowing for temporary combination therapy. Added examples of RNA-t argeted therapy

Wainua

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145767
Guideline Name	Wainua
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

AND

1.2 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb

Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2

Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has NOT had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is NOT receiving Wainua in combination with ONE of the following:

Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Wainua therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

2 - Patient is NOT receiving Wainua in combination with ONE of the following:

Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
4/17/2024	New program.

Wainua

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145767
Guideline Name	Wainua
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

AND

1.2 Documentation that the patient has a pathogenic transthyretin (TTR) mutation (e.g., V30M)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Documentation of ONE of the following:

Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb

Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2

Patient has a baseline neuropathy impairment (NIS) score greater than or equal to 10 and less than or equal to 130

AND

4 - Patient has NOT had a liver transplant

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

AND

6 - Patient is NOT receiving Wainua in combination with ONE of the following:

Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

Tafamidis (e.g., Vyndaqel, Vyndamax)

Product Name:Wainua	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the patient has experienced a positive clinical response to Wainua therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

AND

2 - Patient is NOT receiving Wainua in combination with ONE of the following:

Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

Tafamidis (e.g., Vyndaqel, Vyndamax)

2 . Revision History

Date	Notes
4/17/2024	New program.

Wakix

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129193
Guideline Name	Wakix
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/13/2023

1 . Criteria

Product Name:Wakix	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - One of the following:

3.1 Failure to ALL of the following, as confirmed by claims history or submission of medical records:

An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine) OR a methylphenidate-based stimulant

Armodafinil (generic Nuvigil) OR modafinil (generic Provigil)

Sunosi (solriamfetol)

OR

3.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

An amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine) OR a methylphenidate-based stimulant

Armodafinil (generic Nuvigil) OR modafinil (generic Provigil)

Sunosi (solriamfetol)

OR

3.3 Patient has a history of or potential for a substance abuse disorder

AND

4 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Product Name:Wakix	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy

Product Name:Wakix

Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a MSLT (Multiple Sleep Latency Test) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Pulmonologist

Sleep Medicine Specialist

Product Name:Wakix	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Reduction in symptoms of excessive daytime sleepiness associated with therapy

2 . Revision History

Date	Notes
8/1/2023	No clinical or GPI changes. Adding NY back into GL

Wegovy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152736
Guideline Name	Wegovy
Formulary	Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Wegovy	
Diagnosis	Reduction in the risk of major adverse cardiovascular events
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested to reduce the risk of major adverse cardiovascular events

AND

2 - Patient is 45 years of age or older

AND

3 - Submission of medical records documenting all the following:

3.1 BMI (body mass index) greater than or equal to 27 kg/m2 (kilograms per square meter)

AND

3.2 Established cardiovascular disease as evidenced by one of the following:

3.2.1 Prior myocardial infarction (MI)

OR

3.2.2 Prior ischemic or hemorrhagic stroke

OR

3.2.3 Symptomatic peripheral arterial disease (PAD) evidenced by one of the following:

Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)

Peripheral arterial revascularization procedure

Amputation due to atherosclerotic disease

AND

4 - Used in combination with a reduced calorie diet and increased physical activity

AND

5 - One of the following:

5.1 For patients with history of MI, one of the following:

5.1.1 Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

OR

5.1.2 Patient has a history of intolerance or contraindication to all of the following therapeutic classes (please specify intolerance or contraindication):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Beta blocker (i.e., carvedilol, metoprolol, or bisoprolol)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

OR

5.2 For patients with history of ischemic or hemorrhagic stroke, or symptomatic PAD, one of the following:

5.2.1 Patient is on therapy from each of the following classes (as confirmed by claims history or submission of medical records):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

OR

5.2.2 Patient has a history of intolerance or contraindication to all of the following therapeutic classes (please specify intolerance or contraindication):

Cholesterol lowering medication (e.g., statin, PCSK9i)

Angiotensin-converting enzyme inhibitor (ACE-I)/angiotensin II receptor blocker (ARB)/angiotensin II receptor blocker neprilysin inhibitor (ARNI)

Antiplatelet (e.g., aspirin, clopidogrel)

AND

6 - Patient does NOT have diagnosis of diabetes or HgA1c greater than or equal to 6.5%

AND

7 - Patient does NOT have New York Heart Association class IV heart failure

Product Name:Wegovy	
Diagnosis	Reduction in the risk of major adverse cardiovascular events
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BMI (body mass index) greater than or equal to 27 kg/m2 (kilograms per square meter)

AND

2 - Used in combination with a reduced calorie diet and increased physical activity

AND

3 - Patient does NOT have diagnosis of diabetes or HgA1c greater than or equal to 6.5%

AND

4 - Patient does NOT have New York Heart Association class IV heart failure

Product Name:Wegovy	
Diagnosis	Appetite Suppression or Weight Loss
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than or equal to 12 years of age

AND

3 - Submission of medical records confirming that Wegovy will be used as an adjunct to

lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using Wegovy

AND

4 - ONE of the following:

4.1 BMI (body mass index) greater than or equal to 30 kg/m2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - Wegovy is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Wegovy	
Diagnosis	Appetite Suppression or Weight Loss
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that the patient is tolerating the medication

AND

2 - Submission of medical records confirming that the patient is continuing lifestyle modification

AND

3 - The patient has completed at least 16 weeks of therapy and is currently being treated with the FDA-(Food and Drug Administration) recommended maintenance dose

AND

4 - Submission of medical records confirming the patient has lost at least 5 percent of baseline body weight while taking Wegovy

AND

5 - If this is the patient's subsequent re-authorization, ONE of the following:

Patient has continued to display weight loss

Patient has achieved a normal BMI (18.5-24.9)

If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, submission of medical records showing active participation in a comprehensive weight loss program is required

2 . Revision History

Date	Notes
8/28/2024	New guideline

Weight Loss

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-202201
Guideline Name	Weight Loss
Formulary	Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Brand Adipex-P, generic phentermine, Lomaira	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than 16 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 Body Mass Index (BMI) greater than or equal to 30 kg/m^2 (kilograms/square meter) or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - If the request is for Brand Adipex-P or Lomaira, ONE of the following:

5.1 The brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)

OR

5.2 The brand is being requested due to an incomplete response with a generic/authorized generic equivalent as documented by submission of medical records

AND

6 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:benzphetamine, diethylpropion, diethylpropion ER, phendimetrazine, phendimetrazine ER	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than 16 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 BMI greater than or equal to 30 kg/m^2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Brand Adipex-P, generic phentermine, Lomaira, benzphetamine, diethylpropion, diethylpropion ER, phendimetrazine, phendimetrazine ER	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - Weight loss of greater than or equal to 5% of baseline body weight, as documented by submission of medical records

Product Name:Orlistat, Xenical	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than or equal to 12 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 BMI greater than or equal to 30 kg/m^2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - If the request is for Xenical, BOTH of the following:

5.1 ONE of the following:

5.1.1 The brand is being requested because of an adverse reaction, allergy, or sensitivity to a generic/authorized generic equivalent (specify the adverse reaction, allergy, or sensitivity)

OR

5.1.2 The brand is being requested due to an incomplete response with a generic/authorized generic equivalent as documented by submission of medical records

AND

5.2 ONE of the following:

5.2.1 Patient is less 18 years of age

OR

5.2.2 Patient is greater than or equal to 18 years of age, and ONE of the following:

Failure to OTC Alli as confirmed by claims history or submission of medical records

History of contraindication or intolerance to OTC Alli (specify contraindication or intolerance)

AND

6 - If the request is for Orlistat, ONE of the following:

6.1 Patient is less than 18 years of age

OR

6.2 Patient is greater than or equal to 18 years of age, and ONE of the following:

Failure to OTC Alli as confirmed by claims history or submission of medical records

History of contraindication or intolerance to OTC Alli (specify contraindication or intolerance)

AND

7 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:OTC Alli	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than or equal to 18 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 BMI greater than or equal to 30 kg/m^2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Orlistat, Xenical, OTC Alli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - Weight loss of greater than or equal to 5% of baseline body weight, as documented by submission of medical records

Product Name:Contrave	
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than 16 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 BMI greater than or equal to 30 kg/m^2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Contrave	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - ALL of the following:

3.1 The patient has completed at least 16 weeks of therapy of Contrave and are currently being treated with the FDA-(Food and Drug Administration) recommended maintenance dose

AND

3.2 Submission of medical records confirming the patient lost at least 5 percent of baseline body weight while taking Contrave

AND

3.3 If this is the patient's subsequent re-authorization, ONE of the following:

Patient has continued to display weight loss

Patient has achieved a normal BMI (18.5-24.9)

If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, submission of medical records showing active participation in a comprehensive weight loss program is required

Product Name:Qsymia, Saxenda

Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than or equal to 12 years of age

AND

3 - Submission of medical records confirming that the requested weight loss medication will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using the requested medication

AND

4 - ONE of the following:

4.1 BMI greater than or equal to 30 kg/m^2 or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m^2, as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - The requested medication is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Qsymia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - There has been weight loss of greater than or equal to 3% of baseline body weight, as documented by submission of medical records

Product Name:Saxenda	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - ONE of the following:

3.1 For patients 12 to 17 years of age, ALL of the following:

3.1.1 The patient has completed at least 12 weeks of therapy on maintenance dose of therapy with Saxenda

AND

3.1.2 Submission of medical records confirming the patient had at least a 1 percent reduction in body mass index (BMI) from baseline

AND

3.1.3 If this is the patient's subsequent re-authorization, ONE of the following:

Patient has continued to display weight loss

Patient has achieved a normal BMI standardized for age and sex

If the patient has demonstrated no further weight loss, and the BMI is classified as obese when standardized for age and sex, submission of medical records showing active participation in a comprehensive weight loss program is required

OR

3.2 For patients 18 years of age and older, ALL of the following:

3.2.1 The patient has completed at least 16 weeks of therapy of Saxenda and are currently being treated with the FDA-(Food and Drug Administration) recommended maintenance dose

AND

3.2.2 Submission of medical records confirming the patient lost at least 5 percent of baseline body weight while taking Saxenda

AND

3.2.3 If this is the patient's subsequent re-authorization, ONE of the following:

Patient has continued to display weight loss

Patient has achieved a normal BMI (18.5-24.9)

If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, submission of medical records showing active participation in a comprehensive weight loss program is required

Product Name:Imcivree	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of obesity is due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene deficiency confirmed with genetic testing interpreted as pathogenic, likely pathogenic, or of uncertain significance

OR

1.2 Diagnosis of Bardet-Biedl syndrome

AND

2 - ONE of the following:

2.1 Adult patient with BMI greater than or equal to 30 kg/m^2, as documented by submission of medical records

OR

2.2 Pediatric patient with weight greater than 95th percentile for age on growth chart assessment, as documented by submission of medical records

AND

3 - Patient is currently enrolled in or has history of a weight loss management program

Product Name:Imcivree	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - If on therapy for less than 12 months, documentation of a positive clinical response to Imcivree therapy defined as weight loss greater than or equal to 5% of baseline weight, as documented by submission of medical records

OR

2 - If on therapy for greater than or equal to 12 months, documentation of a positive clinical response to Imcivree therapy defined as greater than or equal to 10% weight loss from baseline, as documented by submission of medical records

2 . Revision History

Date	Notes
2/27/2025	Removed Zepbound and created sperate drug specific guideline.

