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ACE Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144369
Guideline Name	ACE Inhibitors
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Brand Epaned, generic enalapril oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is under 12 years of age

OR

2 - Patient is unable to swallow tablets

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

Approval Criteria

1 - Patient is 6 years of age or older AND less than 12 years of age

OR

2 - Patient is unable to swallow tablets

2 . Revision History

Date	Notes
3/14/2024	Separated criteria for Qbrelis

Acne Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-163148
Guideline Name	Acne Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/10/2025

1 . Criteria

Product Name:Brand Absorica, Aklief, Amnesteem, Claravis, generic isotretinoin, Myorisan, Zenatane, adapalene/benzoyl peroxide, Epiduo, Epiduo Forte, benzoyl peroxide (all formulations and brands), Panoxyl, Benzac AC, Medpura, Benzepro, PR Benzoyl Peroxide, Effaclar Duo, Epsolay, Benzefoam, Zaclir, Benzepro Foaming Cloths, Brand Retin-A, generic tretinoin, Brand Atralin, Altreno, Brand Retin-A Micro and pump, generic tretinoin microsphere and pump, clindamycin/tretinoin, Veltin, Ziana, clindamycin soln/swab, generic clindamycin foam/gel/lotn, Clindacin, Brand Clindagel, Brand Cleocin-T, Clindacin ETZ, Clindacin-P, Cabtreo, clindamycin/benzoyl peroxide, Acanya, Onexton, Benzamycin, erythromycin/benzoyl peroxide, Brand Aczone, generic dapsone, erythromycin soln, generic erythromycin gel, Brand Erygel, Ery, Ovace, generic sodium sulfacetamide, Plexion NS, sodium sulfacetamide/sulfur (all formulations and brands), Sumadan, Plexion, Avar, Sulfacleanse, Clenia Plus, SSS, Sumaxin, Brand Klaron, Lintera, Brand Evoclin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 25 years of age or under

OR

1.2 BOTH of the following:

1.2.1 Patient is 26 years of age or older

AND

1.2.2 Patient has tried and failed therapy with an OTC (over-the-counter) acne product

AND

2 - If the request is non-preferred*, the patient must have had a 14-day trial each of at least 2 preferred* medications

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

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

Approval Criteria

1 - ONE of the following:

1.1 Patient is 25 years of age or under

OR

1.2 BOTH of the following:

1.2.1 Patient is 26 years of age or older

AND

1.2.2 Patient has tried and failed therapy with an OTC (over-the-counter) acne product

AND

2 - BOTH of the following:

2.1 The patient must have trial and failure of concomitant use of individual components for at least 30 days

AND

2.2 There is rationale for use of requested medication over separate individual components

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

Approval Criteria

1 - ONE of the following:

1.1 Patient is 25 years of age or under and has tried a preferred topical tretinoin product*

OR

1.2 Patient is 26 years of age or older and BOTH of the following: **1.2.1** Patient has tried and failed therapy with an OTC (over-the-counter) acne product **AND** **1.2.2** Patient has tried a preferred topical tretinoin product* **AND** **2** - If the request is non-preferred*, the patient must have had a 14-day trial each of at least 2 preferred* medications	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
1/6/2025	Added Aklief and Twyneo

Actimmune

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127783
Guideline Name	Actimmune
Formulary	• Medicaid - Community & State Indiana

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

Aemcolo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-106361
Guideline Name	Aemcolo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2022

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)

Afinitor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155817
Guideline Name	Afinitor
Formulary	• Medicaid - Community & State Indiana

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

Agents for the Treatment of Opioid Use Disorder

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148949
Guideline Name	Agents for the Treatment of Opioid Use Disorder
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Buprenorphine sublingual tablet, Zubsolv, buprenorphine/naloxone sublingual tablet, Brand Suboxone, generic buprenorphine/naloxone sublingual film	
Diagnosis	Age Limit Exception*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been

tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the patient is outside of FDA (Food and Drug Administration)-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e. clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - Both of the following:

2.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 One of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient
- The request is for continuation of therapy from another plan or following inpatient therapy

AND

3.3 One of the following:

3.3.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

OR

3.3.2 The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits

AND

3.4 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	*This criteria comes from the Non-Drug Specific PA policy

Product Name:Buprenorphine sublingual tablet, Zubsolv, buprenorphine/naloxone sublingual tablet, Brand Suboxone, generic buprenorphine/naloxone sublingual film	
Diagnosis	Non-Preferred*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is for a non-preferred medication**, one of the following:

1.1 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

1.2 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	*This criteria comes from the Non-Preferred Drugs Policy **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

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

Approval Criteria

1 - The patient is 18 years of age or older

AND

2 - One of the following:

2.1 Both of the following:

- Previous trial and failure of ONE preferred* oral formulation agent for opioid use disorder for a minimum of 7 days
- Previous trial and failure of Sublocade (buprenorphine)

OR

2.2 Prescriber has provided medical rationale for use of Brixadi (buprenorphine) over all oral formulation agents for opioid use disorder AND Sublocade (buprenorphine)

AND

3 - One of the following:

3.1 Request is for Brixadi (buprenorphine) weekly and weekly dose does not exceed a total of 32 mg/week

OR

3.2 Request is for Brixadi (buprenorphine) monthly and monthly dose does not exceed a total of 128 mg/month

AND

4 - The patient is not using other injectable products (e.g., Sublocade) for opioid use disorder concurrently

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

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

Approval Criteria

1 - One of the following:

1.1 Request is for Brixadi (buprenorphine) weekly and all of the following:

1.1.1 History of the request agent for 14 days of the past 21 days, confirmed by claims history or chart documentation

AND

1.1.2 Weekly dose does not exceed a total of 32 mg/week

OR

1.2 Request is for Brixadi (buprenorphine) monthly and all of the following:

1.2.1 History of the requested agent in the past 45 days, confirmed by claims history or chart documentation

AND

1.2.2 Monthly dose does not exceed a total of 128 mg/month

AND

2 - The patient is not using other injectable products (e.g., Sublocade) for opioid use disorder concurrently

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

Approval Criteria

1 - The patient is 18 years of age or older

AND

2 - One of the following:

- Previous trial of ONE preferred* oral formulation agent for opioid use disorder for a minimum of 7 days

- Prescriber has provided medical rationale for use of Sublocade (buprenorphine) over all oral formulation agents for opioid use disorder

AND

3 - Dose requested does not exceed the following:

- 300 mg/month during initiation phase x 2 months
- 100 mg/month during maintenance phase

AND

4 - The patient is not using other injectable products (e.g., Brixadi) for opioid use disorder concurrently

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

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

Approval Criteria

1 - History of the requested agent in the past 45 days, confirmed by claims history or chart documentation

AND

2 - Dose requested does not exceed the following:

- 300 mg/month during initiation phase x 2 months
- 100 mg/month during maintenance phase

AND **3** - The patient is not using other injectable products (e.g., Brixadi) for opioid use disorder concurrently

2 . Revision History

Date	Notes
6/28/2024	Updated Brixadi dosing limits.

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-151764
Guideline Name	Alecensa
Formulary	• Medicaid - Community & State Indiana

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
8/14/2024	Added criteria for adjuvant treatment following tumor resection of ALK-positive NSCLC per FDA label. Updated references.

Allergy-Specific Immunotherapy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154716
Guideline Name	Allergy-Specific Immunotherapy
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

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

Approval Criteria

1 - Diagnosis of grass-pollen induced allergic rhinitis

AND

2 - Documentation of a positive skin test or in vitro test for Timothy Grass or cross-reactive grass pollens

AND

3 - Patient must be at least 5 years of age and no more than 65 years of age

AND

4 - Prescribed by, or in consultation with, an allergist or immunologist

AND

5 - ONE of the following:

5.1 Previous trial and failure (inadequate response) to at least 90 days of drug therapy with ALL of the following:

- Intranasal corticosteroid
- Leukotriene inhibitor
- Antihistamine agent

OR

5.2 Prescriber has provided documentation of contraindication to or intolerance of intranasal corticosteroids, leukotriene inhibitors, and/or antihistamine agents

AND

6 - ONE of the following:

6.1 Previous trial and failure of injectable immunotherapy (allergy shots)

OR

6.2 Prescriber has provided documentation of contraindication to injectable immunotherapy

AND

7 - The patient does NOT have any of the following contraindications:

- Severe, unstable, or uncontrolled asthma
- Current oral inflammation or wound from previous pollen-specific sublingual immunotherapy

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

Approval Criteria

1 - Diagnosis of house dust mite-induced allergic rhinitis

AND

2 - Documentation of a positive skin test or in vitro test for IgE (immunoglobulin E) antibodies to house dust mites (dermatophagoides farinae or dermatophagoides pteronyssinus)

AND

3 - Patient must be at least 12 years of age and no more than 65 years of age

AND

4 - Prescribed by, or in consultation with, an allergist or immunologist

AND

5 - ONE of the following:

5.1 Previous trial and failure (inadequate response) to at least 90 days of drug therapy with ALL of the following: intranasal corticosteroid, leukotriene inhibitor, antihistamine agent

- Intranasal corticosteroid
- Leukotriene inhibitor
- Antihistamine agent

OR

5.2 Prescriber has provided documentation of contraindication to or intolerance of intranasal corticosteroids, leukotriene inhibitors, and/or antihistamine agents

AND

6 - ONE of the following:

6.1 Previous trial and failure of injectable immunotherapy (allergy shots)

OR

6.2 Prescriber has provided documentation of contraindication to injectable immunotherapy

AND

7 - The patient does NOT have any of the following contraindications:

- Severe, unstable, or uncontrolled asthma
- Current oral inflammation or wound from previous pollen-specific sublingual immunotherapy

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

Approval Criteria

1 - Diagnosis of grass pollen-induced allergic rhinitis

AND

2 - Documentation of a positive skin test or in vitro test for any of the five grass species: Sweet Vernal, Orchard, Perennial Rye, Timothy or Kentucky Blue Grass

AND

3 - Patient must be at least 5 years of age and no more than 65 years of age

AND

4 - Prescribed by, or in consultation with, an allergist or immunologist

AND

5 - ONE of the following:

5.1 Previous trial and failure (inadequate response) to at least 90 days of drug therapy with ALL of the following:

- Intranasal corticosteroid
- Leukotriene inhibitor
- Antihistamine agent

OR

5.2 Prescriber has provided documentation of contraindication to or intolerance of intranasal corticosteroids, leukotriene inhibitors, and/or antihistamine agents

AND

6 - ONE of the following:

6.1 Previous trial and failure of injectable immunotherapy (allergy shots)

OR

6.2 Prescriber has provided documentation of contraindication to injectable immunotherapy

AND

7 - The patient does NOT have any of the following contraindications:

- Severe, unstable, or uncontrolled asthma
- Current oral inflammation or wound from previous pollen-specific sublingual immunotherapy

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

Approval Criteria

1 - Diagnosis of peanut allergy

AND

2 - Patient is at least 1 years of age and no more than 17 years of age

AND

3 - Prescribed by, or in consultation with, an allergist or immunologist

AND

4 - The patient does NOT have any of the following contraindications:

- Severe, unstable, or uncontrolled asthma
- Severe or life-threatening anaphylaxis reaction in the past 60 days
- History of eosinophilic esophagitis or other eosinophilic GI (gastrointestinal) disease

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

Approval Criteria

1 - Diagnosis of short ragweed pollen-induced allergic rhinitis

AND

2 - Documentation of a positive skin test or in vitro test for short ragweed pollen

AND

3 - Patient is at least 5 years of age and no more than 65 years of age

AND

4 - Prescribed by, or in consultation with, an allergist or immunologist

AND

5 - ONE of the following:

5.1 Previous trial and failure (inadequate response) to at least 90 days of drug therapy with ALL of the following:

- Intranasal corticosteroid
- Leukotriene inhibitor
- Antihistamine agent

OR

5.2 Prescriber has provided documentation of contraindication to or intolerance of intranasal corticosteroids, leukotriene inhibitors, and/or antihistamine agents

AND

6 - ONE of the following:

6.1 Previous trial and failure of injectable immunotherapy (allergy shots)

OR

6.2 Prescriber has provided documentation of contraindication to injectable immunotherapy

AND

7 - The patient does NOT have any of the following contraindications:

- Severe, unstable, or uncontrolled asthma
- Current oral inflammation or wound from previous pollen-specific sublingual immunotherapy

Product Name:Grastek, Odactra, Oralair, Palforzia, Ragwitek	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - History of the requested medication within the past 90 days	

2 . Revision History

Date	Notes
9/10/2024	Changed min. age of Palforzia.

Alunbrig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161363
Guideline Name	Alunbrig
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/27/2024	Added Anaplastic Large Cell Lymphoma.

Angiotensin Receptor Blocker Combinations

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124995
Guideline Name	Angiotensin Receptor Blocker Combinations
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:telmisartan/amlodipine, Brand Exforge, generic amlodipine/valsartan, Brand Exforge HCT, generic amlodipine/valsartan/hydrochlorothiazide, Brand Tribenzor, generic olmesartan/amlodipine/hydrochlorothiazide, Brand Azor, generic amlodipine/olmesartan	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Trial and failure of the individual components	

2 . Revision History

Date	Notes
4/25/2023	New

Angiotensin Receptor Blockers (ARBs)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150102
Guideline Name	Angiotensin Receptor Blockers (ARBs)
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Valsartan oral solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is unable to swallow tablets	

2 . Revision History

Date	Notes
7/22/2024	Removed age limits

Antiemetic, Antivertigo Agents

Prior Authorization Guideline

Guideline ID	GL-124875
Guideline Name	Antiemetic, Antivertigo Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Sancuso	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation indicating oral medications are unsuitable for patient use	

Product Name:Emend suspension	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried Emend oral capsules

OR

2 - Patient is unable to swallow or tolerate the capsule formulation

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

Approval Criteria

1 - Patient has tried and failed combination therapy with preferred* agents of the same classes

OR

2 - Medical justification for use

Notes	* PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
4/20/2023	New

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125088
Guideline Name	Antihistamine-Decongestant Combinations - 2nd Generation Antihistamines
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:levocetirizine soln, Xyzal soln	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient had a trial of ONE of the following:

- loratadine solution
- cetirizine syrup

2 . Revision History

Date	Notes
4/27/2023	New guideline

Antimicrobials for Treatment of Vaginal Infections

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132649
Guideline Name	Antimicrobials for Treatment of Vaginal Infections
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Brexafemme	
Approval Length	30 days for acute infection. 6 months for recurrent infection
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of acute vulvovaginal candidiasis and the request does not exceed 4 tablets per treatment course

OR

1.2 Diagnosis of recurrent vulvovaginal candidiasis (defined as 3 or more episodes of vulvovaginal candidiasis within a year) and the request does not exceed 24 tablets per treatment course

AND

2 - ONE of the following:

2.1 Patient is 18 years of age or older

OR

2.2 Patient is less than 18 years of age AND provider attests member is postmenarchal

AND

3 - For those of childbearing potential, documentation of a negative pregnancy test within the past 30 days