Welireg

Prior Authorization Guideline

Guideline ID	GL-155263
Guideline Name	Welireg
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Welireg	
Diagnosis	Von Hippel-Lindau (VHL) Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of von Hippel-Lindau (VHL) disease

AND

2 - Patient requires therapy for ONE of the following:

Renal cell carcinoma (RCC)

Central nervous system (CNS) hemangioblastoma

Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery

Product Name:Welireg	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - Disease has progressed after treatment with BOTH of the following:

2.1 Programmed death receptor 1 (PD-1) or programmed death ligand 1 (PD-L1) checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)]

AND

2.2 Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Cabometyx (cabozantinib), Inlyta (axitinib), Lenvima (lenvatinib)]

Product Name:Welireg	
Diagnosis	Von Hippel-Lindau (VHL) Disease, Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of disease progression while on Welireg

Product Name:Welireg	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Welireg	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Welireg therapy

2 . Revision History

Date	Notes
9/19/2024	Updated examples of PD-L1 checkpoint inhibitors and VEGF-TKIs wi thin advanced RCC criteria.

Welireg

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155263
Guideline Name	Welireg
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Welireg	
Diagnosis	Von Hippel-Lindau (VHL) Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of von Hippel-Lindau (VHL) disease

AND

2 - Patient requires therapy for ONE of the following:

Renal cell carcinoma (RCC)

Central nervous system (CNS) hemangioblastoma

Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery

Product Name:Welireg	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma (RCC)

AND

2 - Disease has progressed after treatment with BOTH of the following:

2.1 Programmed death receptor 1 (PD-1) or programmed death ligand 1 (PD-L1) checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)]

AND

2.2 Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Cabometyx (cabozantinib), Inlyta (axitinib), Lenvima (lenvatinib)]

Product Name:Welireg	
Diagnosis	Von Hippel-Lindau (VHL) Disease, Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of disease progression while on Welireg

Product Name:Welireg	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Welireg	
Diagnosis	NCCN Recommended Regimens

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Welireg therapy

2 . Revision History

Date	Notes
9/19/2024	Updated examples of PD-L1 checkpoint inhibitors and VEGF-TKIs wi thin advanced RCC criteria.

Winrevair

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152465
Guideline Name	Winrevair
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Winrevair	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of pulmonary arterial hypertension (PAH)

AND

1.1.2 PAH has been confirmed by right heart catheterization

AND

1.1.3 Prescriber attestation that other types of pulmonary hypertension (PH) are excluded as a diagnosis

AND

1.1.4 Pulmonary arterial hypertension is symptomatic

OR

1.2 Both of the following:

1.2.1 Diagnosis of pulmonary arterial hypertension

AND

1.2.2 Patient is currently on Winrevair therapy as documented by claims history or submission of medical records

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

AND

2.1.2 Patient is currently taking at least ONE of the following oral therapies:

Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

OR

2.2 Both of the following:

2.2.1 Patient does not have a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

AND

2.2.2 Patient is currently taking oral combination therapy with BOTH of the following:

2.2.2.1 Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]

AND

2.2.2.2 One of the following:

Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

Soluble guanylate cyclase stimulator (sGC) [e.g., Adempas (riociguat)]

AND

3 - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

Product Name:Winrevair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to Winrevair therapy [e.g., improvement in symptoms of right heart failure, exercise tolerance, six-minute walk distance (6MWD), resting and ambulatory oximetry]

AND

2 - Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

2 . Revision History

Date	Notes
8/21/2024	New.

Xalkori

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145949
Guideline Name	Xalkori
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name:Xalkori	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

Metastatic

Recurrent

Advanced

AND

3 - ONE of the following:

Tumor is anaplastic lymphoma kinase (ALK)-positive

Tumor is ROS1-positive

Tumor is positive for mesenchymal-epithelial transition (MET) amplification

Tumor is positive for MET exon 14 skipping mutation

Product Name:Xalkori	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

Tumor is anaplastic lymphoma kinase (ALK)-positive

Tumor is ROS1-positive

Product Name:Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

Product Name:Xalkori	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Langerhans Cell Histiocytosis

Erdheim-Chester Disease

Rosai-Dorfman Disease

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement

Product Name:Xalkori	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic or unresectable cutaneous melanoma

AND

2 - Disease is ROS1 gene fusion-positive

AND

3 - Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy

Product Name:Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT), Non-Small Cell Lung Cancer (NSCLC), Central Nervous System (CNS) Cancers, Anaplastic Large Cell Lymphoma, Histiocytic Neoplasms, Melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xalkori therapy

Product Name:Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xalkori	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xalkori therapy

2 . Revision History

Date	Notes
4/19/2024	Added criteria for melanoma. Added the sprinkle caps.

Xarelto

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208213
Guideline Name	Xarelto
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Continuation of Therapy Upon Hospital Discharge
Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Xarelto will be approved as continuation of therapy upon hospital discharge

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Stroke and Systemic Embolism Prevention in Adult Patients with Non-Valvular Atrial Fibrillation (AF)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atrial fibrillation (AF)

AND

2 - Patient does not have an artificial heart valve

AND

3 - ONE of the following:

Failure to Eliquis as confirmed by claims history or submission of medical records

History of contraindication or intolerance to Eliquis (please specify contraindication or intolerance)

Continuation of prior Xarelto therapy

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Prophylaxis of Venous Thromboembolism (VTE) after Orthopedic Surgery (Hip Replacement or Knee Replacement) in Adult Patients

Approval Length	35 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has or is scheduled to have total knee replacement surgery

OR

1.2 Patient has or is scheduled to have total hip replacement surgery

AND

2 - Patient does not have an artificial heart valve

AND

3 - ONE of the following:

3.1 Xarelto is being prescribed as continuation of therapy following hospitalization after orthopedic surgery

OR

3.2 Provider provides reason or special circumstance why the patient is unable to use Eliquis

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Treatment of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) in Adult Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

AND

2 - Patient does not have an artificial heart valve

AND

3 - ONE of the following:

Failure to Eliquis as confirmed by claims history or submission of medical records

History on intolerance or contraindication to Eliquis (please specify intolerance or contraindication)

Continuation of prior Xarelto therapy

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Reduction in the Risk of Recurrence of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) in Adult Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Previous diagnosis of ONE of the following:

Deep vein thrombosis (DVT)

Pulmonary embolism (PE)

AND

2 - Patient does not have an artificial heart valve

AND

3 - Patient must have been treated with an anticoagulant [e.g., warfarin, Eliquis (apixaban)] for at least 6 months prior to request as confirmed by claims history or submission of medical records

AND

4 - ONE of the following:

4.1 Failure to Eliquis as confirmed by claims history or submission of medical records

OR

4.2 History of intolerance or contraindication to Eliquis (please specify intolerance or contraindication)

OR

4.3 Continuation of prior Xarelto therapy

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Reduction in the Risk of Major Cardiovascular Events [Cardiovascular (CV) Death, Myocardial Infarction (MI) and Stroke] in Adult Patients with Chronic Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD)
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Chronic coronary artery disease (CAD)

Peripheral artery disease (PAD)

AND

2 - Patient does not have an artificial heart valve

AND

3 - Patient is on concurrent aspirin therapy

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Prophylaxis of Venous Thromboembolism (VTE) in Acutely Ill Medical Adult Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient was admitted to the hospital for an acute medical illness

AND

2 - Patient does not have an artificial heart valve

AND

3 - Patient is at risk of thromboembolic complications due to moderate or severe restricted mobility

AND

4 - Patient is not at high risk of bleeding

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Thromboprophylaxis in Pediatric Patients with Congenital Heart Disease After the Fontan Procedure
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital heart disease

AND

2 - Patient does not have an artificial heart valve

AND

3 - Patient is at risk of thromboembolic complications due to Fontan procedure

AND

4 - Patient is 2 years to 17 years of age

Product Name:Xarelto tablets, Xarelto oral suspension, generic rivaroxaban	
Diagnosis	Treatment of VTE and Reduction in the Risk of Recurrent VTE in Pediatric Patients
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used for the treatment of venous thromboembolism (VTE) or the reduction in the risk of recurrent VTE

AND

2 - Patient does not have an artificial heart valve

AND

3 - Patient has received at least 5 days of initial parenteral anticoagulant treatment

AND

4 - Patient is 0 years to 17 years of age

2 . Revision History

Date	Notes
3/5/2025	Updated formularies. Added generic rixaroxaban. Removed step thro ugh Savaysa throughout

Xdemvy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143401
Guideline Name	Xdemvy
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Xdemvy	
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Demodex blepharitis

AND

2 - Patient demonstrates ONE of the following signs of Demodex infestation:

Cylindrical cuff at the root of the eyelashes

Lid margin erythema

Eyelash anomalies (e.g., eyelash misdirection, eyelash loss)

AND

3 - Patient demonstrates TWO of the following symptoms of Demodex infestation:

Itching/Burning

Foreign body sensation

Crusting/matted lashes

Blurry vision

Discomfort/irritation

Tearing/lacrimation

Dryness

Purulence/discharge

AND

4 - Patient is practicing good eye-lid hygiene (e.g., non-prescription tree-tea oil)

AND

5 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist Optometrist

2 . Revision History

Date	Notes
2/22/2024	Updated criteria to include eyelash loss as an example of eyelash an omalies and added tearing/lacrimation, dryness, and purulence/disch arge to the list of symptoms of Demodex infestation.