AND

4 - ONE of the following:

4.1 Patient has tried and failed oral fluconazole within the past year

OR

4.2 Provider has submitted medical rationale supporting the use of Brexafemme over oral fluconazole

Product Name:Vivjoa	
Approval Length	12 Week(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent vulvovaginal candidiasis (defined as 3 or more episodes of vulvovaginal candidiasis within a year)

AND

2 - Patient is 18 years of age or older

AND

3 - Provider attests patient is not considered to be of reproductive potential

AND

4 - ONE of the following:

4.1 Patient has tried and failed oral fluconazole within the past year

OR

4.2 Provider has submitted medical rationale supporting the use of Vivjoa over oral fluconazole

AND

5 - Request does not exceed 18 tablets per treatment course

2 . Revision History

Date	Notes

9/6/2023	Clarified pregnancy requirement for Brexafemme only include those of childbearing potential

Antimigraine Agents

Prior Authorization Guideline

Guideline ID	GL-155047
Guideline Name	Antimigraine Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Aimovig	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring prophylaxis

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Previous trial and failure of an agent listed within ONE of the following categories:

- antiseizure agents (topiramate)
- beta-blockers (metoprolol, propranolol, or timolol)
- tricyclic antidepressants (amitriptyline or nortriptyline)
- valproic acid and derivatives (divalproex or valproic acid)

OR

3.2 Documented intolerance or contraindication to ALL of the following:

- amitriptyline
- nortriptyline
- divalproex
- valproate
- topiramate
- metoprolol
- propranolol
- timolol

Product Name:Aimovig	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Aimovig for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

Product Name:Ajovy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring prophylaxis

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Previous trial and failure of an agent listed within ONE of the following categories:

- antiseizure agents (topiramate)
- beta-blockers (metoprolol, propranolol, or timolol)
- tricyclic antidepressants (amitriptyline or nortriptyline)
- valproic acid and derivatives (divalproex or valproic acid)

OR

3.2 Documented intolerance or contraindication to ALL of the following:

- amitriptyline
- nortriptyline
- divalproex
- valproate
- topiramate
- metoprolol
- propranolol
- timolol

Product Name:Ajovy	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Ajovy for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

Product Name:Emgality	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of migraine with or without aura requiring prophylaxis

AND

1.2 Patient is 18 years of age or older

AND

1.3 One of the following:

1.3.1 Previous trial and failure of an agent listed within ONE of the following categories:

- antiseizure agents (topiramate)
- beta-blockers (metoprolol, propranolol, or timolol)
- tricyclic antidepressants (amitriptyline or nortriptyline)

- valproic acid and derivatives (divalproex or valproic acid)

OR

1.3.2 Documented intolerance or contraindication to ALL of the following:

- amitriptyline
- nortriptyline
- divalproex
- valproate
- topiramate
- metoprolol
- propranolol
- timolol

AND

1.4 The requested dose does not exceed 240mg loading dose, then 120mg per month

OR

2 - ALL of the following

2.1 Diagnosis of episodic cluster headache

AND

2.2 Patient is 18 years of age or older

AND

2.3 The requested dose does not exceed 300mg per month for duration of headache

Product Name:Emgality	
Approval Length	1 year(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of Emgality for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Dose requested does not exceed 120mg per month for diagnosis of migraine with or without aura
- Dose requested does not exceed 300mg per month for diagnosis of episodic cluster headache

Product Name:Nurtec ODT*	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of migraine with or without aura requiring acute treatment

AND

1.2 Patient is 18 years of age or older

AND

1.3 ONE of the following:

- Previous trial and failure of one triptan agent
- Medical justification for use over triptan agents

OR

2 - ALL of the following:

2.1 Diagnosis of episodic migraine requiring prophylaxis

AND

2.2 Patient is 18 years of age or older

AND

2.3 ONE of the following:

2.3.1 Greater than or equal to 60 days of therapy with TWO of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

OR

2.3.2 Medical justification for use over ALL of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

Notes	*Nurtec ODT is hard-coded with a quantity of 8 tablets per 26 days. If criteria are met for a diagnosis of episodic migraine requiring prophyla xis, please enter a quality limit override of #16 tablets per 26 days for

	1 year. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Nurtec ODT*	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 There is a previous PA approval for the diagnosis of migraine requiring acute treatment

AND

1.2 History of Nurtec ODT within the past 90 days, confirmed by claims history or chart documentation

AND

1.3 ONE of the following:

- Prior history of at least one triptan agent
- Medical justification for use over triptan agents

OR

2 - All of the following:

2.1 There is a previous PA approval for the diagnosis of episodic migraine requiring prophylaxis

AND

2.2 History of Nurtec ODT for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.3 ONE of the following:

- Prior history of at least one preferred* injectable prophylaxis agent
- Medical justification for use over preferred* injectable prophylaxis agents

Notes	*Nurtec ODT is hard-coded with a quantity of 8 tablets per 26 days. If criteria are met for a diagnosis of episodic migraine requiring prophylaxis, please enter a quality limit override of #16 tablets per 26 days for 1 year. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Qulipta	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of episodic migraine requiring prophylaxis

AND

1.2 Patient is 18 years of age or older

AND

1.3 ONE of the following:

1.3.1 Greater than or equal to 60 days of therapy with TWO of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

OR

1.3.2 Medical justification for use over ALL of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

OR

2 - All of the following:

2.1 Diagnosis of migraine with or without aura requiring prophylaxis

AND

2.2 Patient is 18 years of age or older

AND

2.3 ONE of the following:

2.3.1 Greater than or equal to 60 days of therapy with TWO of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

OR

2.3.2 Medical justification for use over ALL of the following preferred injectable prophylaxis agents:

- Aimovig (erenumab-aooe)
- Ajovy (fremanezumab-vfrm)
- Emgality (galcanezumab-gnlm)

Notes	IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Qulipta	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Qulipta for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Prior history of at least one preferred* injectable prophylaxis agent
- Medical justification for use over preferred* injectable prophylaxis agents

Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Reyvow	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring acute treatment

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

- Previous trial and failure of ALL preferred* acute migraine treatments
- Medical justification for use over ALL preferred* acute migraine treatments

AND

4 - One of the following:

4.1 Dose requested does not exceed 4 tablets per 30 days (50mg tablet or 100mg tablet)

OR

4.2 BOTH of the following:

- Quantity requested does not exceed eight 100mg tablets per 30 days (200mg per dose)
- Patient has previously tried 100mg dose and has provided documented tolerability of 100mg dose (heart rate, concomitant therapies that can decrease heart rate, etc.)

Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Reyvow	
Approval Length	1 year(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Reyvow within the past 90 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Prior history of ALL preferred* acute migraine treatments
- Medical justification for use over ALL preferred* acute migraine treatments

AND

3 - One of the following:

3.1 Dose requested does not exceed 4 tablets per 30 days (50mg tablet or 100mg tablet)

OR

3.2 BOTH of the following:

- Quantity requested does not exceed eight 100mg tablets per 30 days (200mg per dose)
- Member has previously tried 100mg dose and has provided documented tolerability of 100mg dose (heart rate, concomitant therapies that can decrease heart rate, etc.)

Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Ubrelvy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring acute treatment

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

- Previous trial and failure of one triptan agent
- Medical justification for use over triptan agents

Product Name:Ubrelvy	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Ubrelvy within the past 90 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Prior history of at least one triptan agent

• Medical justification for use over triptan agents	
Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Elyxyb	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring acute treatment

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

- Previous trial and failure of one triptan agent
- Medical justification for use over triptan agents

Product Name:Elyxyb	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Elyxyb within the past 90 days, confirmed by claims history or chart documentation

Product Name:Zavzpret	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura requiring acute treatment

AND

2 - Patient is 18 years of age or older

AND

3 - ONE of the following:

- Previous trial and failure of ALL preferred* acute migraine treatments
- Medical justification for use over ALL preferred* acute migraine treatments

Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Zavzpret	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Zavzpret within the past 90 days, confirmed by claims history or chart documentation **AND** **2** - One of the following: • Prior history of ALL preferred* acute migraine treatments • Medical justification for use over ALL preferred* acute migraine treatments	
Notes	*IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
9/17/2024	Updated T/F language on Aimovig, Ajovy, Emgality, Nurtec and Qulipta

Antiseizure Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161925
Guideline Name	Antiseizure Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Briviact tab/soln, Brand Valium tab, Brand Diazepam inj, Brand Onfi tab/susp, generic carbamazepine susp, generic carbamazepine ER cap/tab, Brand Depakote DR/ER tablet, Aptiom, Brand Zarontin caps/soln, generic felbamate tab/soln, Brand Neurontin soln, Brand Gabapentin Tinytabs, generic lacosamide soln, Brand Vimpat tab/soln, Brand Lamictal tab/ODT/starter packs, Brand Lamictal XR, Libervant, Brand Keppra tab/soln, Brand Keppra XR tab, Brand Trileptal tab, Brand Fycompa, Brand Phenytek caps, Brand Mysoline, generic rufinamide tab/susp, Brand Banzel tab/susp, generic tiagabine, Brand Topamax tab, Brand Topamax sprinkle, generic topiramate ER cap (sprinkle), Brand Trokendi XR, Brand Sabril tablets, generic vigabatrin, Vigadrone tablets, Xcopri, Brand Zonegran, Brand Spritam, generic pregabalin	
Diagnosis	Non-Preferred*
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of seizure disorder

AND

1.2 History of a preferred* antiseizure medication for at least 14 days in the past 90 days

OR

2 - For a non-seizure diagnosis ONE of the following:

2.1 History of one preferred* antiseizure medication

OR

2.2 Medical justification for the use of the requested medication over ALL of the preferred* antiseizure medications (e.g., preferred agents do not have FDA-approved or approved compendia indication for member's diagnosis, member has contraindication or intolerance to preferred agents with appropriate indications, etc.)

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

Product Name:Briviact tab/soln, Brand Valium tab, Brand Diazepam inj, Brand Onfi tab/susp, generic carbamazepine susp, generic carbamazepine ER cap/tab, Brand Depakote DR/ER tablet, Aptiom, Brand Zarontin caps/soln, generic felbamate tab/soln, Brand Neurontin soln, Brand Gabapentin Tinytabs, generic lacosamide soln, Brand Vimpat tab/soln, Brand Lamictal tab/ODT/starter packs, Brand Lamictal XR, Libervant, Brand Keppra tab/soln, Brand Keppra XR tab, Brand Trileptal tab, Brand Fycompa, Brand Phenytek caps, Brand Mysoline, generic rufinamide tab/susp, Brand Banzel tab/susp, generic tiagabine, Brand Topamax tab, Brand Topamax sprinkle, generic topiramate ER cap (sprinkle), Brand Trokendi XR, Brand Sabril tablets, generic vigabatrin, Vigadrone tablets, Xcopri, Brand Zonegran, Brand Spritam, generic pregabalin	
Diagnosis	Non-Preferred*
Approval Length	1 year(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of seizure disorder

AND

1.2 History of the requested medication for 30 of the past 60 days confirmed by claims history or chart documentation

OR

2 - For a non-seizure diagnosis BOTH of the following:

2.1 History of the requested medication for 30 of the past 60 days confirmed by claims history or chart documentation

AND

2.2 ONE of the following:

2.2.1 History of one preferred* antiseizure medication

OR

2.2.2 Medical justification for the use of the requested medication over ALL of the preferred* antiseizure medications (e.g., preferred agents do not have FDA-approved or approved compendia indication for member's diagnosis, member has contraindication or intolerance to preferred agents with appropriate indications, etc.)

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

Product Name:Brand Sabril powder packs, Vigadrone powder packs, Vigpoder	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder

AND

2 - Patient has tried and failed generic vigabatrin packets (powder for oral solution) for 90 of the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Prescriber has submitted medical justification for use of the requested medication over generic vigabatrin packets (powder for oral solution)

Product Name:Vigafyde	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder

AND

2 - ONE of the following:

2.1 Patient has tried and failed vigabatrin packets (powder for oral solution) for 90 of the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

2.2 Prescriber has submitted medical justification for use of the requested medication over vigabatrin packets (powder for oral solution)

Product Name:Brand Sabril powder packs, Vigadrone powder packs, Vigpoder. Vigafyde	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder

AND

2 - Patient has history of the requested medication for 30 of the past 60 days, confirmed by claims history or chart documentation

Product Name:Diacomit	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with ONE of the following:

- Dravet Syndrome
- SCN1A (gene) mutation

Product Name:Epidiolex	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with ONE of the following:

- Lennox-Gastaut syndrome
- Dravet syndrome
- Tuberous sclerosis complex (TSC)

OR

2 - BOTH of the following:

2.1 Diagnosis of refractory epilepsy

AND

2.2 ONE of the following:

- Trial and failure of 2 other antiseizure medications
- Medical justification for use of Epidiolex

Product Name:Eprontia	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is less than 18 years of age

OR

1.2 BOTH of the following:

1.2.1 Patient is 18 years of age or older

AND

1.2.2 Rationale justifying use over other oral formulations (e.g., capsule, sprinkle capsules, tablets, etc.)

Product Name:Fintepla	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Diagnosis of seizures associated with of Dravet syndrome

AND

1.2 ONE of the following:

1.2.1 Trial and failure of Epidiolex and Diacomit

OR

1.2.2 Medical justification for use of Fintepla

OR

2 - BOTH of the following:

2.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2.2 ONE of the following:

2.2.1 Trial and failure of Epidiolex

OR

2.2.2 Medical justification for use of Fintepla

Product Name:Zonisade	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is less than 18 years of age

OR

2 - BOTH of the following:

2.1 Patient is 18 years of age or older

AND

2.2 Rationale justifying use over other oral formulations (e.g., capsule)

Product Name:Ztalmy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizure disorder associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

AND

2 - ONE of the following:

2.1 Trial and failure of at least 2 other medications (e.g., clobazam, levetiracetam, valproic acid, vigabatrin)

OR

2.2 Medical justification for use of Ztalmy

Product Name:Diacomit, Epidiolex, Fintepla, Ztalmy	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for 30 of the past 60 days confirmed by claims history or chart documentation

Product Name:Eprontia, Zonisade	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for 30 of the past 60 days confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Patient is less than 18 years of age

OR

2.2 BOTH of the following:

2.2.1 Patient is 18 years of age or older

AND

2.2.2 Rationale justifying use over other oral formulations (e.g., capsule, sprinkle capsules, tablets, etc.)

2 . Revision History

Date	Notes
12/12/2024	Added Libervant, Vigadrone tabs, Vigpoder and Vigafyde, Xcopri. Clarified heading of second criteria box and added PDL link. Added specific criteria for brand Sabril powder packets, Vigadrone, Vigpoder and Vigafyde. Corrected spelling of Gastaut in Fintepla initial auth section.

Antiulcer Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137617
Guideline Name	Antiulcer Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Brand Carafate suspension	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is 1 year of age or older

AND

1.2 Patient is less than 12 years of age **OR** **2** - Patient is unable to swallow tablets

2 . Revision History

Date	Notes
12/11/2023	Updated guideline name and criteria.

Antiviral Monoclonal Antibodies

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156483
Guideline Name	Antiviral Monoclonal Antibodies
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Synagis*	
Diagnosis	Patients less than 12 months of age at start of RSV season
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient was born before 29 weeks, 0 days' gestation

OR

1.2 BOTH of the following:

- Patient was born before 32 weeks, 0 days' gestation
- Patient has chronic lung disease (CLD) necessitating more than 21% oxygen for at least the first 28 days of life

OR

1.3 Patient has hemodynamically significant heart disease (e.g., acyanotic heart disease receiving medication to control congestive heart failure [CHF] and will require cardiac surgical procedures, or those with moderate to severe pulmonary hypertension)

OR

1.4 Patient has congenital airway abnormality or neuromuscular disease that impairs the ability to clear secretions

OR

1.5 Patient has cystic fibrosis with clinical evidence of CLD and/or nutritional compromise

OR

1.6 The patient is or will be considered to be profoundly immunocompromised (Submission of chart notes or medical records that explicitly state how the member is or will be considered to be profoundly immunocompromised during the RSV season is required), including members undergoing cardiac transplantation during current RSV season

OR

1.7 BOTH of the following:

- Patient was born before 32 weeks, 0 days' gestation
- Patient required at least 28 days of supplemental oxygen after birth and continued to require supplemental oxygen, chronic systemic corticosteroid therapy, diuretic, or bronchodilator therapy within 6 months of the start of the second RSV season

OR **1.8** Patient has cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length less than 10th percentile **AND** **2** - Prescriber has provided medical justification for the use of Synagis (palivizumab) over Beyfortus (nirsevimab) (Please document) **AND** **3** - Patient has not received Beyfortus (nirsevimas) within the same RSV season **AND** **4** - The number of doses requested do not exceed a maximum quantity of 5 per season **AND** **5** - Administered during RSV season **AND** **6** - The patient is not hospitalized for RSV disease

Notes	*Approval duration will be up to a maximum of 5 doses or through the end of the defined RSV season, whichever comes first.

Product Name:Synagis*	
Diagnosis	Patients less than 24 months of age at start of RSV season
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 The patient is or will be considered to be profoundly immunocompromised (Submission of chart notes or medical records that explicitly state how the member is or will be considered to be profoundly immunocompromised during the RSV season is required), including members undergoing cardiac transplantation during current RSV season

OR

1.2 BOTH of the following:

- Patient was born before 32 weeks, 0 days' gestation
- Patient required at least 28 days of supplemental oxygen after birth and continued to require supplemental oxygen, chronic systemic corticosteroid therapy, diuretic, or bronchodilator therapy within 6 months of the start of the second RSV season

OR

1.3 Patient has cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length less than 10th percentile

AND

2 - Prescriber has provided medical justification for the use of Synagis (palivizumab) over Beyfortus (nirsevimab) (Please document)

AND

3 - Patient has not received Beyfortus (nirsevimas) within the same RSV season

AND

4 - The number of doses requested do not exceed a maximum quantity of 5 per season

AND **5** - Administered during RSV season **AND** **6** - The patient is not hospitalized for RSV disease	
Notes	*Approval duration will be up to a maximum of 5 doses or through the end of the defined RSV season, whichever comes first.

2 . Revision History

Date	Notes
9/30/2024	Removed URL referencing RSV seasons.

Antivirals - Anti-herpetic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154699
Guideline Name	Antivirals - Anti-herpetic
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient has a diagnosis of HIV

OR

2 - Patient has tried and failed acyclovir

OR **3** - Medical justification for use over acyclovir

2 . Revision History

Date	Notes
9/10/2024	Added "for use over acyclovir" to medical justification step

Antivirals, Influenza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125099
Guideline Name	Antivirals, Influenza
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

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

Approval Criteria

1 - One of the following:

1.1 Patient is under 60 years of age and one of the following*:

1.1.1 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** **1.1.2** 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 **OR** **1.2** Patient is 60 years of age and older	
Notes	*This criteria comes from the Non-Preferred Drugs Policy. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
4/27/2023	New guideline

Apokyn

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127856
Guideline Name	Apokyn
Formulary	• Medicaid - Community & State Indiana

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

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

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

Arikayce

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123310
Guideline Name	Arikayce
Formulary	• Medicaid - Community & State Indiana

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	Copy NY

Augtyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155870
Guideline Name	Augtyro
Formulary	• Medicaid - Community & State Indiana

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.

Ayvakit

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156204
Guideline Name	Ayvakit
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/25/2024	Updated wording of systemic mastocytosis criteria per NCCN without change to clinical intent.

Balversa

Prior Authorization Guideline

Guideline ID	GL-151777
Guideline Name	Balversa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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

8/14/2024	emoved coverage for FGFR2 genetic alterations. Added that first line of prior systemic therapy should contain an immune checkpoint inhib itor, if eligible.

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

Prior Authorization Guideline

Guideline ID	GL-128544
Guideline Name	Benlysta
Formulary	• Medicaid - Community & State Indiana

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
7/24/2023	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.

Berinert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150091
Guideline Name	Berinert
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

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
7/22/2024	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-164568
Guideline Name	Besremi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	New program

Beta Adrenergic and Anticholinergic Combinations

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132758
Guideline Name	Beta Adrenergic and Anticholinergic Combinations
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Spiriva Respimat 1.25 mcg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of asthma	

Product Name:Spiriva Respimat 2.5 mcg	
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Trial and failure of Spiriva Handihaler for at least 14 days	

2 . Revision History

Date	Notes
9/11/2023	New GL

Beta Adrenergic Blockers

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144411
Guideline Name	Beta Adrenergic Blockers
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Hemangeol	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 5 weeks of age or older AND less than or equal to 1 year of age	

Product Name:Sotylize	
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following: **1.1** Patient is under 12 years of age **OR** **1.2** Patient is unable to swallow tablets/capsules	

2 . Revision History

Date	Notes
3/14/2024	Updated guideline name. Separated Hemangeol criteria.

Beta Adrenergics and Corticosteroids

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144247
Guideline Name	Beta Adrenergics and Corticosteroids
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Trelegy Ellipta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - All of the following:

1.1 Diagnosis of Asthma

AND

1.2 Patient has tried and failed Advair or Symbicort therapy for at least 90 of the past 120 days

OR

2 - All of the following:

2.1 Diagnosis of COPD

AND

2.2 Patient has tried and failed Anoro Ellipta therapy for at least 90 of the past 120 days

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

Approval Criteria

1 - Patient has tried and failed Trelegy Ellipta

OR

2 - Patient has contraindication or intolerance to use of Trelegy Ellipta

Product Name:fluticasone/salmeterol (generic Airduo Respiclick)	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial of at least 90 days of therapy with Airduo Respiclick

2 . Revision History

Date	Notes
3/13/2024	Removed Advair HFA 230/21 (fluticasone/salmeterol) and Advair Dis kus 500/50 (fluticasone/salmeterol)

Beta-Agonists - Short Acting

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125103
Guideline Name	Beta-Agonists - Short Acting
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Xopenex HFA	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried albuterol HFA in the past 90 days	

2 . Revision History

Date	Notes
4/27/2023	New

Biltricide

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82070
Guideline Name	Biltricide
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Bone Formation Stimulating Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-149099
Guideline Name	Bone Formation Stimulating Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Evenity	
Approval Length	1 Year*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient has experienced menopause and is currently post-menopausal

AND

3 - Diagnosis of osteoporosis

AND

4 - ONE of the following:

- Trial and failure of bisphosphonate
- Documentation of a medical rationale against use of bisphosphonate
- Patient has been determined to be a high-risk patient as demonstrated by the World Health Organization (WHO) Fracture Risk Assessment Model

AND

5 - ONE of the following:

- Previous trial and failure of Forteo (teriparatide)
- Documentation of a medical rationale for use over Forteo (teriparatide)

AND

6 - Prescriber attests that the patient does NOT have any of the following conditions:

- Myocardial infarction or stroke within the previous year
- Osteonecrosis of the jaw
- Pre-existing hypocalcemia

Notes	*Up to 1 year approval duration; approval duration should not exceed t he maximum allowable lifetime duration of 1 year (12 monthly doses) of total therapy with Evenity. **PDL Link: https://www.uhcprovider.com /en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Evenity

Approval Length	1 Year*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Evenity (romosozumab) for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Prescriber attests that the patient remains a candidate for treatment, by indicating that they have NOT developed any of the following conditions:

- Myocardial infarction or stroke within the previous year
- Osteonecrosis of the jaw
- Pre-existing hypocalcemia

AND

3 - ONE of the following*:

3.1 Total length of therapy has not exceeded 1 year

OR

3.2 Documentation of a medical rationale for continued use beyond 1 year

Notes	*Up to 1 year approval duration; approval duration should not exceed t he maximum allowable lifetime duration of 1 year (12 monthly doses) of total therapy with Evenity unless medical rationale for continued us e beyond 1 year has been provided.

Product Name:Tymlos	
Approval Length	1 Year*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of osteoporosis

AND

3 - ONE of the following:

- Trial and failure of bisphosphonate
- Documentation of a medical rationale against use of bisphosphonate
- Patient has been determined to be a high-risk patient as demonstrated by the World Health Organization (WHO) Fracture Risk Assessment Model

AND

4 - ONE of the following:

- Previous trial and failure of Forteo (teriparatide)
- Documentation of a medical rationale for use over Forteo (teriparatide)

AND

5 - Prescriber attests to BOTH of the following:

5.1 The patient does NOT have any of the following conditions:

- Bone metastases or skeletal malignancies
- Increased baseline risk for osteosarcoma
- Metabolic bone disease other than osteoporosis
- Paget's disease of bone
- Pre-existing hypercalcemia (Calcium greater than 12mg/dL)

AND

5.2 The patient has NOT undergone prior radiation therapy

Notes	*Up to 1 year approval duration; approval duration should not exceed the maximum allowable lifetime duration of 2 years of total combined therapy with Forteo, teriparatide, and/or Tymlos. **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Brand Forteo, generic teriparatide, Brand Teriparatide	
Approval Length	1 Year*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of osteoporosis

AND

3 - ONE of the following:

- Trial and failure of bisphosphonate
- Documentation of a medical rationale against use of bisphosphonate
- Patient has been determined to be a high-risk patient as demonstrated by the World Health Organization (WHO) Fracture Risk Assessment Model

AND

4 - Prescriber attests to BOTH of the following:

4.1 The patient does NOT have any of the following conditions:

- Bone metastases or skeletal malignancies
- Increased baseline risk for osteosarcoma
- Metabolic bone disease other than osteoporosis
- Paget's disease of bone
- Pre-existing hypercalcemia (Calcium greater than 12mg/dL)

AND

4.2 The patient has NOT undergone prior radiation therapy

Notes	*Up to 1 year approval duration; approval duration should not exceed t he maximum allowable lifetime duration of 2 years of total combined t herapy with Forteo, teriparatide, and/or Tymlos. **PDL Link: https://w ww.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Brand Forteo, generic teriparatide, Brand Teriparatide, Tymlos	
Approval Length	1 Year*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Prescriber attests that the patient remains a candidate for treatment, by indicating BOTH of the following:

2.1 The patient does NOT have any of the following conditions:

- Bone metastases or skeletal malignancies
- Increased baseline risk for osteosarcoma
- Metabolic bone disease other than osteoporosis
- Paget's disease of bone

• Pre-existing hypercalcemia (Calcium greater than 12mg/dL) **AND** **2.2** The patient has NOT undergone prior radiation therapy **AND** **3** - ONE of the following*: **3.1** Total length of therapy has not exceeded 2 years **OR** **3.2** Documentation of a medical rationale for continued use beyond 2 years	
Notes	*Up to 1 year approval duration; approval duration should not exceed the maximum allowable lifetime duration of 2 years of total combined therapy with Forteo, teriparatide, and/or Tymlos unless medical rationale for continued use beyond 2 years has been provided. **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
7/1/2024	Updated notes sections, where applicable. Added generic teriparatide as a target. Updated product name list and GPI table, where applicable. Minor cosmetic updates.

Bone Resorption Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137547
Guideline Name	Bone Resorption Inhibitors
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:risedronate, generic risedronate	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried alendronate within the past 90 days	

Product Name:alendronate oral solution	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is 5 years of age or older

AND

1.2 Patient is less than 12 years of age

OR

2 - Patient is unable to swallow tablets

Product Name:Brand Miacalcin, generic calcitonin salmon inj	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure of calcitonin-salmon nasal

OR

2 - Medical justification for use

2 . Revision History

Date	Notes

12/11/2023	Updated alendronate soln criteria, updated product name list.

Bosulif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147641
Guideline Name	Bosulif
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/22/2024	Added Bosulif capsules.

BPH Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125064
Guideline Name	BPH Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Jalyn, generic dutasteride/tamsulosin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that the separate components are not suitable for use	

Product Name:Brand Rapaflo, generic silodosin	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has had a trial of BOTH of the following:

- Alfuzosin ER
- Tamsulosin

OR

2 - Medical justification for use of silodosin

Product Name:Brand Cialis 2.5mg and 5mg, generic tadalafil 2.5mg and 5mg*	
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Documentation of a trial and failure of ALL of the following:

- A nonselective alpha-blocker
- A selective alpha-blocker
- A 5-alpha reductase inhibitor
- A combination product for the treatment of BPH

OR

1.2 A medically justifiable reason why ALL of the following are not suitable for use:

- A nonselective alpha-blocker
- A selective alpha-blocker
- A 5-alpha reductase inhibitor
- A combination product for the treatment of BPH

Notes	*Approval Duration: 26 weeks when being requested in combination w ith finasteride, 12 months for all other approvals

Product Name:Entadfi	
Approval Length	26 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Documentation of a trial and failure of ALL of the following:

- A nonselective alpha-blocker
- A selective alpha-blocker
- A 5-alpha reductase inhibitor (must include finasteride)
- A combination product for the treatment of BPH

OR

1.2 A medically justifiable reason why ALL of the following are not suitable for use

- A nonselective alpha-blocker
- A selective alpha-blocker
- A 5-alpha reductase inhibitor (must include finasteride)
- A combination product for the treatment of BPH

2 . Revision History

Date	Notes
4/26/2023	New

Braftovi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156253
Guideline Name	Braftovi
Formulary	• Medicaid - Community & State Indiana

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

Bronchitol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124644
Guideline Name	Bronchitol
Formulary	• Medicaid - Community & State Indiana

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

Brukinsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156257
Guideline Name	Brukinsa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/25/2024	Clinical coverage criteria added for follicular lymphoma and hairy cell leukemia. Updated B-cell lymphoma formatting

Bylvay

Prior Authorization Guideline

Guideline ID	GL-156301
Guideline Name	Bylvay
Formulary	• Medicaid - Community & State Indiana

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-86368
Guideline Name	Cablivi
Formulary	• Medicaid - Community & State Indiana

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-164370
Guideline Name	Cabometyx
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/27/2025	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.