Xeljanz, Xeljanz XR, Xeljanz Oral Solution

Prior Authorization Guideline

Guideline ID	GL-208200
Guideline Name	Xeljanz, Xeljanz XR, Xeljanz Oral Solution
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Xeljanz tabs, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

1.2 One of the following:

1.2.1 Failure to a 3 month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to one non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), Olumiant (baricitinib), Rinvoq (upadacitinib)]

AND

1.3 BOTH of the following:

1.3.1 ONE of the following:

1.3.1.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

OR

1.3.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

OR

1.3.1.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.3.2 One of the following:

1.3.2.1 Failure to Olumiant (baricitinib) as confirmed by claims history or submission of medical records

OR

1.3.2.2 History of intolerance or contraindication to Olumiant (baricitinib) (please specify intolerance or contraindication

AND

1.4 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Diagnosis of moderately to severely active RA

AND

2.2 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

2.3 Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See Table 1 in Background for PDL Links

Product Name:Xeljanz tabs, Xeljanz XR	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active psoriatic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to a 3 month trial of methotrexate at the maximally indicated dose as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to methotrexate (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Orencia (abatacept), ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 One of the following:

1.3.1.1.1 Failure to TWO of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

OR

1.3.1.1.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products*

Enbrel (etanercept)

One of the preferred ustekinumab products*

AND

1.3.1.2 One of the following:

1.3.1.2.1 Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

OR

1.3.1.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

OR

1.3.2 Patient has a documented needle-phobia to the degree that the patient has previously

refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.4 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

1.5 Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active psoriatic arthritis

AND

2.3 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]

Potent immunosuppressant (e.g., azathioprine or cyclosporine)

AND

2.4 Prescribed by or in consultation with ONE of the following:

Rheumatologist

Dermatologist

Notes	*See Table 1 in Background for PDL Links

Product Name:Xeljanz tabs, Xeljanz XR	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

1.2 ONE of the following:

1.2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submitted medical records

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., Simponi (golimumab), ustekinumab, Rinvoq (upadacitinib)]

AND

1.3 ONE of the following:

1.3.1 Failure to ONE of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

One of the preferred ustekinumab products*

OR

1.3.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products*

One of the preferred ustekinumab products*

OR

1.3.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.4 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - ALL of the following:

2.1 Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active UC

AND

2.3 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib), ustekinumab, Skyrizi (risankizumab)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

2.4 Prescribed by or in consultation with a gastroenterologist

Notes	*See Table 1 in Background for PDL Links

Product Name:Xeljanz tabs, Xeljanz XR	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active ankylosing spondylitis

AND

1.2 One of the following:

1.2.1 Failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, as confirmed by claims history or submission of medical records

OR

1.2.2 History of intolerance or contraindication to two NSAIDs (e.g., ibuprofen, naproxen) (please specify intolerance or contraindication)

OR

1.2.3 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as confirmed by claims history or submission of medical records [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Simponi (golimumab), Rinvoq (upadacitinib)]

AND

1.3 ONE of the following:

1.3.1 BOTH of the following:

1.3.1.1 One of the following:

1.3.1.1.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

OR

1.3.1.1.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

One of the preferred adalimumab products*

Enbrel (etanercept)

AND

1.3.1.2 ONE of the following:

1.3.1.2.1 Failure to Cosentyx (secukinumab) as confirmed by claims history or submission of medical records

OR

1.3.1.2.2 History of intolerance or contraindication to Cosentyx (secukinumab) (please specify intolerance or contraindication)

OR

1.3.2 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.4 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

1.5 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Xeljanz/Xeljanz XR therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active ankylosing spondylitis

AND

2.3 Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Rinvoq (upadacitinib), Olumiant (baricitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See Table 1 in Background for PDL Links

Product Name:Xeljanz tabs, Xeljanz XR	
Diagnosis	Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC), Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz/Xeljanz XR therapy

AND

2 - Patient is NOT receiving Xeljanz/Xeljanz XR in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Rinvoq (upadacitinib), Olumiant (baricitinib), Otezla (apremilast)]*

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)*

Notes	* Examples of drug(s) may not be applicable based on the requested i ndication.

Product Name:Xeljanz tabs/oral soln	
Diagnosis	Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

1.2 ONE of the following:

1.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

One of the preferred adalimumab products*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

OR

1.2.2 History of intolerance or contraindication to ALL of the following (please specific intolerance or contraindication):

One of the preferred adalimumab products*

Enbrel (etanercept)

Tyenne (tocilizumab-aazg)

OR

1.2.3 Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria)

AND

1.3 Patient is NOT receiving Xeljanz/Xeljanz oral solution in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

1.4 Prescribed by or in consultation with a rheumatologist

OR

2 - ALL of the following:

2.1 Patient is currently on Xeljanz/Xeljanz Oral Solution as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2.3 Patient is NOT receiving Xeljanz/Xeljanz Oral Solution in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

AND

2.4 Prescribed by or in consultation with a rheumatologist

Notes	*See Table 1 in Background for PDL Links

Product Name:Xeljanz tabs/oral soln	
Diagnosis	Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xeljanz or Xeljanz oral solution therapy

AND

2 - Patient is NOT receiving Xeljanz or Xeljanz oral solution in combination with either of the following:

Targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib)]

Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

2 . Background

Benefit/Coverage/Program Information

Table 1. PDL Links

CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA CHIP: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Updated formularies. Added ustekinumab as a step therapy option in PsA and UC. Replaced Stelara with ustekinumab throughout. Added NM to PDL links in background.

Xenazine

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135293
Guideline Name	Xenazine
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Xenazine, generic tetrabenazine	
Diagnosis	Chorea associated with Huntington’s Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

Product Name:Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia

AND

2 - ONE of the following:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Product Name:Brand Xenazine, generic tetrabenazine	
Diagnosis	Tourette's Syndrome (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome

AND

2 - ONE of the following:

2.1 Failure of haloperidol confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to haloperidol (please specify intolerance or contraindication)

AND

3 - Prescribed by or in consultation with ONE of the following:

Neurologist

Psychiatrist

Product Name:Brand Xenazine, generic tetrabenazine	
Diagnosis	Tardive Dyskinesia (Off-Label), Tourette's Syndrome (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
10/23/2023	Removed RMH CO Formulary

Xenleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121318
Guideline Name	Xenleta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name:Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 One of the following:

1.3.3.1 Failure to three of the following antibiotics or antibiotic regimens confirmed by claims history or submitted medical records:

Amoxicillin

A macrolide

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

OR

1.3.3.2 History of contraindication or intolerance to all of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication):

Amoxicillin

A macrolide

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name:Xenleta	
Diagnosis	Off-Label Uses
Approval Length	Based on provider and IDSA recommended treatment durations, not to exceed 6 months
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

2 . Revision History

Date	Notes
2/15/2023	Updated trial/failure language. Moved approval duration from notes t o approval length box for Off-Label Uses.

Xenleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121318
Guideline Name	Xenleta
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2023

1 . Criteria

Product Name:Xenleta	
Diagnosis	Community-acquired bacterial pneumonia
Approval Length	7 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 All of the following:

1.3.1 Diagnosis of community-acquired bacterial pneumonia (CABP)

AND

1.3.2 Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Xenleta

AND

1.3.3 One of the following:

1.3.3.1 Failure to three of the following antibiotics or antibiotic regimens confirmed by claims history or submitted medical records:

Amoxicillin

A macrolide

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

OR

1.3.3.2 History of contraindication or intolerance to all of the following antibiotics or antibiotic regimens (please specify intolerance or contraindication):

Amoxicillin

A macrolide

Doxycycline

A fluoroquinolone

Combination therapy with amoxicillin/clavulanate or cephalosporin AND a macrolide or doxycycline

Product Name:Xenleta	
Diagnosis	Off-Label Uses
Approval Length	Based on provider and IDSA recommended treatment durations, not to exceed 6 months
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For continuation of therapy upon hospital discharge

OR

1.2 As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

1.3 The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

2 . Revision History

Date	Notes
2/15/2023	Updated trial/failure language. Moved approval duration from notes t o approval length box for Off-Label Uses.

Xermelo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151732
Guideline Name	Xermelo
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome diarrhea

AND

2 - Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide), as confirmed by claims history or submission of medical records

AND

3 - Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)

Product Name:Xermelo	
Diagnosis	Carcinoid Syndrome Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xermelo

2 . Revision History

Date	Notes
8/14/2024	Updated initial authorization duration to 12 months.

Xifaxan

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154833
Guideline Name	Xifaxan
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Xifaxan 200mg	
Diagnosis	Travelers' Diarrhea
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of travelers' diarrhea

AND

2 - ONE of the following:

2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

Azithromycin (generic Zithromax)

Ciprofloxacin (generic Cipro)

Levofloxacin (generic Levaquin)

Ofloxacin (generic Floxin)

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

Azithromycin (generic Zithromax)

Ciprofloxacin (generic Cipro)

Levofloxacin (generic Levaquin)

Ofloxacin (generic Floxin)

Product Name:Xifaxan 550mg	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - ONE of the following:

2.1 BOTH of the following:

Used as add-on therapy to lactulose, confirmed by claims history or submitted medical records

Patient is unable to achieve an optimal clinical response with lactulose monotherapy, confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to lactulose (please specify intolerance or contraindication)

Product Name:Xifaxan 550mg	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xifaxan therapy

Product Name:Xifaxan 550mg	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - ONE of the following:

2.1 Failure of ONE tricyclic antidepressant (e.g. amitriptyline) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to tricyclic antidepressants (e.g. amitriptyline) (please specify intolerance or contraindication)

Product Name:Xifaxan 550mg	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to need Xifaxan and has experienced positive results with prior use

Product Name:Xifaxan 200mg	
Diagnosis	Inflammatory Bowel Disease (e.g. Crohn's Disease, Ulcerative Colitis, Diverticulitis) (Off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory bowel disease

AND

2 - ONE of the following:

2.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

Ciprofloxacin (generic Cipro)

Metronidazole (generic Flagyl)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Ciprofloxacin (generic Cipro)

Metronidazole (generic Flagyl)

Product Name:Xifaxan 200mg	
Diagnosis	Inflammatory Bowel Disease (e.g. Crohn's Disease, Ulcerative Colitis, Diverticulitis) (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xifaxan therapy

2 . Revision History

Date	Notes
9/12/2024	Removed MD from markets in scope. MD will have specific criteria cr eated to remove MD carveout drugs as step through agents.