Calcium Channel Blockers

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150095
Guideline Name	Calcium Channel Blockers
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Norliqva	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is unable to swallow tablets	

Product Name:Nymalize	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient is unable to swallow capsules

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

Approval Criteria

1 - One of the following:

1.1 Patient is 6 years of age or older AND less than 12 years of age

OR

1.2 Patient is unable to swallow tablets

AND

2 - One of the following:

2.1 Previous trial and failure of Norliqva

OR

2.2 Medical rational for use of Katerzia

Product Name:Brand Caduet, generic amlodipine/atorvastatin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that separate components are not suitable for use	

2 . Revision History

Date	Notes
7/22/2024	Removed age limit for Norliqva

Calquence

Prior Authorization Guideline

Guideline ID	GL-127149
Guideline Name	Calquence
Formulary	• Medicaid - Community & State Indiana

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	Copy NY

Caprelsa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164389
Guideline Name	Caprelsa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/27/2025	Updated criteria for medullary thyroid carcinoma

Cardiac Agents

Prior Authorization Guideline

Guideline ID	GL-154931
Guideline Name	Cardiac Agents
Formulary	• Medicaid - Community & State Indiana • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Heart failure due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable, symptomatic heart failure due to dilated cardiomyopathy

AND

2 - Documentation of all of the following:

- Left ventricular ejection fraction is less than or equal to 45%
- Patient is in sinus rhythm
- Resting heart rate is elevated

AND

3 - Both of the following:

3.1 Patient is 6 months through 17 years of age

AND

3.2 Patient weighs greater than or equal to 40 kilograms (kg)

AND

4 - Both of the following:

4.1 Requested dose does not exceed 15mg/day (milligrams/day)

AND

4.2 Requested dose does not exceed 2 tablets/day

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Heart failure due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Both of the following:

2.1 Patient is 6 months through 17 years of age

AND

2.2 Patient weighs greater than 40 kilograms (kg)

AND

3 - Both of the following:

3.1 Requested dose does not exceed 15mg/day (milligrams per day)

AND

3.2 Requested dose does not exceed 2 tablets/day

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Heart failure NOT due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure

AND

2 - Patient is 18 years of age or older

AND

3 - Documentation of both of the following:

- Left ventricular ejection fraction is less than or equal to 35%
- Resting heart rate is greater than or equal to 70 beats per minute

AND

4 - One of the following:

- Patient is currently maximized on beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

5 - Both of the following:

5.1 Requested dose does not exceed 15mg/day (milligrams per day)

AND

5.2 Requested dose does not exceed 2 tablets/day

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Heart failure NOT due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient continues to be maximized on concurrent beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Both of the following:

4.1 Requested dose does not exceed 15mg/day (milligrams/day)

AND

4.2 Requested dose does not exceed 2 tablets/day

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Inappropriate sinus tachycardia
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inappropriate sinus tachycardia

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient is currently maximized on beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Both of the following:

4.1 Requested dose does not exceed 15mg/day (milligrams per day)

AND

4.2 Requested dose does not exceed 2 tablets/day

Product Name:Brand Corlanor tablets, generic ivabradine tablet	
Diagnosis	Inappropriate sinus tachycardia
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient continues to be maximized on concurrent beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Both of the following:

4.1 Requested dose does not exceed 15mg/day (milligrams per day)

AND

4.2 Requested dose does not exceed 2 tablets/day

Product Name:Corlanor oral solution	
Diagnosis	Heart failure due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stable, symptomatic heart failure due to dilated cardiomyopathy

AND

2 - Documentation of all of the following:

- Left ventricular ejection fraction is less than or equal to 45%
- Patient is in sinus rhythm
- Resting heart rate is elevated

AND

3 - Patient is 6 months through 17 years of age

AND

4 - One of the following:

4.1 Patient weighs less than 40 kilograms and one of the following:

4.1.1 If patient is 6 months through less than 1 year of age, the requested dose does not exceed 0.2 mg/kg/dose (milligrams per kilograms per dose) twice daily

OR

4.1.2 If patient is 1 year of age through 17 years of age, the requested dose does not exceed 0.3 mg/kg/dose twice daily, maximum of 15 milliliters per day (15 milligrams per day)

OR

4.2 Patient weighs greater than or equal to 40 kilograms and one of the following:

4.2.1 If patient is 6 months through 11 years of age, the requested dose does not exceed 15 milliliters per day (15 milligrams per day)

OR

4.2.2 If patient is 12 years of age through 17 years of age, both of the following:

- The requested dose does not exceed 15 milliliters per day (15 milligrams per day)
- Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Corlanor oral solution	
Diagnosis	Heart failure due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is 6 months through 17 years of age

AND

3 - One of the following:

3.1 Patient weighs less than 40 kilograms and one of the following:

3.1.1 If patient is 6 months through less than 1 year of age, the requested dose does not exceed 0.2 mg/kg/dose (milligrams per kilograms per dose) twice daily

OR

3.1.2 If patient is 1 year of age through 17 years of age, the requested dose does not exceed 0.3 mg/kg/dose twice daily, maximum of 15 milliliters per day (15 milligrams per day)

OR

3.2 Patient weighs greater than or equal to 40 kilograms and one of the following:

3.2.1 If patient is 6 months through 11 years of age, the requested dose does not exceed 15 milliliters per day (15 milligrams per day)

OR

3.2.2 If patient is 12 years of age through 17 years of age, both of the following:

- The requested dose does not exceed 15 milliliters per day (15 milligrams per day)
- Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Corlanor oral solution	
Diagnosis	Heart failure NOT due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure

AND

2 - Patient is 18 years of age or older

AND

3 - Documentation of both of the following:

- Left ventricular ejection fraction is less than or equal to 35%
- Resting heart rate is greater than or equal to 70 beats per minute

AND

4 - One of the following:

- Patient is currently maximized on beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

5 - Requested dose does not exceed 15 milliliters per day (15 milligrams per day)

AND

6 - Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Corlanor oral solution	
Diagnosis	Heart failure NOT due to dilated cardiomyopathy
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient continues to be maximized on concurrent beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Requested dose does not exceed 15 milliliters per day (15 milligrams per day)

AND

5 - Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Corlanor oral solution	
Diagnosis	Inappropriate sinus tachycardia
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inappropriate sinus tachycardia

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient is currently maximized on beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Requested dose does not exceed 15 milliliters per day (15 milligrams per day)

AND

5 - Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Corlanor oral solution	
Diagnosis	Inappropriate sinus tachycardia
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient continues to be maximized on concurrent beta-blocker therapy
- Patient has contraindication to beta-blocker use

AND

4 - Requested dose does not exceed 15 milliliters per day (15 milligrams per day)

AND

5 - Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Entresto tablet	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is not using an angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) concurrently with Entresto

OR

1.2 The provider has submitted valid medical justification for the use of an angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) concurrently with Entresto

Product Name:Entresto sprinkle	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is not using angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) concurrently with Entresto

OR

1.2 The provider has submitted valid medical justification for the use of an angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) concurrently with Entresto

AND

2 - One of the following:

2.1 One of the following:

- Patient is less than 12 years of age
- Patient weighs less than 50kg

OR

2.2 ALL of the following:

- Patient is 12 years of age or older
- Patient weighs at least 50kg
- Submission of medical records (e.g., chart notes) confirming patient cannot swallow tablets

Product Name:Verquvo	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of stable, symptomatic heart failure

AND

1.3 Documentation of left ventricular ejection fraction less than or equal to 45%

AND

1.4 One of the following:

- Patient has been hospitalized within the past 180 days for symptomatic heart failure
- Patient has received outpatient treatment with IV diuretics within the past 90 days

AND

1.5 Both of the following:

1.5.1 Requested dose does not exceed 10 mg/day (milligrams per day)

AND

1.5.2 Requested dose does not exceed 1 tablet/day

AND

1.6 For women of childbearing age, documentation of a negative pregnancy test within the past 60 days

Product Name:Verquvo	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Both of the following:

2.1 Requested dose does not exceed 10 mg/day (milligrams per day)

AND

2.2 Requested dose does not exceed 1 tablet/day

AND

3 - For women of childbearing age, documentation of a negative pregnancy test within the past 60 days

Product Name:Camzyos	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM)

AND

1.3 Documentation of both of the following:

- Left ventricular ejection fraction that is greater than or equal to 55%
- Left ventricular outflow tract (LVOT) gradient of 50 mmHg or greater

AND

1.4 One of the following:

- At least 90 days of drug therapy with a beta-adrenergic blocker or non-dihydropyridine calcium channel blocker
- Prescriber has provided valid medical rationale for the use of Camzyos over beta-adrenergic blocker and non-dihydropyridine calcium channel blocker therapy

AND

1.5 Patient is enrolled in the Camzyos/mavacamten REMS (Risk Evaluation and Mitigation Strategy) program

AND

1.6 Both of the following:

1.6.1 Requested dose does not exceed 15 mg/day (milligrams per day)

AND

1.6.2 Requested dose does not exceed 1 capsule/day

Product Name:Camzyos	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for a least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - Both of the following:

2.1 Requested dose does not exceed 15 mg/day (milligrams per day)

AND

2.2 Requested dose does not exceed 1 capsule/day

2 . Revision History

Date	Notes
9/17/2024	Added generic ivabradine. Added criteria for Entresto sprinkle.

Carisoprodol Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126509
Guideline Name	Carisoprodol Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:generic carisoprodol, Brand Soma, Brand Vanadom	
Approval Length	90 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have diagnosis of an acute musculoskeletal condition in the past 60 days

AND

2 - Patient is between 16 and 65 years of age

AND

3 - No history of meprobamate use in the past 90 days

AND

4 - ONE of the following*:

4.1 Trial and failure of ALL of the preferred non-liquid oral agents

OR

4.2 Documented history of intolerance to ALL of the preferred non-liquid oral agents

OR

4.3 Valid medical justification for the use of carisoprodol over the preferred non-liquid oral agents

AND

5 - Patient will not use concurrently with opiates or benzodiazepines

AND

6 - The request must be no more than a 21 days' supply, to be used within a 90-day period, every 180 days

Notes	Approvals will be granted for up to 21 days' supply, to be used within a 90-day period, every 180 days. *PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
6/9/2023	Updated guideline name, updated GPI and product name lists, removed carisoprodol/asa/codeine, updated criteria and note.

Cayston

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123638
Guideline Name	Cayston
Formulary	• Medicaid - Community & State Indiana

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
3/22/2023	Updated trial/failure language.

Cerdelga and Zavesca

Prior Authorization Guideline

Guideline ID	GL-136327
Guideline Name	Cerdelga and Zavesca
Formulary	• Medicaid - Community & State Indiana

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
11/14/2023	Annual review. Added Yargesa product.

Cholbam

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127506
Guideline Name	Cholbam
Formulary	• Medicaid - Community & State Indiana

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.

Cinryze

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147159
Guideline Name	Cinryze
Formulary	• Medicaid - Community & State Indiana

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.

Cipro Suspension and Levaquin Solution

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123771
Guideline Name	Cipro Suspension and Levaquin Solution
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Cipro suspension, generic ciprofloxacin suspension	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Patient is 12 years of age or older

AND

1.2 Patient is unable to swallow tablet formulation

OR

2 - Both of the following:

2.1 Patient is less than 12 years of age

AND

2.2 Patient has one of the following diagnoses:

- Anthrax
- Cystic fibrosis
- Community acquired pneumonia
- Shigella dysentery type 1
- Urinary tract infection (complicated) or pyelonephritis
- Tularemia

Product Name:Brand Cipro suspension, generic ciprofloxacin suspension	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Patient is 12 years of age or older

AND

1.2 Patient has history of use of ciprofloxacin suspension

OR

2 - Both of the following:

2.1 Patient is less than 12 years of age

AND

2.2 Medical rationale for continued use of the requested medication

Product Name:Levofloxacin solution	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Patient is 12 years of age or older

AND

1.2 Patient is unable to swallow tablet formulation

OR

2 - Both of the following:

2.1 Patient is less than 12 years of age

AND

2.2 Patient has one of the following diagnoses:

- Anthrax
- Community acquired pneumonia
- Acute bacterial rhinosinusitis
- Tularemia
- Pneumonic plague

Product Name:Levofloxacin solution	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Patient is 12 years of age or older

AND

1.2 Patient has history of use of levofloxacin solution

OR

2 - Both of the following:

2.1 Patient is less than 12 years of age

AND

2.2 Medical rationale for continued use of the requested medication

2 . Revision History

Date	Notes
4/7/2023	SPDL eff 7.1.23

Cometriq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127888
Guideline Name	Cometriq
Formulary	• Medicaid - Community & State Indiana

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

Complement Inhibitor Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164532
Guideline Name	Complement Inhibitor Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

1 . Criteria

Product Name:Empaveli	
Approval Length	6 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 high sensitivity flow cytometry

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by, or in consultation with, a hematologist

AND

4 - Prescriber attests to all of the following:

- Patient does not have unresolved serious infection caused by encapsulated bacteria including S. pneumoniae, N. meningitidis, and H. influenzae type B
- Prescriber is enrolled in the Empaveli (pegcetacoplan) REMS (Risk Evaluation and Mitigation Strategy) program
- Patient will not be using Empaveli (pegcetacoplan) in combination with another complement inhibitor

AND

5 - One of the following:

5.1 Dose requested does not exceed 1,080 milligrams twice weekly (40 milliliters per week)

OR

5.2 For patients with lactate dehydrogenase (LDH) more than 2 times the upper limit of normal, dose does not exceed 1,080 milligrams every 3 days

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

Approval Criteria

1 - History of requested agent for 90 of the past 120 days, as confirmed by claims history, chart documentation, or prescriber attestation including trial dates

AND

2 - Prescriber attests to all of the following:

- Patient does not have unresolved serious infection caused by encapsulated bacteria including S. pneumoniae, N. meningitidis, and H. influenzae type B
- Patient will not be using Empaveli (pegcetacoplan) in combination with another complement inhibitor
- Patient continues to show positive clinical response to Empaveli (pegcetacoplan) as confirmed by chart documentation (e.g., increased hemoglobin level/stabilization, decreased need for transfusions, normalized lactate dehydrogenase levels, improved fatigue)

AND

3 - One of the following:

3.1 Dose requested does not exceed 1,080 milligrams twice weekly (40 milliliters per week)

OR

3.2 For patients with lactate dehydrogenase (LDH) more than 2 times the upper limit of normal, dose does not exceed 1,080 milligrams every 3 days

Product Name:Fabhalta	
Approval Length	6 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 high sensitivity flow cytometry

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by, or in consultation with, a hematologist

AND

4 - Prescriber attests to all of the following:

- Patient does not have unresolved serious infection caused by encapsulated bacteria including S. pneumoniae, N. meningitidis, and H. influenzae type B
- Prescriber is enrolled in the Fabhalta (iptacopan) REMS (Risk Evaluation and Mitigation Strategy) program
- Patient will not be using Fabhalta (iptacopan) in combination with another complement inhibitor

AND

5 - Dose requested does not exceed 200 milligrams twice daily

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

Approval Criteria

1 - History of requested agent for 90 of the past 120 days, as confirmed by claims history, chart documentation, or prescriber attestation including trial dates

AND

2 - Prescriber attests to all of the following:

- Patient does not have unresolved serious infection caused by encapsulated bacteria including S. pneumoniae, N. meningitidis, and H. influenzae type B
- Patient will not be using Fabhalta (iptacopan) in combination with another complement inhibitor
- Patient continues to show positive clinical response to Fabhalta (iptacopan) as confirmed by chart documentation (e.g., increased hemoglobin level/stabilization, decreased need for transfusions, normalized lactate dehydrogenase levels, improved fatigue)

AND

3 - Dose requested does not exceed 200 milligrams twice daily

2 . Revision History

Date	Notes
1/30/2025	New guideline

Compounds and Bulk Powders

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-105739
Guideline Name	Compounds and Bulk Powders
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2022

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

4/6/2022	Updated criteria requirement for unique vehicle needed. Defined AS HP.