Xifaxan

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154833
Guideline Name	Xifaxan
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Xifaxan 200mg	
Diagnosis	Travelers' Diarrhea
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of travelers' diarrhea

AND

2 - ONE of the following:

2.1 Failure of ONE of the following confirmed by claims history or submitted medical records:

Azithromycin (generic Zithromax)

Ciprofloxacin (generic Cipro)

Levofloxacin (generic Levaquin)

Ofloxacin (generic Floxin)

OR

2.2 History of intolerance or contraindication to ALL of the following (please specify intolerance or contraindication):

Azithromycin (generic Zithromax)

Ciprofloxacin (generic Cipro)

Levofloxacin (generic Levaquin)

Ofloxacin (generic Floxin)

Product Name:Xifaxan 550mg	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - ONE of the following:

2.1 BOTH of the following:

Used as add-on therapy to lactulose, confirmed by claims history or submitted medical records

Patient is unable to achieve an optimal clinical response with lactulose monotherapy, confirmed by claims history or submitted medical records

OR

2.2 History of contraindication or intolerance to lactulose (please specify intolerance or contraindication)

Product Name:Xifaxan 550mg	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xifaxan therapy

Product Name:Xifaxan 550mg	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

AND

2 - ONE of the following:

2.1 Failure of ONE tricyclic antidepressant (e.g. amitriptyline) confirmed by claims history or submitted medical records

OR

2.2 History of intolerance or contraindication to tricyclic antidepressants (e.g. amitriptyline) (please specify intolerance or contraindication)

Product Name:Xifaxan 550mg	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient continues to need Xifaxan and has experienced positive results with prior use

Product Name:Xifaxan 200mg	
Diagnosis	Inflammatory Bowel Disease (e.g. Crohn's Disease, Ulcerative Colitis, Diverticulitis) (Off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory bowel disease

AND

2 - ONE of the following:

2.1 Failure of BOTH of the following confirmed by claims history or submitted medical records:

Ciprofloxacin (generic Cipro)

Metronidazole (generic Flagyl)

OR

2.2 History of intolerance or contraindication to BOTH of the following (please specify intolerance or contraindication):

Ciprofloxacin (generic Cipro)

Metronidazole (generic Flagyl)

Product Name:Xifaxan 200mg	
Diagnosis	Inflammatory Bowel Disease (e.g. Crohn's Disease, Ulcerative Colitis, Diverticulitis) (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xifaxan therapy

2 . Revision History

Date	Notes
9/12/2024	Removed MD from markets in scope. MD will have specific criteria cr eated to remove MD carveout drugs as step through agents.

Xolair

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150970
Guideline Name	Xolair
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/6/2024

1 . Criteria

Product Name:Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Xolair for moderate to severe persistent asthma under an active UnitedHealthcare medical benefit prior authorization

AND

2 - Documentation of positive clinical response to Xolair therapy as demonstrated by at least ONE of the following

2.1 Reduction in the frequency of exacerbations

OR

2.2 Decreased utilization of rescue medications

OR

2.3 Increase in percent predicted forced expiratory volume (FEV1) from pretreatment baseline

OR

2.4 Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

AND

3 - Xolair is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

4 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate or severe asthma

AND

2 - Classification of asthma as uncontrolled or inadequately controlled as defined by at least ONE of the following:

2.1 Poor symptom control [e.g., Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20]

OR

2.2 Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

OR

2.3 Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

OR

2.4 Airflow limitation [e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second (FEV1) less than 80% predicted (in the face of reduced FEV1-forced vital capacity [FVC] defined as less than the lower limit of normal)]

OR

2.5 Patient is currently dependent on oral corticosteroids for the treatment of asthma

AND

3 - Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting a baseline (pre-omalizumab treatment) serum total IgE (immunoglobulin E) level greater than or equal to 30 IU/mL (international units/milliliter) and less than or equal to 1300 IU/mL

AND

4 - Positive skin test or in vitro reactivity to a perennial aeroallergen

AND

5 - Used in combination with ONE of the following:

5.1 ONE maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)-long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate-salmeterol (AirDuo, Advair), budesonide-formoterol (Symbicort)]

OR

5.2 Combination therapy including BOTH of the following:

5.2.1 One maximally-dosed (appropriately adjusted for age) ICS (inhaled corticosteroid)

product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

AND

5.2.2 One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist - montelukast (Singulair); theophylline]

AND

6 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by ONE of the following:

Allergist

Immunologist

Pulmonologist

Product Name:Xolair	
Diagnosis	Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response as demonstrated by at least ONE of the following:

Reduction in frequency of exacerbations

Decreased utilization of rescue medications

Increase in percent predicted FEV1 (forced expiratory volume in 1 second) from pretreatment baseline

Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

AND

2 - Used in combination with an ICS (inhaled corticosteroid)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)]

AND

3 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	Chronic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Xolair for chronic urticaria under an active UnitedHealthcare medical benefit prior authorization

AND

2 - Documentation of positive clinical response to Xolair therapy (e.g., reduction in exacerbations, itch severity, hives)

AND

3 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	Chronic Urticaria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic urticaria

AND

2 - ONE of the following:

2.1 Patient remains symptomatic despite at least a 2-week trial and failure of two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]* (confirmed by claims history or submitted medical records)

OR

2.2 Patient remains symptomatic despite at least a 2-week trial and failure of BOTH of the following taken in combination (confirmed by claims history or submitted medical records):

2.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.2.2 ONE of the following:

Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*

H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]

Leukotriene modifier [e.g., Singulair (montelukast)]

OR

2.3 History of contraindication or intolerance to ONE of the following (please specify contraindication or intolerance):

2.3.1 Two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*

OR

2.3.2 BOTH of the following taken in combination:

2.3.2.1 Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

AND

2.3.2.2 ONE of the following:

Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*

H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]

Leukotriene modifier [e.g., Singulair (montelukast)]

AND

3 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

4 - Prescribed by one of the following:

Allergist

Dermatologist

Immunologist

Notes	*Patients 65 years of age and older in whom first generation H1-antihi stamines are considered high risk medications to be avoided (e.g., Be

	ers criteria, HEDIS) should be directed to try alternatives that are not c onsidered high risk.

Product Name:Xolair	
Diagnosis	Chronic Urticaria
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

AND

2 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	Nasal Polyps
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Xolair for nasal polyps under an active UnitedHealthcare medical benefit prior authorization

AND

2 - Documentation of positive clinical response to Xolair therapy

AND

3 - Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

4 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	Nasal Polyps
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nasal polyps

AND

2 - TWO or more of the following symptoms for longer than 12 weeks duration:

Nasal mucopurulent discharge

Nasal obstruction, blockage, or congestion

Facial pain, pressure, and/or fullness

Reduction or loss of sense of smell

AND

3 - ONE of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

Purulent mucus or edema in the middle meatus or ethmoid regions

Polyps in the nasal cavity or the middle meatus

Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

AND

4 - ONE of the following:

4.1 Patient has required prior sinus surgery

OR

4.2 Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for nasal polyps in the previous 2 years

OR

4.3 Patient has been unable to obtain symptom relief after trial of BOTH of the following confirmed by claims history or submitted medical records:

Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

One other therapy used in management of nasal polyps [i.e., nasal saline irrigations, antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]

AND

5 - Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

6 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by one of the following:

Allergist

Immunologist

Otolaryngologist

Pulmonologist

Product Name:Xolair	
Diagnosis	Nasal Polyps

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xolair therapy

AND

2 - Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

AND

3 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has been established on therapy with Xolair for IgE-Mediated food allergy under an active UnitedHealthcare medical benefit prior authorization

AND

2 - Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)

AND

3 - Xolair will be used in conjunction with food allergen avoidance

AND

4 - Patient access to epinephrine

AND

5 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

6 - Prescribed by an allergist or immunologist

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization - Not transitioning from UHC medical benefits
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of IgE-mediated food allergy to one or more foods

AND

2 - Patient is at least 1 year of age

AND

3 - IgE-mediated food allergy to specific food(s) has been confirmed by both of the following:

3.1 History of type I allergic reactions (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of the lips, face or throat, wheezing, lightheadedness, syncope)

AND

3.2 One of the following:

Food specific skin prick testing (SPT)

IgE antibody in vitro testing

Oral food challenge (OFC)

AND

4 - Xolair will be used in conjunction with food allergen avoidance

AND

5 - Patient has access to epinephrine

AND

6 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

7 - Prescribed by allergist or immunologist

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xolair therapy (e.g., reduction in type I allergic reactions)

AND

2 - Xolair will be used in conjunction with food allergen avoidance

AND

3 - Patient has access to epinephrine

AND

4 - Patient is not receiving Xolair in combination with any of the following:

Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

AND

5 - Prescribed by an allergist or immunologist

2 . Revision History

Date	Notes
8/5/2024	Expanded coverage of Xolair for IgE-mediated food allergy to all foods. Updated references.

Xolremdi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156888
Guideline Name	Xolremdi
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Xolremdi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome

AND

2 - Patient has a genotype-confirmed mutation of chemokine (C-X-C motif) receptor 4 (CXCR4) consistent with WHIM phenotype

AND

3 - Patient has an absolute neutrophil count (ANC) less than or equal to 500 cells per microliter

AND

4 - Prescribed by or in consultation with ONE of the following:

Allergist

Geneticist

Hematologist

Immunologist

Product Name:Xolremdi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response [e.g., improvement in absolute neutrophil

counts (ANC), improvement in absolute lymphocyte counts (ALC), reduction in infections] to Xolremdi therapy

AND

2 - Prescribed by or in consultation with ONE of the following:

Allergist

Geneticist

Hematologist

Immunologist

2 . Revision History

Date	Notes
10/2/2024	New program

Xopenex Respules

Prior Authorization Guideline

Guideline ID	GL-120204
Guideline Name	Xopenex Respules
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name:Brand Xopenex inhalation soln, generic levalbuterol inhalation soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	

1 - Failure to treatment with albuterol inhalation solution, as confirmed by claims history or submission of medical records **OR** **2** - History of contraindication or intolerance to albuterol inhalation solution (please specify contraindication or intolerance)

2 . Revision History

Date	Notes
1/30/2023	Updated trial/failure language.