Continuous Glucose Monitors

Prior Authorization Guideline

Guideline ID	GL-157611
Guideline Name	Continuous Glucose Monitors
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Non-preferred Continuous Glucose Monitors, sensors, and transmitters (includes all brands except Dexcom G6 and Dexcom G7)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - If the request is non-preferred, the non-preferred continuous glucose monitor (CGM) system integrates with the member's pre-existing or plan authorized insulin infusion device *

OR **2** - A documented, medically justifiable reason that the non-preferred product should be used instead of the preferred product is provided	
Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Non-preferred Continuous Glucose Monitors, sensors, and transmitters (includes all brands except Dexcom G6 and Dexcom G7)	
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
10/17/2024	Updated GPIs and product name list

Copiktra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127439
Guideline Name	Copiktra
Formulary	• Medicaid - Community & State Indiana

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

Copper Chelating Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151321
Guideline Name	Copper Chelating Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/12/2024	Updated trial/failure requirements for Cuprimine, Syprine, and trientine 500 mg capsules.

Cotellic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164367
Guideline Name	Cotellic
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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 positive for one of the following mutations:

- BRAF V600E
- BRAF V600K

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
1/27/2025	Updated melanoma, central nervous system cancers, and histiocytic neoplasms criteria

Cuvrior

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151263
Guideline Name	Cuvrior
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/9/2024	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

Optum Rx®

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.

Danziten

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

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-151781
Guideline Name	Daybue
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	Updated initial approval duration from 6 months to 12 months.

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-123772
Guideline Name	Dificid
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Dificid	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clostridium difficile infection (CDI)

AND

2 - Patient is 6 months of age or older

AND

3 - One of the following:

3.1 Patient has an initial episode of CDI and one of the following:

- Patient is at increased risk of CDI recurrence
- Documentation supporting diagnosis of vancomycin-resistant pseudomembraneous colitis

OR

3.2 Patient has a recurrent episode of CDI

2 . Revision History

Date	Notes
4/7/2023	SPDL eff 7.1.23

Direct Oral Anticoagulants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137624
Guideline Name	Direct Oral Anticoagulants
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient is under 12 years of age

OR

2 - Patient is unable to swallow tablets

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

Approval Criteria

1 - Patient has tried and failed Brand Pradaxa

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

Approval Criteria

1 - Patient has tried Eliquis and Xarelto

OR

2 - Documentation of medical justification for use of Savaysa

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

Approval Criteria

1 - Patient is under 8 years of age

OR

2 - Patient is unable to swallow capsules **OR** **3** - Documentation of medical rational for use of pellet formulation

2 . Revision History

Date	Notes
12/11/2023	Updaed Xarelto susp ST age to 12.

Disposable Insulin Delivery Devices

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158063
Guideline Name	Disposable Insulin Delivery Devices
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Omnipod Classic (Gen 3) pods and kits, Omnipod Dash (Gen 4) pods and kits, Omnipod Go, V-Go 20, V-Go 30, V-Go 40, CeQur Simplicity 2U patch and inserter*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type I or Type II diabetes mellitus requiring insulin treatment

AND

2 - Daily dosing requirements are less than the disposable insulin delivery device's capacity

AND

3 - One of the following:

3.1 Patient has difficulty maintaining stable blood glucose levels (hyperglycemia or hypoglycemia) despite intensive insulin therapy and blood glucose monitoring (3 or more injections and blood glucose readings per day)

OR

3.2 Patient is less than 18 years of age and requires intensive insulin therapy and blood glucose monitoring (3 or more injections and blood glucose readings per day)

OR

3.3 Patient has physical impairments resulting in difficulty with self-injection of insulin

OR

3.4 Patient is pregnant

OR

3.5 Prescriber has provided other valid medical justification for use of a disposable insulin delivery device

AND

4 - For all requests other than CeQur Simplicity, other long-acting insulins/insulin analogs will be discontinued

Notes	*For Omnipod 5 see Omnipod 5 guideline

2 . Revision History

Date	Notes
10/28/2024	Updated Omnipod classic pod, Omnipod Dash pod and V-Go GPIs. Added Omnipod Go GPIs. Clarified hyper and hypo in step 3.1. Updated language to physical impairments in step 3.3. Updated step 4 to be excluded for CeQur Simplicity.

Dojolvi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151783
Guideline Name	Dojolvi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	New guideline

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

DPP4 Inhibitors and Combination Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161804
Guideline Name	DPP4 Inhibitors and Combination Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Januvia, Tradjenta, Janumet, Janumet XR, Jentadueto, Jentadueto XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried metformin for 90 days of the past 120 days

OR

2 - Prescriber has provided a medical justification for use (please document)

Product Name:Brand Alogliptin, Brand Onglyza, generic saxagliptin, Sitagliptin, Zituvio	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried a preferred* medication for 90 days of the past 120 days **OR** **2** - Prescriber has provided a medical justification for use (please document)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Brand Alogliptin/Metformin, Brand Kombiglyze XR, generic saxagliptin/metformin ER, Sitagliptin/Metformin, Zituvimet, Zituvimet XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried a preferred* combination medication for 90 days of the past 120 days **OR** **2** - Prescriber has provided a medical justification for use (please document)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Brand Alogliptin/Pioglitazone	
Approval Length	12 month(s)

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried and failed combination therapy with preferred* medications of the same classes for 90 days of the past 120 days **OR** **2** - Prescriber has provided a medical justification for use (please document)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
12/10/2024	Updated lookback period to 90days within 120 days or medical rationale. Added Zituvimet XR.

Dronabinol

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126573
Guideline Name	Dronabinol
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Marinol, Generic dronabinol	
Diagnosis	Malignant cancer
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of malignant cancer	

AND

2 - History of an antineoplastic or radiation therapy in the past 45 days

AND

3 - One of the following:

3.1 Patient has tried and failed ONE of the following in the past 6 months:

- An oral selective 5HT3 receptor antagonist
- A substance P/NK-1 receptor antagonist

OR

3.2 Medical justification for use of dronabinol over BOTH of the following:

- Selective 5-HT3 receptor antagonists
- Substance P/NK-1 receptor antagonists

AND

4 - Patient is NOT currently receiving megestrol acetate suspension

Product Name:Brand Marinol, Generic dronabinol	
Diagnosis	Malignant cancer
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of the requested agent

AND

2 - Diagnosis of malignant cancer

AND

3 - History of an antineoplastic or radiation therapy in the past 45 days

AND

4 - Patient is NOT currently receiving megestrol acetate suspension

Product Name:Brand Marinol, Generic dronabinol	
Diagnosis	HIV/AIDS
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV/AIDS with ONE of the following concurrent diagnoses in the past 2 years:

- Cachexia
- Anorexia
- Failure to thrive

AND

2 - Patient is 18 years of age or older

AND

3 - Patient is NOT currently receiving megestrol acetate suspension

AND

4 - ONE of the following:

- Member has tried and failed megestrol acetate suspension in the past six months
- Medical justification for use of dronabinol over megestrol acetate suspension

Product Name:Brand Marinol, Generic dronabinol	
Diagnosis	HIV/AIDS
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of the requested agent

AND

2 - Diagnosis of HIV/AIDS with ONE of the following concurrent diagnoses in the past 2 years:

- Cachexia
- Anorexia
- Failure to thrive

AND

3 - Patient is NOT currently receiving megestrol acetate suspension

Product Name:Brand Marinol, Generic dronabinol

Diagnosis	Failure to thrive
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of failure to thrive

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

- Patient has tried and failed megestrol acetate suspension in the past six months
- Medical justification for use of dronabinol over megestrol acetate suspension

AND

4 - Patient is NOT currently receiving megestrol acetate suspension

Product Name:Brand Marinol, Generic dronabinol	
Diagnosis	Failure to thrive
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of the requested medication **AND** **2** - Diagnosis of failure to thrive **AND** **3** - Patient is NOT currently receiving megestrol acetate suspension

2 . Revision History

Date	Notes
6/12/2023	Removed Syndros from the criteria

Dry Eye Disease or Keratoconjunctivitis Agents

Prior Authorization Guideline

Guideline ID	GL-148906
Guideline Name	Dry Eye Disease or Keratoconjunctivitis Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Cequa	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of keratoconjunctivitis sicca (dry eye disease)

AND

2 - One of the following:

2.1 Previous trial and failure of BOTH Restasis single-dose vials and Xiidra

OR

2.2 Prescriber has provided valid medical justification for the use of Cequa over Restasis single-dose vials and Xiidra

Product Name:Miebo	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dry eye disease

AND

2 - One of the following:

2.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

2.2 Prescriber has provided valid medical justification for the use of Miebo (perfluorohexyloctane) over Restasis single-dose vials and Xiidra

Product Name:Restasis MultiDose	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet all of the following:

1.1 Diagnosis of keratoconjunctivitis sicca (dry eye disease)

AND

1.2 One of the following:

1.2.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

1.2.2 Prescriber has provided valid medical justification for the use of Restasis MultiDose over Restasis single-dose vials and Xiidra

Product Name:Brand Restasis Single-Dose Vials, generic cyclosporine single-dose vials	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet both of the following:

1.1 Diagnosis of keratoconjunctivitis sicca (dry eye disease)

AND

1.2 Trial of artificial tears within the past 90 days

Product Name:Tyrvaya

Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dry eye disease

AND

2 - One of the following:

2.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

2.2 Prescriber has provided valid medical justification for the use of Tyrvaya over Restasis single-dose vials and Xiidra

Product Name:Verkazia, Cyclosporine in Klarity	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet all of the following:

1.1 Diagnosis of vernal keratoconjunctivitis

AND

1.2 One of the following:

1.2.1 Trial and failure of two of the following for at least 15 days (per agent):

- Artificial tears
- Ophthalmic antihistamines (e.g., olopatadine, azelastine, ketotifen)
- Ophthalmic corticosteroids (e.g., dexamethasone, fluorometholone, loteprednol, prednisolone)
- Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)

OR

1.2.2 Prescriber has provided valid medical justification for the use of Verkazia/Cyclosporine in Klarity over artificial tears, ophthalmic antihistamines, corticosteroids, and mast cell stabilizers

Product Name:Vevye	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of keratoconjunctivitis sicca (dry eye disease)

AND

2 - One of the following:

2.1 Previous trial and failure of BOTH Restasis single-dose vials and Xiidra

OR

2.2 Prescriber has provided valid medical justification for the use of Vevye over Restasis single-dose vials and Xiidra

Product Name:Xiidra

Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet both of the following:

1.1 Diagnosis of dry eye disease

AND

1.2 Trial of artificial tears within the past 90 days

Product Name:Eysuvis	
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet all of the following:

1.1 Diagnosis of dry eye disease

AND

1.2 Requested duration of therapy does not exceed 14 days

AND

1.3 One of the following:

1.3.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

1.3.2 Prescriber has provided valid medical justification for the use of Eysuvis over Restasis single-dose vials and Xiidra

Product Name:Cequa, Miebo, Restasis Multidose, Tyrvaya, Vevye	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent in the past 180 days

AND

2 - One of the following:

2.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

2.2 Prescriber has provided valid medical justification for the use of the requested drug over Restasis single-dose vials and Xiidra

Product Name:Brand Restasis Single-Dose Vials, generic cyclosporine single-dose vials, Verkazia, Cyclosporine in Klarity, Xiidra	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent in the past 180 days

Product Name:Eysuvis	
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent

AND

2 - Requested duration of therapy does not exceed 14 days

AND

3 - One of the following:

3.1 Previous trial and failure of both Restasis single-dose vials and Xiidra

OR

3.2 Prescriber has provided valid medical justification for the use of Eysuvis over Restasis single-dose vials and Xiidra

AND

4 - Prescriber has performed an ophthalmic evaluation under magnification AND an

examination of intraocular pressure and has determined that Eysuvis is an appropriate treatment

2 . Revision History

Date	Notes
6/26/2024	Addition of Vevye. Updated reauth criteria. Aligned criteria to policy.

Duopa

Prior Authorization Guideline

Guideline ID	GL-164346
Guideline Name	Duopa
Formulary	• Medicaid - Community & State Indiana

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

Egrifta

Prior Authorization Guideline

Guideline ID	GL-86261
Guideline Name	Egrifta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	5/11/2021
P&T Approval Date:	
P&T Revision Date:	

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
4/30/2021	Update GPI's and product name list

Electrolyte Depleters

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144364
Guideline Name	Electrolyte Depleters
Formulary	• Medicaid - Community & State Indiana • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Fosrenol Powder Packets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is under 18 years of age

OR

2 - Patient is unable to swallow tablets

Product Name:Xphozah	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried and failed preferred phosphate binders **OR** **2** - Medical rationale for use of requested medication over all preferred phosphate binders	
Notes	PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
3/14/2024	Added SP formulary and Xphozah criteria.

Elmiron

Prior Authorization Guideline

Guideline ID	GL-97793
Guideline Name	Elmiron
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name:Elmiron	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records showing diagnosis of bladder pain or discomfort associated with interstitial cystitis

OR

2 - Submission of medical records showing diagnosis of hemorrhagic cystitis in a patient who previously received pelvic irradiation or chemotherapy with cyclophosphamide

Product Name:Elmiron	
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has history of the requested medication within the past 90 days

AND

2 - Documentation of symptom improvement (i.e., pain relief)

2 . Revision History

Date	Notes
11/3/2021	Updated all criteria to match state policy.

Emverm

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-108749
Guideline Name	Emverm
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

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

Approval Criteria

1 - Diagnosis of Ascariasis (Roundworm)

Product Name:Emverm	
Diagnosis	Toxocariasis (Roundworm)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Toxocariasis (Roundworm)

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

Approval Criteria

1 - Diagnosis of Trichinellosis

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

Approval Criteria

1 - Diagnosis of Trichuriasis (Whipworm)

Product Name:Emverm	
Diagnosis	Capillariasis
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Capillariasis	

Product Name:Emverm	
Diagnosis	Baylisascaris
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Baylisascaris	

2 . Revision History

Date	Notes
6/28/2022	Updated trial/failure language

Endari

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123757
Guideline Name	Endari
Formulary	• Medicaid - Community & State Indiana

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	Copy NY

Enspryng

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164392
Guideline Name	Enspryng
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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 - 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

4 - Prescribed by, or in consultation with, a neurologist

AND

5 - 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
1/28/2025	Updated examples of complement inhibitors

Erivedge

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117571
Guideline Name	Erivedge
Formulary	• Medicaid - Community & State Indiana

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

Erleada

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138263
Guideline Name	Erleada
Formulary	• Medicaid - Community & State Indiana

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.

Esbriet, Ofev

Prior Authorization Guideline

Guideline ID	GL-147181
Guideline Name	Esbriet, Ofev
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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 - 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 - 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 - 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 - 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 - The prescriber is a pulmonologist

2 . Revision History

Date	Notes
5/8/2024	Removed criteria that Esbriet and ofev should not be used in combin ation

Exkivity

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-99462
Guideline Name	Exkivity
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	2/1/2022

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** - Exkivity will be approved for uses 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
12/8/2021	New guideline

Febuxostat

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128909
Guideline Name	Febuxostat
Formulary	• Medicaid - Community & State Indiana

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)

Fentanyl IR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126579
Guideline Name	Fentanyl IR
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Actiq, generic fentanyl citrate lozenge, Fentora, fentanyl citrate buccal tabs	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cancer or diagnosis within approved compendia	

AND

2 - Member is enrolled in the TIRF REMS (Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy) Access program and prescriber is monitoring in accordance with REMS requirements

AND

3 - Patient is currently utilizing a long-acting opioid medication around the clock

AND

4 - Patient must be tolerant to opioids, as defined by at least one week without adequate pain relief using ONE of the following:

- Greater than or equal to 60 milligrams (mg) oral morphine per day
- Greater than or equal to 25 micrograms per hour (mcg/hr) transdermal fentanyl
- Greater than or equal to 30 mg oral oxycodone per day
- Greater than or equal to 8 mg oral hydromorphone per day
- Greater than or equal to 25 mg oral oxymorphone per day
- Equianalgesic dose of another opioid

AND

5 - ONE of the following:

- If the request is for Actiq (fentanyl citrate lozenge) the patient is 16 years of age or older
- If the request is for Fentora (fentanyl citrate buccal tab) or Subsys the patient is 18 years of age or older

AND

6 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), within the past 45 days*

AND

7 - Patient is not using concurrently with a carisoprodol-containing product

AND

8 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

9 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

10 - One of the following:

10.1 Member is not using the recommended medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

10.2 Both of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

10.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

10.4 ALL of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

10.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

10.4.2 Documentation of previous therapies attempted for the given indications

AND

10.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

Product Name:Brand Actiq, generic fentanyl citrate lozenge, Fentora, fentanyl citrate buccal tabs	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 45 days

AND

2 - If the request is for Actiq (fentanyl citrate lozenge), one of the following:

- Patient is maintaining the same strength and not exceeding 4 units of a single strength per day
- Patient is increasing strength and does not exceed 6 units of a single strength per day

AND

3 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), within the past 45 days*

AND

4 - Patient is not using concurrently with a carisoprodol-containing product

AND

5 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

6 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

7 - One of the following:

7.1 Member is not using the recommended medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

7.2 Both of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

7.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

7.4 ALL of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

7.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

7.4.2 Documentation of previous therapies attempted for the given indications

AND

7.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

2 . Revision History

Date	Notes
6/14/2023	Removed Subsys, updated initial criteria and DUR criteria. Added Re-auth box.

Fexofenadine

Prior Authorization Guideline

Guideline ID	GL-96662
Guideline Name	Fexofenadine
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/15/2021

1 . Criteria

Product Name:Brand Allegra tablets, generic fexofenadine tablets	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Patient has had a trial of cetirizine and loratadine within the past 90 days	

2 . Revision History

Date	Notes
10/14/2021	New guideline

Filsuvez

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150827
Guideline Name	Filsuvez
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/2/2024

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)

Firazyr, Sajazir

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150097
Guideline Name	Firazyr, Sajazir
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

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
7/22/2024	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.

Firdapse

Optum Rx®

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.

Firdapse

Optum Rx®

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.

Fruzaqla

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147173
Guideline Name	Fruzaqla
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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	New guideline

Galafold

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136357
Guideline Name	Galafold
Formulary	• Medicaid - Community & State Indiana

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
11/15/2023	Added Elfabrio as a drug to not be used in combination

Gattex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134512
Guideline Name	Gattex
Formulary	• Medicaid - Community & State Indiana

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

Gavreto

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164423
Guideline Name	Gavreto
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/28/2025	Updated criteria for hepatobiliary cancers

Gilotrif

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127916
Guideline Name	Gilotrif
Formulary	• Medicaid - Community & State Indiana

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
7/12/2023	Updated GPI and Brain Metastases criteria to match the most update d policy

Gleevec

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-135837
Guideline Name	Gleevec
Formulary	• Medicaid - Community & State Indiana

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

GLP-1 Receptor Agonists and Combinations

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161610
Guideline Name	GLP-1 Receptor Agonists and Combinations
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Byetta	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Previous trial of metformin for at least 90 days within a 120-day period, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

3.2 Documented intolerance or contraindication to metformin therapy

AND

4 - Dose requested does not exceed 20 mcg/day

Product Name:Byetta	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient has a history of Byetta for at least 90 days within the past 120 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Dose requested does not exceed 20 mcg/day

Product Name:Ozempic	
Diagnosis	Type 2 diabetes
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease, as confirmed by chart documentation or claims history

AND

3 - One of the following:

3.1 Previous trial of metformin for at least 90 days within a 120-day period, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

3.2 Documented intolerance or contraindication to metformin therapy

AND

4 - Dose requested does not exceed 2 mg/week

Product Name:Ozempic	
Diagnosis	Metabolic dysfunction-associated steatohepatitis (MASH), Metabolic dysfunction-associated steatotic liver disease (MASLD)
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - One of the following diagnosis

- Metabolic dysfunction-associated steatohepatitis (MASH)
- Metabolic dysfunction-associated steatotic liver disease (MASLD)

AND

3 - One of the following confirming the diagnosis (submission of medical records required)

3.1 FibroScan assessed liver stiffness (FAST) score greater than or equal to 0.67

OR

3.2 Patient is 35 years of age or older, with a Fibrosis-4 index (FIB-4) score between 2.67 and 3.47

OR

3.3 Liver biopsy

OR

3.4 MEFIB (magnetic resonance elastography [MRE] plus FIB-4) score with both of the following:

- FIB-4 score greater than or equal to 1.6
- MRE greater than or equal to 3.3 kPA

OR

3.5 MRE between 3.63 and 5 kPA

OR

3.6 MRI-PDFF*, MRE, and serum AST (MAST) score greater than or equal to 0.242

AND

4 - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist

AND

5 - Prescriber attests that patient does not have any of the following:

- Celiac disease
- Daily alcohol consumption exceeding 30 grams (2 standard drinks) per day
- Familial hypobetalipoproteinemia (FHBL)
- Hepatitis A, B, or C
- Lysosomal acid lipase (LAL) deficiency

- Wilson disease

AND

6 - Patient does not have history of any of the following in the past 90 days OR prescriber attests that alternate therapies are not appropriate for the patient and prescriber has a monitoring plan in place

- Amiodarone
- Glucocorticoids
- Methotrexate
- Synthetic estrogens
- Tamoxifen

AND

7 - Dose requested does not exceed 2 mg/week

Notes	*MRI-PDFF= Magnetic Resonance Imaging Proton Density Fat Fraction

Product Name:Ozempic	
Diagnosis	Type 2 diabetes, Metabolic dysfunction-associated steatohepatitis (MASH), Metabolic dysfunction-associated steatotic liver disease (MASLD)
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease, as confirmed by chart documentation or claims history

OR

1.2 Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD), as confirmed by chart documentation or claims history

AND

2 - History of Ozempic for at least 84 days within the past 112 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Dose requested does not exceed 2 mg/week

Product Name:Trulicity	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease or cardiovascular disease risk factors, as confirmed by chart documentation or claims history

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Previous trial of metformin for at least 90 days within a 120-day period, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

3.2 Documented intolerance or contraindication to metformin therapy

AND

4 - Dose requested does not exceed ONE of the following:

- 0.75 mg injection: 2 injections/week
- 1.5 mg, 3 mg, or 4.5 mg injection: 1 injection/week

Product Name:Trulicity	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease or cardiovascular disease risk factors, as confirmed by chart documentation or claims history

AND

2 - History of Trulicity for at least 84 days within the past 112 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Dose requested does not exceed ONE of the following:

- 0.75 mg injection: 2 injections/week
- 1.5 mg, 3 mg, or 4.5 mg injection: 1 injection/week

Product Name:Victoza, Liraglutide	
Diagnosis	Type 2 diabetes, polycystic ovary syndrome
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 10 years of age or older

AND

2 - One of the following diagnoses, as confirmed by chart documentation or claims history:

- Type 2 diabetes mellitus with or without cardiovascular disease
- Polycystic ovary syndrome

AND

3 - One of the following:

3.1 Previous trial of metformin for at least 90 days within a 120-day, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

3.2 Documented intolerance or contraindication to metformin therapy

AND

4 - Dose requested does not exceed 1.8 mg/day

AND

5 - If the request is for liraglutide, prescriber has submitted medical justification for use of liraglutide (Victoza authorized generic) over brand name Victoza

Product Name:Victoza, Liraglutide	
Diagnosis	Metabolic-dysfunction associated steatotic liver disease (MASLD), Metabolic dysfunction associated steatohepatitis (MASH)
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 10 years of age or older

AND

2 - One of the following diagnosis:

- Metabolic dysfunction associated steatohepatitis (MASH)
- Metabolic dysfunction-associated steatotic liver disease (MASLD)

AND

3 - One of the following confirming the diagnosis (submission of medical records required)

3.1 FibroScan assessed liver stiffness (FAST) score greater than or equal to 0.67

OR

3.2 Patient is 35 years of age or older, with a Fibrosis-4 index (FIB-4) score between 2.67 and 3.47

OR

3.3 Liver biopsy

OR

3.4 MEFIB (magnetic resonance elastography [MRE] plus FIB-4) score with both of the following:

- FIB-4 score greater than or equal to 1.6
- MRE greater than or equal to 3.3 kPA

OR

3.5 MRE between 3.63 and 5 kPA

OR

3.6 MRI-PDFF*, MRE, and serum AST (MAST) score greater than or equal to 0.242

AND

4 - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist

AND

5 - Prescriber attests that patient does not have any of the following:

- Celiac disease
- Daily alcohol consumption exceeding 30 grams (2 standard drinks) per day
- Familial hypobetalipoproteinemia (FHBL)
- Hepatitis A, B, or C
- Lysosomal acid lipase (LAL) deficiency

- Wilson disease

AND

6 - Patient does not have history of any of the following in the past 90 days OR prescriber attests that alternate therapies are not appropriate for the patient and prescriber has a monitoring plan in place

- Amiodarone
- Glucocorticoids
- Methotrexate
- Synthetic estrogens
- Tamoxifen

AND

7 - Dose requested does not exceed 1.8 mg/day

AND

8 - If the request is for liraglutide, prescriber has submitted medical justification for use of liraglutide (Victoza authorized generic) over brand name Victoza

Notes	*MRI-PDFF= Magnetic Resonance Imaging Proton Density Fat Fracti on

Product Name:Victoza, Liraglutide	
Diagnosis	Type 2 diabetes, polycystic ovary syndrome, Metabolic-dysfunction associated steatotic liver disease (MASLD), Metabolic dysfunction associated steatohepatitis (MASH)
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of type 2 diabetes mellitus with or without cardiovascular disease, as confirmed by chart documentation or claims history

OR

1.2 Diagnosis of metabolic dysfunction associated steatohepatitis (MASH) OR metabolic dysfunction-associated steatotic liver disease (MASLD), as confirmed by chart documentation or claims history

OR

1.3 Diagnosis of polycystic ovary syndrome, as confirmed by chart documentation or claims history

AND

2 - History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Dose requested does not exceed 1.8 mg/day

AND

4 - If the request is for liraglutide, both of the following:

- Previous trial of brand name Victoza
- Prescriber has submitted medical justification for use of liraglutide (Victoza authorized generic) over brand name Victoza

Product Name:Soliqua	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 18 years of age or older

AND

3 - Previous trial with ONE of the following for at least 90 days in the past 120 days:

- A preferred* non-insulin injectable hypoglycemic
- A preferred* long-acting insulin

AND

4 - Dose requested does not exceed 60 units insulin glargine/20 mcg lixisenatide per day

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

Product Name:Soliqua	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - History of Soliqua for at least 90 days within the past 120 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

3 - Dose requested does not exceed 60 units insulin glargine/20 mcg lixisenatide per day

Product Name:Bydureon BCise	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)

- One additional preferred** GLP-1 receptor agonist

AND

3.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

OR

3.2 Medical justification for use of Bydureon BCise (exenatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

4 - Dose requested does not exceed 2 mg/week

Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Bydureon BCise	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 Receptor Agonist

AND

2.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 Receptor Agonist

OR

2.2 Medical justification for use of Bydureon BCise (exenatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

3 - History of Bydureon BCise for at least 84 days within the past 112 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

4 - Dose requested does not exceed 2 mg/week

Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Mounjaro	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

AND

3.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)

- One additional preferred** GLP-1 receptor agonist

OR

3.2 Medical justification for use of Mounjaro (tirzepatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

4 - Dose requested does not exceed 15 mg/week

Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Mounjaro	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)

- One additional preferred** GLP-1 receptor agonist

AND

2.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

OR

2.2 Medical justification for use of Mounjaro (tirzepatide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

3 - History of Mounjaro for at least 84 days within the past 112 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

4 - Dose requested does not exceed 15 mg/week

Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Rybelsus	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

AND

3.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

OR

3.2 Medical justification for use of Rybelsus (semaglutide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

4 - Dose requested does not exceed 1 tablet/day	
Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Rybelsus	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of at least 90 days at an optimized dose*, supported by claims history, chart documentation, or provider attestation including dates of trial to both of the following:

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

AND

2.1.2 Prescriber has submitted laboratory reports (e.g., HbA1c) with respective collection dates and times illustrating insufficient response to both of the following

- Ozempic (semaglutide) or Trulicity (dulaglutide)
- One additional preferred** GLP-1 receptor agonist

OR

2.2 Medical justification for use of Rybelsus (semaglutide) over Byetta (exenatide), Ozempic (semaglutide), Trulicity (dulaglutide), AND Victoza (liraglutide) (any medical justification regarding intolerance or adverse effects must be supported by documentation within submitted chart notes. Gastrointestinal adverse effects are not considered an intolerance as they are expected class effects)

AND

3 - History of Rybelsus for at least 90 days within the past 120 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

4 - Dose requested does not exceed 1 tablet/day

Notes	*See Table 1 in Background section **PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Xultophy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - Patient is 18 years of age or older

AND

3 - One of the following:

3.1 Trial and failure of Soliqua as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

3.2 Both of the following:

3.2.1 Medical justification for use of Xultophy over Soliqua

AND

3.2.2 Patient has had a previous trial of ONE of the following for at least 90 days in the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial:

- A preferred* non-insulin injectable hypoglycemic
- A preferred* long-acting insulin

AND

4 - Dose requested does not exceed 50 units insulin degludec/1.8 mg liraglutide per day

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

Product Name:Xultophy	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of type 2 diabetes mellitus, as confirmed by chart documentation or claims history

AND

2 - One of the following:

2.1 Patient has a prior history of Soliqua, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

OR

2.2 Medical justification for the use of Xultophy over Soliqua

AND

3 - History of Xultophy for at least 90 days within the past 120 days, confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

4 - Dose requested does not exceed 50 units insulin degludec/1.8 mg liraglutide per day

2 . Background

Benefit/Coverage/Program Information

Table 1: Optimized Dose

AGENT	OPTIMIZED DOSE
Byetta (exenatide)	10 mcg twice daily
Ozempic (semaglutide)	2 mg weekly
Trulicity (dulaglutide)	4.5 mg weekly
Victoza (liraglutide)	1.8 mg daily

3 . Revision History

Date	Notes
12/6/2024	Multiple criteria updates- Dx must be confirmed with documentation. Addition of MASLD, changes to look back period for reauths, brand V ictoza is preferred.