Xospata

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145966
Guideline Name	Xospata
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Xospata	
Diagnosis	Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive

AND

3 - ONE of the following:

Used in combination with azacitidine as low-intensity treatment induction when not a candidate for intensive induction therapy

Follow-up after induction therapy with response to previous lower intensity therapy with the same regimen

Post-allogeneic hematopoietic cell transplantation and in remission

Disease is relapsed or refractory

Product Name:Xospata	
Diagnosis	Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

AND

2 - ONE of the following:

2.1 Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic phase

OR

2.2 Patient has an FMS-like tyrosine kinase 3 (FLT3) rearrangement in blast phase

Product Name:Xospata	
Diagnosis	Acute Myeloid Leukemia, Myeloid/Lymphoid Neoplasms
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xospata therapy

Product Name:Xospata	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Xospata will be approved for uses supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xospata	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xospata therapy

2 . Revision History

Date	Notes
4/22/2024	Updated treatment criteria for AML to include additional NCCN recommendations.

Xphozah

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-199196
Guideline Name	Xphozah
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Xphozah	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient is receiving dialysis

AND

3 - Serum phosphorus is greater than 6.5 mg/dL (milligrams per deciliter)

AND

4 - Patient has had an inadequate response to at least a 4-week maximally tolerated dose of BOTH of the following phosphate binders as confirmed by claims history or submission of medical records:

4.1 calcium acetate (generic PhosLo)

AND

4.2 sevelamer carbonate (generic Renvela)

AND

5 - Xphozah will be used as add-on therapy

AND

6 - Prescribed by or in consultation with a nephrologist

Product Name:Xphozah	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xphozah therapy [e.g., reduction of serum phosphorus towards the normal range (3.5 to 5.5 milligrams per deciliter)]

AND

2 - Prescribed by or in consultation with a nephrologist

2 . Revision History

Date	Notes
2/26/2025	Combined formularies. No changes to clinical criteria. Minor cosmetic update.

Xpovio

Prior Authorization Guideline

Guideline ID	GL-211192
Guideline Name	Xpovio
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Xpovio	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of relapsed or refractory multiple myeloma (RRMM)

AND

1.2 Patient has received at least four prior therapies

AND

1.3 Disease is refractory to ALL of the following:

Two proteasome inhibitors

Two immunomodulatory agents

An anti-CD38 monoclonal antibody

AND

1.4 Used in combination with dexamethasone

OR

2 - ALL of the following:

2.1 Diagnosis of multiple myeloma

AND

2.2 Patient has received at least one prior therapy

AND

2.3 Used in combination with ONE of the following:

Velcade (bortezomib) and dexamethasone

Darzalex (daratumumab) and dexamethasone

Kyprolis (carfilzomib) and dexamethasone

OR

3 - ALL of the following:

3.1 Diagnosis of multiple myeloma

AND

3.2 Patient has received at least 2 prior therapies, including an immunomodulatory agent (e.g., lenalidomide, thalidomide) and a proteasome inhibitor (e.g., bortezomib, carfilzomib)

AND

3.3 Patient has demonstrated progression on or within 60 days of completion of the last therapy

AND

3.4 Used in combination with Pomalyst (pomalidomide) and dexamethasone

Product Name:Xpovio	
Diagnosis	Diffuse Large B-cell Lymphoma (DLBCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (including histologic transformation of indolent lymphomas to DLBCL)

OR

1.2 Diagnosis of relapsed or refractory HIV (human immunodeficiency virus)-related diffuse large B-cell lymphoma, primary effusion lymphoma, or HHV8-positive diffuse large B-cell lymphoma

OR

1.3 Diagnosis of relapsed or refractory monomorphic B-Cell type post-transplant lymphoproliferative disorder

AND

2 - Patient has received at least 2 lines of systemic therapies

Product Name:Xpovio	
Diagnosis	Multiple Myeloma, Diffuse Large B-cell Lymphoma (DLBCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xpovio therapy

Product Name:Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xpovio	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xpovio therapy

2 . Revision History

Date	Notes
3/6/2025	Updated formularies

Xtandi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152478
Guideline Name	Xtandi
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 Both of the following:

2.1.1 Disease is castration-resistant

AND

2.1.2 One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.2 Both of the following:

2.2.1 Disease is metastatic castration-sensitive

AND

2.2.2 One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.3 Disease is non-metastatic castration-sensitive with biochemical recurrence at high risk for metastasis

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is castration-resistant

AND

3.1.2 ONE of the following:

3.1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.1.2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.1.2.3 Continuation of ongoing Xtandi therapy

OR

3.2 BOTH of the following:

3.2.1 Disease is BOTH of the following:

Metastatic

Castration-sensitive

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.2.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.2.2.3 Continuation of ongoing Xtandi therapy

OR

3.3 BOTH of the following:

3.3.1 Disease is ALL of the following:

Non-metastatic

Castration-sensitive

Recurrent

High risk for metastasis

AND

3.3.2 ONE of the following:

3.3.2.1 Failure to abiraterone (generic Zytiga) as confirmed by claims history or submission of medical records

OR

3.3.2.2 History of contraindication or intolerance to abiraterone (generic Zytiga) (please specify contraindication or intolerance)

OR

3.3.2.3 Continuation of ongoing Xtandi therapy

Product Name:Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Product Name:Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xtandi therapy

2 . Revision History

Date	Notes

8/22/2024	Updated criteria to reflect that for non-metastatic castration-sensitive prostate cancer concommitent use with GnRH is not required

Xtandi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152478
Guideline Name	Xtandi
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Product Name:Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 Both of the following:

2.1.1 Disease is castration-resistant

AND

2.1.2 One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.2 Both of the following:

2.2.1 Disease is metastatic castration-sensitive

AND

2.2.2 One of the following:

Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

Patient has had bilateral orchiectomy

OR

2.3 Disease is non-metastatic castration-sensitive with biochemical recurrence at high risk for metastasis

AND

3 - ONE of the following:

3.1 BOTH of the following:

3.1.1 Disease is castration-resistant

AND

3.1.2 ONE of the following:

3.1.2.1 Failure to BOTH of the following as confirmed by claims history or submission of medical records:

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.1.2.2 History of contraindication or intolerance to BOTH of the following (please specify contraindication or intolerance):

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.1.2.3 Continuation of ongoing Xtandi therapy

OR

3.2 BOTH of the following:

3.2.1 Disease is BOTH of the following:

Metastatic

Castration-sensitive

AND

3.2.2 ONE of the following:

3.2.2.1 Failure to ALL of the following as confirmed by claims history or submission of medical records:

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.2.2.2 History of contraindication or intolerance to ALL of the following (please specify contraindication or intolerance):

abiraterone (generic Zytiga)

Erleada (apalutamide)

Nubeqa (darolutamide)

OR

3.2.2.3 Continuation of ongoing Xtandi therapy

OR

3.3 BOTH of the following:

3.3.1 Disease is ALL of the following:

Non-metastatic

Castration-sensitive

Recurrent

High risk for metastasis

AND

3.3.2 ONE of the following:

3.3.2.1 Failure to abiraterone (generic Zytiga) as confirmed by claims history or submission of medical records

OR

3.3.2.2 History of contraindication or intolerance to abiraterone (generic Zytiga) (please specify contraindication or intolerance)

OR

3.3.2.3 Continuation of ongoing Xtandi therapy

Product Name:Xtandi	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Xtandi therapy

Product Name:Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Xtandi	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xtandi therapy

2 . Revision History

Date	Notes

8/22/2024	Updated criteria to reflect that for non-metastatic castration-sensitive prostate cancer concommitent use with GnRH is not required

Xuriden

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127838
Guideline Name	Xuriden
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of a hereditary orotic aciduria

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xuriden therapy	

2 . Revision History

Date	Notes
7/11/2023	Combining all Cag's

Xuriden

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127838
Guideline Name	Xuriden
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of a hereditary orotic aciduria

Product Name:Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Xuriden therapy	

2 . Revision History

Date	Notes
7/11/2023	Combining all Cag's

Xyrem, Xywav, Lumryz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158009
Guideline Name	Xyrem, Xywav, Lumryz
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

AND

3 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Pulmonologist

AND

4 - ONE of the following:

4.1 Failure to Wakix (pitolisant) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to Wakix (pitolisant) (please specify intolerance or contraindication)

Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating a reduction in frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with BOTH of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of less than or equal to 8 minutes and two or more sleep onset rapid eye movement (REM) periods (SOREMPs) are found on a Multiple Sleep Latency Test (MSLT) performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT

AND

2 - Physician attestation to BOTH of the following:

2.1 Cataplexy is absent

AND

2.2 Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - ONE of the following:

3.1 Failure of BOTH of the following confirmed by claims history or submission of medical records:

3.1.1 ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

AND

3.1.2 ONE of the following:

Modafinil (Provigil)

Armodafinil (Nuvigil)

OR

3.2 History of contraindication or intolerance of ALL of the following (please specify intolerance or contraindication):

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

Modafinil (Provigil)

Armodafinil (Nuvigil)

AND

4 - ONE of the following:

4.1 Failure to Sunosi (solriamfetol) as confirmed by claims history or submission of medical records

OR

4.2 History of contraindication or intolerance to Sunosi (solriamfetol) (please specify intolerance or contraindication)

AND

5 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Pulmonologist

Product Name:Xyrem, Sodium Oxybate, Xywav, Lumryz	
Diagnosis	Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name:Xywav	
Diagnosis	Idiopathic Hypersomnia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, lab values) documenting a diagnosis of idiopathic hypersomnia with both of the following:

1.1 The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months

AND

1.2 A mean sleep latency of < 8 minutes and fewer than two REM (rapid eye movement) periods (SOREMPs) are found on a MSLT (multiple sleep latency test) performed according to standard techniques following a normal overnight polysomnogram, or no SOREMPs if the REM sleep latency on the preceding polysomnogram was < 15 minutes

AND

2 - Physician attestation that other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders)

AND

3 - ONE of the following:

3.1 Failure of BOTH of the following confirmed by claims history or submission of medical records:

3.1.1 ONE of the following:

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

AND

3.1.2 ONE of the following:

Modafinil (Provigil)

Armodafinil (Nuvigil)

OR

3.2 History of contraindication or intolerance of ALL of the following (please specify intolerance or contraindication):

Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)

Methylphenidate based stimulant

Modafinil (Provigil)

Armodafinil (Nuvigil)

AND

4 - Prescribed by ONE of the following:

Neurologist

Psychiatrist

Sleep medicine specialist

Pulmonologist

Product Name:Xywav	
Diagnosis	Idiopathic Hypersomnia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with therapy

2 . Revision History

Date	Notes
10/25/2024	Added new Lumryz GPI. Removed * from Narcolepsy Type 1 Reauth . Updated initial auth length for idiopathic Hypersomnia.

Yonsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-145067
Guideline Name	Yonsa
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (e.g., N1)

OR

2.3 Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

AND

3 - Used in combination with methylprednisolone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - ONE of the following:

5.1 Prescriber provides a reason or special circumstance the patient cannot take abiraterone (generic Zytiga)

OR

5.2 Patient is currently on Yonsa therapy

Product Name:Yonsa	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Yonsa therapy

Product Name:Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Yonsa	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Yonsa therapy

2 . Revision History

Date	Notes
3/29/2024	Replaced GPI "21406010200310" with new GPI "21406010250310". No changes to criteria.

Yorvipath

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-205218
Guideline Name	Yorvipath
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State Nebraska Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington Medicaid - Community & State Pennsylvania

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Yorvipath	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypoparathyroidism

AND

2 - Confirmation of initial diagnosis by both of the following:

2.1 Pretreatment low albumin-corrected serum calcium (i.e., less than or equal to 8.5 milligrams per deciliter) confirmed on at least two occasions separated by at least 2 weeks

AND

2.2 Pretreatment undetectable or inappropriately low intact PTH concentration (i.e., less than 20 picograms per milliliter), by second- or third-generation immunoassay, on at least two occasions

AND

3 - Yorvipath is not being used to treat acute post-surgical hypoparathyroidism

AND

4 - Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by both of the following:

4.1 Albumin-corrected serum calcium 7.8–10.6 micrograms per deciliter

AND

4.2 Serum 25(OH) vitamin D 20–80 nanograms per milliliter

AND

5 - Prescribed by one of the following:

Endocrinologist

Nephrologist

Product Name:Yorvipath	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response [e.g., albumin-corrected serum calcium level in normal range (approximately 8.3-10.6 milligrams per deciliter), independence from conventional therapy (e.g., requiring no active vitamin D, less than or equal to 600 milligrams per day of calcium)]

AND

2 - Prescribed by one of the following:

Endocrinologist

Nephrologist

2 . Revision History

Date	Notes
2/28/2025	Added PA-CAID for 4/1 go-live. No change to criteria.

Zejula

Prior Authorization Guideline

Guideline ID	GL-164847
Guideline Name	Zejula
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Zejula	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - Disease is stage II-IV

AND

3 - ONE of the following:

3.1 Maintenance therapy for those who are in complete or partial response to a platinum-based chemotherapy

OR

3.2 Recurrence therapy for platinum-sensitive disease in combination with bevacizumab

Product Name:Zejula	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant distant metastatic (M1) prostate cancer

AND

2 - Patient is positive for pathogenic BRCA1 or BRCA2 mutation

AND

3 - Patient has not had treatment since disease progression to metastatic castration-resistant prostate cancer (mCRPC)

AND

4 - ONE of the following:

Patient has not received prior docetaxel and prior novel hormone therapy

Patient had progression on prior docetaxel therapy and has not received prior novel hormone therapy

Patient had progression on prior novel hormone therapy and has not received prior docetaxel therapy

AND

5 - Used in combination with Yonsa (fine-particle abiraterone) and methylprednisolone

Product Name:Zejula	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA-2 (breast cancer) altered uterine leiomyosarcoma (LMS)

AND

2 - Disease is advanced, recurrent/metastatic, or inoperable

AND

3 - Used as second-line or subsequent therapy

Product Name:Zejula	
Diagnosis	Ovarian Cancer, Prostate Cancer, Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zejula therapy

Product Name:Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zejula therapy

2 . Revision History

Date	Notes
2/6/2025	Updated criteria for Ovarian cancer per NCCN guidelines and consolidated sections for maintenance therapy and treatment. Added new criteria for prostate cancer per NCCN guidelines. Updated Uterine Sarcoma section per NCCN guidelines.

Zejula

Prior Authorization Guideline

Guideline ID	GL-164847
Guideline Name	Zejula
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Zejula	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

AND

2 - Disease is stage II-IV

AND

3 - ONE of the following:

3.1 Maintenance therapy for those who are in complete or partial response to a platinum-based chemotherapy

OR

3.2 Recurrence therapy for platinum-sensitive disease in combination with bevacizumab

Product Name:Zejula	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant distant metastatic (M1) prostate cancer

AND

2 - Patient is positive for pathogenic BRCA1 or BRCA2 mutation

AND

3 - Patient has not had treatment since disease progression to metastatic castration-resistant prostate cancer (mCRPC)

AND

4 - ONE of the following:

Patient has not received prior docetaxel and prior novel hormone therapy

Patient had progression on prior docetaxel therapy and has not received prior novel hormone therapy

Patient had progression on prior novel hormone therapy and has not received prior docetaxel therapy

AND

5 - Used in combination with Yonsa (fine-particle abiraterone) and methylprednisolone

Product Name:Zejula	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of BRCA-2 (breast cancer) altered uterine leiomyosarcoma (LMS)

AND

2 - Disease is advanced, recurrent/metastatic, or inoperable

AND

3 - Used as second-line or subsequent therapy

Product Name:Zejula	
Diagnosis	Ovarian Cancer, Prostate Cancer, Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zejula therapy

Product Name:Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zejula	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zejula therapy

2 . Revision History

Date	Notes
2/6/2025	Updated criteria for Ovarian cancer per NCCN guidelines and consolidated sections for maintenance therapy and treatment. Added new criteria for prostate cancer per NCCN guidelines. Updated Uterine Sarcoma section per NCCN guidelines.

Zelboraf

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147384
Guideline Name	Zelboraf
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Zelboraf	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

Unresectable melanoma

Metastatic melanoma

AND

2 - Patient is positive for BRAF V600 mutation

Product Name:Zelboraf	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 BOTH of the following:

Patient has metastatic brain lesions

Zelboraf is active against primary tumor (melanoma)

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of glioma

AND

1.2.2 ONE of the following:

Incomplete resection, biopsy, or surgically inaccessible location

Disease is recurrent or progressive

AND

2 - Cancer is positive for BRAF V600E mutation

AND

3 - Used in combination with Cotellic (cobimetinib)

Product Name:Zelboraf	
Diagnosis	Hairy Cell Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia

Product Name:Zelboraf	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is ONE of the following:

Metastatic

Advanced

Recurrent

AND

3 - Cancer is positive for BRAF V600E mutation

Product Name:Zelboraf	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Erdheim-Chester Disease

Langerhans Cell Histiocytosis

AND

2 - Cancer is positive for BRAF V600 mutation

Product Name:Zelboraf	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

Follicular carcinoma

Oncocytic carcinoma

Papillary carcinoma

AND

2 - ONE of the following:

Unresectable locoregional recurrent disease

Metastatic disease

Persistent disease

AND

3 - ONE of the following:

Patient has symptomatic disease

Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine

AND

5 - Cancer is positive for BRAF V600 mutation

Product Name:Zelboraf	
Diagnosis	Melanoma, CNS Cancers, Hairy Cell Leukemia, NSCLC, Histiocytic Neoplasms, Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zelboraf therapy

Product Name:Zelboraf	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zelboraf

Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zelboraf therapy

2 . Revision History

Date	Notes
5/14/2024	Under thyroid cancer initial criteria section, updated diagnosis option from Hurthle cell carcinoma to oncocytic carcinoma.

Zepbound

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-202200
Guideline Name	Zepbound
Formulary	Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Zepbound	
Diagnosis	Obstructive Sleep Apnea
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for obstructive sleep apnea (OSA)

AND

2 - Patient is greater than or equal to 18 years of age

AND

3 - Submission of medical records confirming all of the following:

3.1 Moderate-to-severe obstructive sleep apnea evidenced by both of the following:

3.1.1 Sleep study

AND

3.1.2 One of the following:

Apnea Hypopnea Index (AHI) greater than or equal to 15

Respiratory Disturbance Index (RDI) greater than or equal to 15

Respiratory Event Index (REI) greater than or equal to 15

AND

3.2 BMI (body mass index) greater than or equal to 30 kg/m2 (kilograms per square meter) in the past 6 months

AND

3.3 At least one previous unsuccessful dietary effort to lose weight

AND

3.4 One of the following:

3.4.1 Both of the following:

Patient is currently on positive airway pressure (PAP) therapy for at least 3 consecutive months

Patient is adherent to PAP therapy, defined as greater than or equal to 4 hours of use per night for greater than or equal to 70 percent of nights

OR

3.4.2 Patient is not a candidate for, or is intolerant to, PAP therapy (e.g., upper airway anatomic abnormalities, etc.)

AND

4 - Used in combination with a reduced calorie diet and increased physical activity

AND

5 - Provider attests to both of the following:

Patient counseled on appropriate positional therapy

Patient counseled on avoidance of alcohol and/or sedatives before bedtime

AND

6 - Patient does NOT have a diagnosis of diabetes or HgA1c (hemoglobin A1c) greater than 6.5%

AND

7 - Prescriber attests the patient does NOT have any one of the following:

Planned surgery for sleep apnea or obesity

Significant craniofacial abnormalities

A diagnosis of central or mixed sleep apnea

AND

8 - Prescribed by, or in consultation with, a sleep specialist

Product Name:Zepbound	
Diagnosis	Obstructive Sleep Apnea
Approval Length	For patients who have been on Zepbound therapy for fewer than 52 weeks of consecutive therapy, authorization of 6 months; OR for patients who have been on Zepbound therapy for greater than or equal to 52 weeks of consecutive therapy, authorization of 12 months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 If patient has been on Zepbound for less than 52 weeks of consecutive therapy, submission of medical records confirming a decrease from baseline in one of the following:

Apnea Hypopnea Index (AHI)

Respiratory Disturbance Index (RDI)

Respiratory Event Index (REI)

OR

1.2 If patient has been on Zepbound for greater than or equal to 52 weeks of consecutive therapy, submission of medical records confirming a 50% decrease from baseline in one of the following:

Apnea Hypopnea Index (AHI)

Respiratory Disturbance Index (RDI)

Respiratory Event Index (REI)

AND

2 - Patient has had a weight loss of greater than or equal to 10% of baseline body weight

AND

3 - Used in combination with a reduced calorie diet and increased physical activity

AND

4 - Patient does NOT have a diagnosis of diabetes or HgA1c (hemoglobin A1c) greater than 6.5%

AND

5 - Patient continues to require treatment for obstructive sleep apnea

Product Name:Zepbound	
Diagnosis	Weight Loss
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss

AND

2 - Patient is greater than or equal to 18 years of age

AND

3 - Submission of medical records confirming that Zepbound will be used as an adjunct to lifestyle modification (e.g., dietary or caloric restriction, exercise, behavioral support, community-based program) and participation has been for at least 6 months (of lifestyle modification) prior to using Zepbound

AND

4 - ONE of the following:

4.1 BMI (body mass index) greater than or equal to 30 kg/m2, or for pediatric patients a BMI greater than 95th percentile, as documented by submission of medical records

OR

4.2 BOTH of the following:

4.2.1 BMI greater than or equal to 27 kg/m2 (kilograms per square meter), as documented by submission of medical records

AND

4.2.2 Patient has a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea) (please specify comorbidity, as documented by submission of medical records)

AND

5 - Zepbound is prescribed by, or in consultation with, an endocrinologist, weight loss clinic or a dietician/nutritionist

Product Name:Zepbound	
Diagnosis	Weight Loss

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records confirming that member is tolerating the medication

AND

2 - Submission of medical records confirming that member is continuing lifestyle modification

AND

3 - The patient has completed at least 16 weeks of therapy of the requested medication and is currently being treated with the FDA-(Food and Drug Administration) recommended maintenance dose

AND

4 - Submission of medical records confirming the patient lost at least 5 percent of baseline body weight while taking the requested medication

AND

5 - If this is the patient's subsequent re-authorization, ONE of the following:

Patient has continued to display weight loss

Patient has achieved a normal BMI (18.5-24.9)

If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, submission of medical records showing active participation in a comprehensive weight loss program is required

2 . Revision History

Date	Notes
2/27/2025	New guideline

Zeposia

Prior Authorization Guideline

Guideline ID	GL-208215
Guideline Name	Zeposia
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis (MS)

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Failure to a trial of a preferred* dimethyl fumarate product, as confirmed by claims history or submission of medical records

AND

2.1.2 Failure to a trial of at least ONE additional preferred* alternative, as confirmed by claims history or submission of medical records

OR

2.2 History of intolerance or contraindication to ALL preferred* alternatives (please specify intolerance or contraindication)

OR

2.3 Patient is currently on Zeposia therapy as confirmed by claims history or submission of medical records

Notes	*PDL links are in Table 1 of Background.

Product Name:Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zeposia therapy

Product Name:Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

1.2 ONE of the following:

1.2.1 Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) as confirmed by claims history or submission of medical records

OR

1.2.2 Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as confirmed by claims history or submission of medical records [e.g., adalimumab, Simponi (golimumab), ustekinumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

AND

1.3 Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g.,

adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

AND

1.4 ONE of the following:

1.4.1 Failure to ONE of the preferred adalimumab products* as confirmed by claims history or submission of medical records

OR

1.4.2 History of intolerance or contraindication to ONE of the preferred adalimumab products* (please specify intolerance or contraindication)

AND

1.5 Prescribed by or in consultation with a gastroenterologist

OR

2 - ALL of the following:

2.1 Patient is currently on Zeposia therapy as confirmed by claims history or submission of medical records

AND

2.2 Diagnosis of moderately to severely active ulcerative colitis

AND

2.3 Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

AND **2.4** Prescribed by or in consultation with a gastroenterologist

Notes	*PDL links are in Table 1 of Background.

Product Name:Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zeposia therapy

AND

2 - Patient is not receiving Zeposia in combination with a targeted immunomodulator [e.g., adalimumab, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), ustekinumab, Skyrizi (risankizumab), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

2 . Background

Benefit/Coverage/Program Information
Table 1. PDL links CO: https://www.uhcprovider.com/en/health-plans-by-state/colorado-health-plans/co-comm-plan-home/co-cp-pharmacy.html

HI: https://www.uhcprovider.com/en/health-plans-by-state/hawaii-health-plans/hi-comm-plan-home/hi-cp-pharmacy.html

MD: https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-cp-pharmacy.html

NJ: https://www.uhcprovider.com/en/health-plans-by-state/new-jersey-health-plans/nj-comm-plan-home/nj-cp-pharmacy.html

NM: https://www.uhcprovider.com/en/health-plans-by-state/new-mexico-health-plans/nm-comm-plan-home/nm-cp-pharmacy.html

NY: https://www.uhcprovider.com/en/health-plans-by-state/new-york-health-plans/ny-comm-plan-home/ny-cp-pharmacy.html

PA: https://www.uhcprovider.com/en/health-plans-by-state/pennsylvania-health-plans/pa-comm-plan-home/pa-cp-pharmacy.html?rfid=UHCCP

RI: https://www.uhcprovider.com/en/health-plans-by-state/rhode-island-health-plans/ri-comm-plan-home/ri-cp-pharmacy.html

3 . Revision History

Date	Notes
3/5/2025	Updated formularies. Replaced Stelara with ustekinumab throughout. Updated safety check language

Zilbrysq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-208209
Guideline Name	Zilbrysq
Formulary	Medicaid - Community & State Arizona (ACUAZ, ACUAZEC) Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Indiana Medicaid - Community & State Maryland Medicaid - Community & State Nebraska Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Virginia

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Zilbrysq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming ALL of the following:

1.1 Diagnosis of generalized myasthenia gravis (gMG)

AND

1.2 Positive serologic test for anti-AChR antibodies

AND

1.3 Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy

AND

1.4 Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score greater than or equal to 6 at initiation of therapy

AND

2 - ONE of the following:

2.1 History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.) as confirmed by claims history or submission of medical records

OR

2.2 Patient has a history of failure of at least one immunosuppressive therapy (as confirmed by claims history or submission of medical records) and has required four or more courses of

plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control

OR

2.3 Contraindication or intolerance to at least two immunosuppressive agents (please specify contraindication or intolerance)

AND

3 - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)]

AND

4 - Prescribed by, or in consultation with, a neurologist

Product Name:Zilbrysq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by at least ALL of the following:

1.1 Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline

AND

1.2 Reduction in signs and symptoms of myasthenia gravis

AND **1.3** Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Zilbrysq* **AND** **2** - Patient is not receiving Zilbrysq in combination with another complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravulizumab-cwvz)] or a neonatal Fc receptor blocker [e.g., Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab),Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)] **AND** **3** - Prescribed by, or in consultation with, a neurologist

Notes	*Add on, dose escalation of IST, or additional rescue therapy from bas eline to treat myasthenia gravis or exacerbation of symptoms while on Zilbrysq therapy will be considered as treatment failure

2 . Revision History

Date	Notes
3/5/2025	Combined formularies. Updated listing of examples of complement in hibitors and neonatal Fc receptor blockers.

Zokinvy

Prior Authorization Guideline

Guideline ID	GL-124463
Guideline Name	Zokinvy
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Zokinvy	
Diagnosis	Hutchinson-Gilford Progeria Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of Hutchinson-Gilford Progeria Syndrome

Product Name:Zokinvy	
Diagnosis	Progeroid Laminopathies
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of processing deficient Progeroid Laminopathies

AND

2 - Documentation of ONE of the following:

Heterozygous LMNA (gene) mutation with progerin-like protein accumulation

Homozygous or compound heterozygous ZMPSTE24 (gene) mutations

2 . Revision History

Date	Notes
4/10/2023	Cleaned up criteria, updated formularies.

Zokinvy

Prior Authorization Guideline

Guideline ID	GL-124463
Guideline Name	Zokinvy
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	6/1/2023

1 . Criteria

Product Name:Zokinvy	
Diagnosis	Hutchinson-Gilford Progeria Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of Hutchinson-Gilford Progeria Syndrome

Product Name:Zokinvy	
Diagnosis	Progeroid Laminopathies
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of processing deficient Progeroid Laminopathies

AND

2 - Documentation of ONE of the following:

Heterozygous LMNA (gene) mutation with progerin-like protein accumulation

Homozygous or compound heterozygous ZMPSTE24 (gene) mutations

2 . Revision History

Date	Notes
4/10/2023	Cleaned up criteria, updated formularies.

Zolinza

Prior Authorization Guideline

Guideline ID	GL-117476
Guideline Name	Zolinza
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - Patient has progressive, persistent, or recurrent disease on or following two systemic therapies [e.g., Adcetris (brentuximab vedotin), bexarotene, interferon alfa-db, interferon gamma-1b, methotrexate, Poteligeo (mogamulizumab), romidepsin]

Product Name:Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zolinza therapy

Product Name:Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zolinza therapy

2 . Revision History

Date	Notes
11/30/2022	Combined formularies. No changes to clinical criteria

Zolinza

Prior Authorization Guideline

Guideline ID	GL-117476
Guideline Name	Zolinza
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name:Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - Patient has progressive, persistent, or recurrent disease on or following two systemic therapies [e.g., Adcetris (brentuximab vedotin), bexarotene, interferon alfa-db, interferon gamma-1b, methotrexate, Poteligeo (mogamulizumab), romidepsin]

Product Name:Zolinza	
Diagnosis	Cutaneous T-Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zolinza therapy

Product Name:Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zolinza	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zolinza therapy

2 . Revision History

Date	Notes
11/30/2022	Combined formularies. No changes to clinical criteria

Zoryve

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164689
Guideline Name	Zoryve
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - ONE of the following:

2.1 Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

OR

2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

AND

3 - Patient is not receiving Zoryve 0.3% cream in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a dermatologist

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve 0.3% cream in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Product Name:Zoryve foam	
Diagnosis	Seborrheic dermatitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seborrheic dermatitis

AND

2 - ONE of the following:

2.1 Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

OR

2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

3 - Patient is not receiving Zoryve foam in combination with either of the following:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve foam in combination with either of the following:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - ONE of the following:

2.1 For mild atopic dermatitis:

2.1.1 Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.1.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.2 For moderate atopic dermatitis:

2.2.1 Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

AND

3 - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

2 . Revision History

Date	Notes
2/5/2025	Updated cream product names to specify strengths. Updated all auth orizations to 12 months. Updated targeted immunomodulator langua ge. Removed prescriber requirements for Zoryve foam initial auth. Ad ded criteria for Zoryve 0.15% cream for atopic dermatitis.