Gonadotropin-Releasing Hormone Agonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161375
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Medicaid - Community & State Indiana

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

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

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
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: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
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
- Unresectable
- Metastatic

AND

3 - Disease is androgen receptor positive (AR+)

Product Name:leuprolide acetate inj kit 5 mg/mL	
Diagnosis	Salivary Gland 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:leuprolide acetate inj kit 5 mg/mL	
Diagnosis	Uterine Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Low-grade endometrial stromal sarcoma (ESS)
- Adenosarcoma without sarcomatous overgrowth
- Estrogen receptor/progesterone receptor positive (ER/PR+) uterine sarcoma

Product Name:leuprolide acetate inj kit 5 mg/mL	
Diagnosis	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 therapy

Product Name:Lupron Depot, Lupron Depot-Ped, leuprolide acetate inj kit 5 mg/mL	
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:Lupron Depot, Lupron Depot-Ped, leuprolide acetate inj kit 5 mg/mL	
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
11/27/2024	Updated GPIs. Updated step therapy in CPP section as Fensolvi was moved to preferred and Lupron Depot Ped was moved to NP

Gralise, Horizant, and Lyrica CR

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132243
Guideline Name	Gralise, Horizant, and Lyrica CR
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

Product Name:Gralise	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of postherpetic neuralgia (PHN)

AND

3 - One of the following:

3.1 Previous trial and failure of immediate-release gabapentin for 90 days in the past 180 days

OR

3.2 Medical rationale for use of Gralise (gabapentin ER) over immediate-release gabapentin (Document medical rationale)

AND

4 - Both of the following:

4.1 The dose requested does not exceed 1800 mg/day

AND

4.2 The dose requested does not exceed one of the following:

- 300 mg strength - max of 1 tablet/day
- 450 mg strength - max of 1 tablet/day
- 600 mg strength -max of 2 tablets/day
- 750 mg strength - max of 2 tablets/day
- 900 mg strength - max of 2 tablets/day
- Titration pack - 1 pack/90 days

Product Name:Gralise	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Both of the following:

2.1 The dose requested does not exceed 1800 mg/day

AND

2.2 The dose requested does not exceed one of the following:

- 300 mg strength - max of 1 tablet/day
- 450 mg strength - max of 1 tablet/day
- 600 mg strength -max of 2 tablets/day
- 750 mg strength - max of 2 tablets/day
- 900 mg strength - max of 2 tablets/day
- Titration pack - 1 pack/90 days

Product Name:Horizant	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of postherpetic neuralgia (PHN)

AND

2.1.2 One of the following:

- Previous trial and failure of immediate-release gabapentin for 90 days in the past 180 days
- Medical rationale for use of Horizant (gabapentin ER) over immediate-release gabapentin (Document medical rationale)

OR

2.2 All of the following:

2.2.1 Diagnosis of moderate-to-severe primary restless legs syndrome (RLS)

AND

2.2.2 One of the following:

- Previous trial and failure of gabapentin IR, pramipexole, ropinirole or rotigotine patches for 90 days in the past 180 days
- Medical rationale for use of Horizant (gabapentin ER) over gabapentin IR, pramipexole, ropinirole and rotigotine patches (Document medical rationale)

AND

3 - Both of the following:

3.1 Dose requested does not exceed 1200 mg/day

AND

3.2 Dose requested does not exceed one of the following:

- 300 mg strength - max of 2 tablets/day
- 600 mg strength - max of 2 tablets/day

Product Name:Horizant	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Both of the following:

2.1 Dose requested does not exceed 1200 mg/day

AND

2.2 Dose requested does not exceed one of the following:

- 300 mg strength - max of 2 tablets/day
- 600 mg strength - max of 2 tablets/day

Product Name:Brand Lyrica CR, generic pregabalin ER	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2.1.2 Both of the following:

2.1.2.1 Dose requested does not exceed 330 mg/day

AND

2.1.2.2 Dose requested does not exceed one of the following:

- 82.5 mg strength - max of 3 tablets/day
- 165 mg strength - max of 1 tablet/day
- 330 mg strength - max of 1 tablet/day

OR

2.2 All of the following:

2.2.1 Diagnosis of postherpetic neuralgia (PHN)

AND

2.2.2 Both of the following:

2.2.2.1 Dose requested does not exceed 660 mg/day

AND

2.2.2.2 Dose requested does not exceed one of the following:

- 82.5 mg strength - max of 3 tablets/day
- 165 mg strength - max of 3 tablets/day
- 330 mg strength - max of 2 tablets/day

AND

3 - One of the following:

3.1 Previous trial and failure of immediate-release pregabalin for 90 days in the past 180 days

OR

3.2 Medical rationale for use of Lyrica CR (pregabalin ER) over immediate-release pregabalin (Document medical rationale)

Product Name:Brand Lyrica CR, generic pregabalin ER	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of diabetic peripheral neuropathy (DPN)

AND

2.1.2 Both of the following:

2.1.2.1 Dose requested does not exceed 330 mg/day

AND

2.1.2.2 Dose requested does not exceed one of the following:

- 82.5 mg strength - max of 3 tablets/day
- 165 mg strength - max of 1 tablet/day
- 330 mg strength - max of 1 tablet/day

OR

2.2 All of the following:

2.2.1 Diagnosis of postherpetic neuralgia (PHN)

AND

2.2.2 Both of the following:

2.2.2.1 Dose requested does not exceed 660 mg/day

AND

2.2.2.2 Dose requested does not exceed one of the following:

- 82.5 mg strength - max of 3 tablets/day
- 165 mg strength - max of 3 tablets/day

- 330 mg strength - max of 2 tablets/day

2 . Revision History

Date	Notes
9/1/2023	Updated T/F for Horizant RLS to include gabapentin IR and look bac k of 90 in the last 180 days

Growth Hormones

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161934
Guideline Name	Growth Hormones
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Serostim, Zomacton	
Diagnosis	Pediatric Patients (Less than 18 Years of Age)
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following:	

1.1 ONE of the following diagnoses (submission of biochemical evidence or other applicable testing supporting the diagnosis is required):

1.1.1 Growth-hormone deficiency

OR

1.1.2 BOTH of the following:

- Noonan syndrome
- The request is for Norditropin

OR

1.1.3 Prader-Willi syndrome

OR

1.1.4 BOTH of the following:

- Renal function impairment associated with growth failure
- The request is for Nutropin AQ Nuspin

OR

1.1.5 BOTH of the following:

- Short stature homeobox-containing gene (SHOX) deficiency
- The request is for Humatrope or Zomacton

OR

1.1.6 Small for gestational age (SGA)

OR

1.1.7 Turner syndrome

OR

1.2 ALL of the following:

1.2.1 Diagnosis of idiopathic short stature

AND

1.2.2 Submission of growth chart confirming BOTH of the following:

- Height measurement of more than 2.0 standard deviations below population mean for given age
- Growth rate of 5 cm (centimeters)/year or less prior to starting growth hormone therapy

AND

2 - Submission of a radiology report showing BOTH of the following:

- Bone age of 14-15 or less in patients assigned female at birth, 16-17 or less in patients assigned male at birth
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

3 - Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

AND

4 - If the request is non-preferred*, ONE of the following:

4.1 Medication is requested for a product-specific indication**

OR

4.2 Prescriber has provided valid medical justification for the use of the non-preferred medication over a preferred medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html **Humatrope and Zomactan are non-preferred unless the patient has a diagnosis of SHOX deficiency, Nutropin AQ is non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Serostim, Zomacton	
Diagnosis	Pediatric Patients (Less than 18 Years of Age)
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has ONE of the following diagnoses:

- Growth-hormone deficiency
- Noonan syndrome (Norditropin only)
- Prader-Willi syndrome
- Renal function impairment associated with growth failure (Nutropin AQ only)
- Short stature homeobox-containing gene (SHOX) deficiency (Humatrope or Zomacton only)
- Small for gestational age (SGA)
- Turner syndrome

AND

2 - Patient has a history of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3 - Submission of a radiology report showing BOTH of the following:

- Bone age of 14-15 or less in patients assigned female at birth, 16-17 or less in patients assigned male at birth
- If patient is nearing or at puberty (estimated age range 10-17 years of age) open epiphyses

AND

4 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate

AND

5 - ONE of the following:

5.1 Growth rate of 2 to 2.5 cm/year or more with growth hormone therapy

OR

5.2 BOTH of the following:

- The patient's diagnosis is idiopathic short stature
- The provider has documented valid medical justification for continued use

AND

6 - If the request is non-preferred*, ONE of the following:

6.1 Medication is requested for a product-specific indication**

OR

6.2 Prescriber has provided valid justification for the use of the non-preferred medication over a preferred medication

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html **Humatrope and Zomactan are non-preferred unless the patient has a diagnosis of SHOX deficiency, Nutropin AQ is non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Serostim, Zomacton	
Diagnosis	Adult Patients (18 Years of Age or Older) or Patients with Closed Epiphyses
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is transitioning from pediatric growth hormone therapy, and ALL of the following:

1.1.1 Patient has reached adult height

AND

1.1.2 Patient stopped growth hormone therapy for at least 1 month before re-evaluation of the need for continued therapy

AND

1.1.3 Prescriber has determined that the patient will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

OR

1.2 BOTH of the following:

1.2.1 Patient has a diagnosis of adult growth-hormone deficiency

AND

1.2.2 Biochemical evidence or other applicable testing supporting the diagnosis

AND

2 - If the request is non-preferred*, ONE of the following:

2.1 Medication is requested for a product-specific indication**

OR

2.2 Prescriber has provided valid justification for the use of the non-preferred medication over a preferred medication

AND

3 - Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html **Humatrope and Zomactan are non-preferred unless the patient has a diagnosis of SHOX deficiency, Nutropin AQ is non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency.

Product Name:Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Serostim, Zomacton

Diagnosis	Adult Patients (18 Years of Age or Older) or Patients with Closed Epiphyses
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has previously been transitioned from pediatric growth hormone therapy

OR

1.2 Patient has a diagnosis of adult growth hormone deficiency

AND

2 - Patient has a history of growth hormone therapy for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

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

3.1 Medication is requested for a product-specific indication**

OR

3.2 Prescriber has provided valid justification for the use of the non-preferred medication over a preferred medication

AND

4 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor

recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html **Humatrope and Zomactan are non-preferred unless the patient has a diagnosis of SHOX deficiency, Nutropin AQ is non-preferred unless patient has a diagnosis of growth failure associated with chronic renal insufficiency.

Product Name:Serostim	
Diagnosis	HIV-Associated Wasting or Cachexia
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)-associated wasting or cachexia

AND

2 - Patient has failed one other therapy for HIV-associated wasting or cachexia (e.g., anabolic steroids, or for adults 18 years or older: dronabinol, megestrol)

AND

3 - Patient must be on AIDS (acquired immunodeficiency syndrome)/HIV anti-retroviral therapy

AND

4 - Patient must have ONE of the following:

- Involuntary weight loss of greater than 10% of baseline total body weight
- Body cell mass of less than 30%

AND

5 - Patient must have a quantitative measurement of lean body mass using dual energy X-ray absorptiometry (DEXA) or bioelectric impedance analysis (BIA) prior to initiation of therapy

AND

6 - Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

Product Name:Serostim	
Diagnosis	HIV-Associated Wasting or Cachexia
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV (human immunodeficiency virus)-associated wasting or cachexia

AND

2 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3 - Documentation stating patient is continuing to utilize AIDS (acquired immunodeficiency syndrome)/HIV antiretroviral therapy

AND

4 - Documentation of the patient's current total body weight or lean body mass, showing total

body weight or lean body mass has increased from treatment baseline during treatment period

AND

5 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate

Product Name:Increlex	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented diagnosis of growth failure due to ONE of the following:

- Severe primary insulin-like growth factor-1 deficiency (primary IGFD)
- Growth hormone (GH) gene deletion with acquired neutralizing antibodies to GH

AND

2 - Submission of radiology report confirming open epiphyses

AND

3 - Patient is greater than or equal to 2 years of age and less than 18 years of age

AND

4 - Documentation of baseline height and weight

Product Name:Increlex

Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is less than 18 years of age

AND

3 - Submission of radiology report confirming open epiphyses

AND

4 - ONE of the following:

- Documentation of improvement in annualized growth velocity (AGV)
- Provider has documented valid medical justification for continued use

Product Name:Ngenla	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of growth failure due to growth hormone deficiency (documentation of biochemical evidence or other applicable testing supporting the diagnosis is required)

AND

2 - BOTH of the following:

- Patient is at least 3 years of age
- Patient is less than 18 years of age

AND

3 - Submission of a radiology report showing BOTH of the following:

- Bone age of 14-15 or less in females, 16-17 or less in males
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

4 - Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

AND

5 - ONE of the following:

5.1 Trial and failure of Skytrofa (lonapegsomatropin) or Sogroya (somapacitan), confirmed by claims history or chart documentation

OR

5.2 Prescriber has documented valid medical justification as to why Skytrofa (lonapegsomatropin) or Sogroya (somapacitan), are unsuitable for use

Product Name:Ngenla

Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is less than 18 years of age

AND

3 - Submission of a radiology report showing BOTH of the following:

- Bone age of 14-15 or less in females, 16-17 or less in males
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

4 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate

Product Name:Skytrofa	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of growth failure due to growth hormone deficiency (submission of biochemical evidence or other applicable testing supporting the diagnosis is required)

AND

2 - Patient is less than 18 years of age

AND

3 - Patient weighs 11.5 kg (kilograms) or greater

AND

4 - Submission of radiology report showing BOTH of the following:

- Bone age of 14-15 or less in females, 16-17 or less in males
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

5 - Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

AND

6 - ONE of the following:

- Trial and failure of ONE preferred* somatropin product, confirmed by claims history or chart documentation
- Prescriber has documented valid medical justification as to why the available preferred* somatropin agent(s) are unsuitable for use