Zoryve

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164689
Guideline Name	Zoryve
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New Mexico Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - ONE of the following:

2.1 Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

OR

2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Corticosteroids (e.g., betamethasone, clobetasol, desonide)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

AND

3 - Patient is not receiving Zoryve 0.3% cream in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

AND

4 - Prescribed by, or in consultation with, a dermatologist

Product Name:Zoryve 0.3% cream	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve 0.3% cream in combination with a Targeted Immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, ustekinumab, Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Product Name:Zoryve foam	
Diagnosis	Seborrheic dermatitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seborrheic dermatitis

AND

2 - ONE of the following:

2.1 Submission of medical records or claims history confirming failure to a minimum duration of a 4-week trial to TWO of the following topical therapies:

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

OR

2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

Topical corticosteroids (e.g., betamethasone, hydrocortisone)

Topical, shampoo, or systemic antifungals (e.g., ketoconazole, ciclopirox, itraconazole)

Topical calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

AND

3 - Patient is not receiving Zoryve foam in combination with either of the following:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Product Name:Zoryve foam	
Diagnosis	Seborrheic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve foam in combination with either of the following:

Biologic immunomodulator [e.g., Dupixent (dupilumab), Adbry (tralokinumab-ldrm)]

Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate atopic dermatitis

AND

2 - ONE of the following:

2.1 For mild atopic dermatitis:

2.1.1 Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.1.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid [e.g., DesOwen (desonide), hydrocortisone] (any potency)

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.2 For moderate atopic dermatitis:

2.2.1 Submission of medical records or claims history confirming failure to TWO of the following topical therapeutic classes:

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

OR

2.2.2 History of intolerance or contraindication to ALL of the following topical therapies (please specify intolerance or contraindication):

A topical corticosteroid of at least a medium- to high-potency [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

Eucrisa (crisaborole)

AND

3 - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

Product Name:Zoryve 0.15% cream	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Patient is not receiving Zoryve 0.15% cream in combination with a targeted immunomodulator [e.g., Adbry (tralokinumab-ldrm), Cibinqo (abrocitinib), Dupixent (dupilumab), Rinvoq (upadacitinib)]

2 . Revision History

Date	Notes
2/5/2025	Updated cream product names to specify strengths. Updated all auth orizations to 12 months. Updated targeted immunomodulator langua ge. Removed prescriber requirements for Zoryve foam initial auth. Ad ded criteria for Zoryve 0.15% cream for atopic dermatitis.

Zurzuvae

Prior Authorization Guideline

Guideline ID	GL-164996
Guideline Name	Zurzuvae
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Nebraska Medicaid - Community & State Washington

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Zurzuvae	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of postpartum depression (PPD) **AND** **2** - Onset of current depressive episode was during the third trimester or within 4 weeks postpartum

2 . Revision History

Date	Notes
2/11/2025	Updated formularies. No changes to clinical criteria.

Zydelig

Prior Authorization Guideline

Guideline ID	GL-159292
Guideline Name	Zydelig
Formulary	Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island Medicaid - Community & State Colorado

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Zydelig	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL)

AND

2 - ONE of the following:

Disease has relapsed

Disease is refractory

Product Name:Zydelig	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zydelig therapy

Product Name:Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zydelig	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to Zydelig therapy	

2 . Revision History

Date	Notes
11/5/2024	Updated CO cag to SP

Zykadia

Prior Authorization Guideline

Guideline ID	GL-145969
Guideline Name	Zykadia
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

Disease is metastatic

Disease is recurrent

Disease is advanced

AND

3 - ONE of the following:

Tumor is ALK (anaplastic lymphoma kinase)-positive

Tumor is ROS-1 (gene) positive

Product Name:Zykadia	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name:Zykadia	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Zykadia	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester Disease

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement

Product Name:Zykadia	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, metastatic, or inoperable inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) translocation

Product Name:Zykadia	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

AND

4 - Used as palliative intent therapy or second-line and subsequent therapy

Product Name:Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma, Central Nervous System (CNS) Cancers, Histiocytic Neoplasms, Inflammatory Myofibroblastic Tumor (IMT), Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name:Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Zykadia therapy

2 . Revision History

Date	Notes
4/22/2024	Added coverage criteria for inoperable inflammatory myofibroblastic t umor and anaplastic large cell lymphoma per NCCN. Corrected Erdh eim-Chester Disease spelling.

Zykadia

Prior Authorization Guideline

Guideline ID	GL-145969
Guideline Name	Zykadia
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	5/1/2024

1 . Criteria

Product Name:Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - ONE of the following:

Disease is metastatic

Disease is recurrent

Disease is advanced

AND

3 - ONE of the following:

Tumor is ALK (anaplastic lymphoma kinase)-positive

Tumor is ROS-1 (gene) positive

Product Name:Zykadia	
Diagnosis	Soft Tissue Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT) with anaplastic lymphoma kinase (ALK) translocation

Product Name:Zykadia	
Diagnosis	Central Nervous System (CNS) Cancers
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic brain cancer from non-small cell lung cancer (NSCLC)

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

Product Name:Zykadia	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Erdheim-Chester Disease

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) rearrangement

Product Name:Zykadia	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced, recurrent, metastatic, or inoperable inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is positive for anaplastic lymphoma kinase (ALK) translocation

Product Name:Zykadia	
Diagnosis	Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma

AND

2 - Tumor is anaplastic lymphoma kinase (ALK)-positive

AND

3 - Disease is relapsed or refractory

AND

4 - Used as palliative intent therapy or second-line and subsequent therapy

Product Name:Zykadia	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Soft Tissue Sarcoma, Central Nervous System (CNS) Cancers, Histiocytic Neoplasms, Inflammatory Myofibroblastic Tumor (IMT), Anaplastic Large Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zykadia therapy

Product Name:Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Product Name:Zykadia	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to Zykadia therapy

2 . Revision History

Date	Notes
4/22/2024	Added coverage criteria for inoperable inflammatory myofibroblastic t umor and anaplastic large cell lymphoma per NCCN. Corrected Erdh eim-Chester Disease spelling.

Zymfentra

Prior Authorization Guideline

Guideline ID	GL-163904
Guideline Name	Zymfentra
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

3 - One of the following:

3.1 Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

3.2 Patient is currently on Zymfentra therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zymfentra therapy

AND

2 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

Product Name:Zymfentra	
Diagnosis	Crohn’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active Crohn’s disease (CD)

AND

3 - One of the following:

3.1 Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active crohn's disease

OR

3.2 Patient is currently on Zymfentra therapy for moderately to severely active crohn's disease as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Zymfentra	
Diagnosis	Crohn's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zymfentra therapy

AND **2** - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

2 . Revision History

Date	Notes
1/16/2025	Added requirement for justification of subq infliximab vs IV

Zymfentra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163904
Guideline Name	Zymfentra
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	2/1/2025

1 . Criteria

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active ulcerative colitis (UC)

AND

3 - One of the following:

3.1 Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active ulcerative colitis

OR

3.2 Patient is currently on Zymfentra therapy for moderately to severely active ulcerative colitis as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Zymfentra	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zymfentra therapy

AND

2 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

Product Name:Zymfentra	
Diagnosis	Crohn’s disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting clinical rationale for need of subcutaneous infliximab (Zymfentra) in place of infliximab administered intravenously (covered under the medical benefit)

AND

2 - Diagnosis of moderately to severely active Crohn’s disease (CD)

AND

3 - One of the following:

3.1 Patient has been established on therapy with an infliximab product under an active UnitedHealthcare prior authorization for the treatment of moderately to severely active crohn's disease

OR

3.2 Patient is currently on Zymfentra therapy for moderately to severely active crohn's disease as confirmed by claims history or submission of medical records

AND

4 - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name:Zymfentra	
Diagnosis	Crohn's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zymfentra therapy

AND **2** - Patient is not receiving Zymfentra in combination with a targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Stelara (ustekinumab), Xeljanz (tofacitinib)]

2 . Revision History

Date	Notes
1/16/2025	Added requirement for justification of subq infliximab vs IV

Zytiga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150946
Guideline Name	Zytiga
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York EPP Medicaid - Community & State New York Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	8/5/2024

1 . Criteria

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prostate cancer

AND

2 - ONE of the following:

2.1 Disease is metastatic

OR

2.2 Disease is regional node positive (Any T, N1, M0)

OR

2.3 Patient is in a very-high-risk group receiving external beam radiation therapy (EBRT)

OR

2.4 Positive pelvic persistence/recurrence after prostatectomy

AND

3 - Used in combination with prednisone or dexamethasone

AND

4 - ONE of the following:

4.1 Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

OR

4.2 Patient has had bilateral orchiectomy

AND

5 - If the request is for the 500 mg (milligram) tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on the requested therapy

AND

2 - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of salivary gland tumor

AND

2 - Used in combination with prednisone

AND

3 - Androgen receptor positive recurrent disease

AND

4 - If the request is for the 500mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250mg

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	Salivary Gland Tumor
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Zytiga therapy

AND

2 - If the request is for the 500mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250mg

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

AND

2 - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

Product Name:Brand Zytiga, generic abiraterone	
Diagnosis	NCCN Recommended Regimens
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Zytiga therapy

AND

2 - If the request is for the 500 mg tablet, the prescriber provides a reason or special circumstance the patient cannot take abiraterone 250 mg

2 . Revision History

Date	Notes
8/5/2024	Added criteria for salivary gland tumor per NCCN

Zyvox

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124794
Guideline Name	Zyvox
Formulary	Medicaid - Community & State Colorado Medicaid - Community & State Hawaii Medicaid - Community & State Maryland Medicaid - Community & State New Jersey Medicaid - Community & State New York Medicaid - Community & State New York EPP Medicaid - Community & State Pennsylvania CHIP Medicaid - Community & State Rhode Island

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Zyvox, generic linezolid	
Guideline Type	Prior Authorization
Approval Criteria **1** - For continuation of therapy upon hospital discharge	

OR

2 - As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

OR

3 - ONE of the following diagnoses:

Nosocomial pneumonia

Community-acquired pneumonia

Skin and skin structure infections (complicated and uncomplicated)

OR

4 - Invasive infection caused by or likely to be caused by vancomycin-resistant Enterococcus faecium (VRE)

OR

5 - The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA)

Notes	Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals are for 14 days.