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

Product Name:Skytrofa	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is less than 18 years of age

AND

3 - Submission of radiology report showing BOTH of the following:

- Bone age of 14-15 or less in females, 16-17 or less in males
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

4 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate

Product Name:Sogroya	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of growth failure due to growth hormone deficiency (submission of biochemical evidence or other applicable testing supporting the diagnosis is required)

AND

1.2 BOTH of the following:

- Patient is at least 2.5 years of age
- Patient is less than 18 years of age

AND

1.3 Submission of a radiology report showing BOTH of the following:

- Bone age of 14-15 or less in females, 16-17 or less in males
- If patient is nearing or at puberty (estimated age range 10-17 years of age), open epiphyses

AND

1.4 Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

AND

1.5 ONE of the following:

- Trial and failure of ONE preferred* somatropin product, confirmed by claims history or chart documentation
- Prescriber has documented valid medical justification as to why all of the available preferred* somatropin agent(s) are unsuitable for use

OR

2 - ALL of the following:

2.1 Diagnosis of adult growth hormone deficiency (documentation of biochemical evidence or other applicable testing supporting the diagnosis is required)

AND

2.2 Patient is 18 years of age or older

AND

2.3 Prescriber attestation that they have performed all necessary testing to ensure there are no expanding intracranial lesions or tumors prior to initiating growth hormone therapy

AND

2.4 ONE of the following:

- Trial and failure of ONE preferred* somatropin product, confirmed by claims history or chart documentation
- Prescriber has documented valid medical justification as to why all of the available preferred* somatropin agent(s) are unsuitable for use

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

Product Name:Sogroya	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Patient is less than 18 years of age and BOTH of the following:

2.1.1 Submission of a radiology report showing a bone age of 14-15 or less in females, 16-17 or less in males

AND

2.1.2 If patient is nearing or at puberty (estimated age range 10-17 years of age), submission of a radiology report showing open epiphyses

OR

2.2 Patient is 18 years of age or older

AND

3 - Prescriber attestation that they are continuing to monitor the patient for intracranial tumor recurrence, progression of underlying disease, or malignant transformation of skin lesions, if appropriate

Product Name:Voxzogo	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented diagnosis of achondroplasia

AND

2 - Submission of radiology report confirming open epiphyses

AND

3 - Patient is less than 18 years of age

AND

4 - Documentation of baseline height and weight

Product Name:Voxzogo	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient is less than 18 years of age

AND

3 - Submission of radiology report confirming open epiphyses

AND

4 - ONE of the following:

- Documentation of improvement in annualized growth velocity (AGV) of 1.5 cm/year
- Provider has documented valid medical justification for continued use

2 . Revision History

Date	Notes
12/11/2024	Removed Saizen/Saizenprep. Updated criteria to reflect Sogroya is p referred.

H2 Receptor Antagonists

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137625
Guideline Name	H2 Receptor Antagonists
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient is under 12 years of age

OR

2 - Patient is unable to swallow tablets

2 . Revision History

Date	Notes
12/11/2023	Updated age requirement in criteria.

Haegarda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147297
Guideline Name	Haegarda
Formulary	• Medicaid - Community & State Indiana

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	Copy core

HCG

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138448
Guideline Name	HCG
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	2/1/2024

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	

Hematinic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124339
Guideline Name	Hematinic Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Aranesp	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has anemia with ONE of the following:

- Chronic kidney disease (CKD)
- Myelodysplastic syndrome (MDS)

OR

2 - BOTH of the following:

2.1 Patient has chemotherapy-induced anemia with non-myeloid malignancies/neoplastic disease

AND

2.2 Patient has at least 2 additional months of chemotherapy planned

Product Name:Epogen	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has anemia with ONE of the following:

- Chronic kidney disease
- Congestive heart failure
- Hepatitis C for a patient receiving ribavirin with interferon alfa or ribavirin with peginterferon alfa
- HIV (human immunodeficiency virus)-infected patient receiving zidovudine
- Multiple myeloma
- Myelodysplastic syndrome (MDS)
- Myelofibrosis
- Neoplastic disease not associated with chemotherapy
- Rheumatoid arthritis
- Transfusion-dependent beta thalassemia

OR

1.2 Patient has anemia associated with radiation therapy

OR

1.3 Patient has anemia due to trauma or postsurgical event, transfusion refusal (e.g., Jehovah's Witness)

OR

1.4 Patient has anemia of prematurity

OR

1.5 Request is for blood unit collection in preparation for autotransfusion

OR

1.6 BOTH of the following:

1.6.1 Patient has chemotherapy-induced anemia with non-myeloid malignancies/neoplastic disease

AND

1.6.2 Patient has at least 2 additional months of chemotherapy planned

OR

1.7 Patient has chronic anemia in neoplastic disease not associated with chemotherapy

OR

1.8 Request is for iron overload transfusion

OR

1.9 Patient has post-partum anemia (during the puerperium)

OR

1.10 Request is for reduction in allogenic blood transfusions in an anemic surgical patient (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss

Product Name:Mircera	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has anemia with chronic kidney disease

AND

2 - ONE of the following:

2.1 Trial and failure of all preferred* agents

OR

2.2 Prescriber has submitted valid medical rationale for the use of Mircera over all preferred* agents

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

Product Name:Procrit	
Approval Length	6 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient has anemia with ONE of the following:

- Chronic kidney disease
- Congestive heart failure
- Hepatitis C for a patient receiving ribavirin with interferon alfa or ribavirin with peginterferon alfa
- HIV (human immunodeficiency virus)-infected patient receiving zidovudine
- Multiple myeloma
- Myelodysplastic syndrome (MDS)
- Myelofibrosis
- Neoplastic disease not associated with chemotherapy
- Rheumatoid arthritis
- Transfusion-dependent beta thalassemia

OR

1.2 Patient has anemia associated with radiation therapy

OR

1.3 Patient has anemia due to trauma or postsurgical event, transfusion refusal (e.g., Jehovah's Witness)

OR

1.4 Patient has anemia of prematurity

OR

1.5 Request is for blood unit collection in preparation for autotransfusion

OR

1.6 BOTH of the following:

1.6.1 Patient has chemotherapy-induced anemia with non-myeloid malignancies/neoplastic disease

AND

1.6.2 Patient has at least 2 additional months of chemotherapy planned

OR

1.7 Patient has chronic anemia in neoplastic disease not associated with chemotherapy

OR

1.8 Request is for iron overload transfusion

OR

1.9 Patient has post-partum anemia (during the puerperium)

OR

1.10 Request is for reduction in allogenic blood transfusions in an anemic surgical patient (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss

AND

2 - ONE of the following:

2.1 Trial and failure of all preferred* agents

OR

2.2 Prescriber has submitted valid medical rationale for the use of Procrit over all preferred* agents

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

Product Name:Retacrit	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has anemia with ONE of the following:

- Chronic kidney disease
- Congestive heart failure
- Hepatitis C for a patient receiving ribavirin with interferon alfa or ribavirin with peginterferon alfa
- HIV (human immunodeficiency virus)-infected patient receiving zidovudine
- Multiple myeloma
- Myelodysplastic syndrome (MDS)
- Myelofibrosis
- Neoplastic disease not associated with chemotherapy
- Rheumatoid arthritis
- Transfusion-dependent beta thalassemia

OR

2 - Patient has anemia associated with radiation therapy

OR

3 - Patient has anemia due to trauma or postsurgical event, transfusion refusal (e.g., Jehovah's Witness)

OR

4 - Patient has anemia of prematurity

OR

5 - Request is for blood unit collection in preparation for autotransfusion

OR

6 - BOTH of the following:

6.1 Patient has chemotherapy-induced anemia with non-myeloid malignancies/neoplastic disease

AND

6.2 Patient has at least 2 additional months of chemotherapy planned

OR

7 - Patient has chronic anemia in neoplastic disease not associated with chemotherapy

OR

8 - Request is for iron overload transfusion

OR

9 - Patient has post-partum anemia (during the puerperium)

OR **10** - Request is for reduction in allogenic blood transfusions in an anemic surgical patient (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss

2 . Revision History

Date	Notes
4/17/2023	Removed NP language from Epogen to match policy.

Hepatitis B Agents

Prior Authorization Guideline

Guideline ID	GL-146287
Guideline Name	Hepatitis B Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Vemlidy	
Approval Length	Lifetime approval
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient has a diagnosis of chronic viral hepatitis type B with documentation of ALL of the following:

- Compensated liver disease
- Negative HIV status
- Creatinine clearance greater than 15 mL/minute (milliliters per minute)

AND

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

- Gastroenterologist
- Hepatologist
- Infectious disease specialist

AND

3 - Patient is 6 years of age or older

AND

4 - Patient weighs at least 25 kilograms (kg)

AND

5 - ONE of the following:

- Previous trial and failure of entecavir at a maximum indication-based dose
- Prescriber has submitted valid medical rationale for the use of Vemlidy (tenofovir alafenamide) over entecavir

2 . Revision History

Date	Notes
4/29/2024	Updated minimum age requirement and added weight requirement; F ormatting updates.

Hetlioz

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124146
Guideline Name	Hetlioz
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Hetlioz capsules, generic tasimelteon	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of non-24-hour sleep-wake disorder and all of the following:

1.1.1 Patient is 18 years of age or older

AND

1.1.2 Dose does not exceed 20mg daily

OR

1.2 Diagnosis of nighttime sleep disturbances in patients with Smith-Magenis syndrome and all of the following:

1.2.1 Patient is 3 years of age or older

AND

1.2.2 One of the following:

- Dose does not exceed 20mg daily for those ages 3 years and older weighing more than 28kg
- Dose does not exceed 0.7mg/kg/dose daily for those ages 3 to 15 years weighing less than 28kg

Product Name:Hetlioz suspension	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of non-24-hour sleep-wake disorder and all of the following:

1.1.1 Patient is 18 years of age or older

AND

1.1.2 Dose does not exceed 20mg daily

AND

1.1.3 Patient is unable to swallow capsule formulation

OR

1.2 Diagnosis of nighttime sleep disturbances in patients with Smith-Magenis syndrome and all of the following:

1.2.1 Patient is 3 years of age or older

AND

1.2.2 One of the following:

- Dose does not exceed 20mg daily for those ages 3 years and older weighing more than 28kg
- Dose does not exceed 0.7mg/kg/dose daily for those ages 3 to 15 years weighing less than 28kg

AND

1.2.3 Patient is between 3 and 17 years of age OR unable to swallow capsule formulation

2 . Revision History

Date	Notes
4/3/2023	Added generic caps

HIV

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-203227
Guideline Name	HIV
Formulary	• Medicaid - Community & State Colorado • Medicaid - Community & State Indiana • Medicaid - Community & State Maryland • Medicaid - Community & State New Mexico • Medicaid - Community & State Pennsylvania CHIP

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

Product Name:Brand Viread, generic tenofovir disoproxil fumarate	
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following diagnoses: • HIV (human immunodeficiency virus) • Hepatitis B	

• HIV post-exposure prophylaxis (PEP)	
Notes	Approval Duration: 12 months for HIV and hepatitis B; 4 weeks for PEP.

Product Name:Brand Truvada, generic emtricitabine/tenofovir disoproxil fumarate*	
Guideline Type	Prior Authorization
Approval Criteria **1** - ONE of the following diagnoses: • HIV (human immunodeficiency virus) • Pre-exposure prophylaxis (PrEP) • HIV post-exposure prophylaxis (PEP)	
Notes	Approval Duration: 12 months for HIV and PrEP; 4 weeks for PEP. *This criteria does not apply to Maryland, the medication is open access.

Product Name:Aptivus, Viracept, nevirapine, nevirapine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of HIV (human immunodeficiency virus)	

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. *See Table 1 in Background for PDL links.

Product Name:(All other HIV medications which do not have criteria above) Brand Selzentry, generic maraviroc, Fuzeon, Tivicay, Tivicay PD, Isentress, Isentress HD, Brand Reyataz, generic atazanavir, Brand Prezista, generic darunavir, Brand Lexiva, generic fosamprenavir, Brand Norvir, generic ritonavir, Brand Ziagen, generic abacavir, Brand Emtriva, generic emtricitabine, Brand Epivir, generic lamivudine, stavudine, Brand Retrovir, generic zidovudine, Pifeltro, Brand Sustiva, generic efavirenz, Brand Intelence, generic etravirine, Edurant, Tybost, Brand Epzicom, generic abacavir/lamivudine, Evotaz, Dovato, Prezcobix, Cimduo, Brand Combivir, generic lamivudine/zidovudine, Brand Kaletra, generic lopinavir/ritonavir, Triumeq, Triumeq PD, Trizivir, Delstrigo, efavirenz/emtricitabine/tenofovir, Brand Symfi Lo, Brand Symfi, generic efavirenz/lamivudine/tenofovir, Odefsey, Symtuza, Juluca, Biktarvy, Complera, Genvoya

Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 If the request is for a preferred* medication, ONE of the following diagnoses:

- HIV (human immunodeficiency virus)
- HIV post-exposure prophylaxis (PEP)

OR

1.2 If the request is for a non-preferred* medication, ONE of the following:

1.2.1 Diagnosis of post-exposure prophylaxis (PEP)

OR

1.2.2 BOTH of the following:

1.2.2.1 Diagnosis of HIV (human immunodeficiency virus)

AND

1.2.2.2 ONE of the following:

1.2.2.2.1 Provider gives a reason or special circumstance as to why the patient is not an appropriate candidate for three preferred* products (please specify why the patient is not a candidate)

OR

1.2.2.2.2 Continuation of current therapy

Notes	This guideline does NOT include Descovy and Rukobia. These medic ations have drug specific guidelines. Approval Duration: 12 months for HIV; 4 weeks for PEP.

	*See Table 1 in Background for PDL links.

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 **MD:** https://www.uhcprovider.com/en/health-plans-by-state/maryland-health-plans/md-comm-plan-home/md-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 **IN:** https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-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	Combined formularies, but removed NY/NY EPP from markets in scope as HIV drugs are moving to open access for these markets. Removed Brand Atripla as a target (obsolete). Moved Biktarvy, Complera, Genvoya, and Stribild as targets to this guideline (previously all stand alone gls). Updated criteria for non-preferred requests. Updated list of PDL links in background section. Updated notes, where applicable. Minor cosmetic updates.

HMG CoA Reductase Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-132806
Guideline Name	HMG CoA Reductase Inhibitors
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2023

1 . Criteria

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

Approval Criteria

1 - Patient is 10 years of age or older AND less than 12 years of age

OR

2 - Patient is unable to swallow tablets

2 . Revision History

Date	Notes
9/8/2023	New

Hycamtin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138238
Guideline Name	Hycamtin
Formulary	• Medicaid - Community & State Indiana

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

Ibrance

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147459
Guideline Name	Ibrance
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/16/2024	Specified type of unresectable WD-DDLS to be “retroperitoneal”.

Iclusig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138750
Guideline Name	Iclusig
Formulary	• Medicaid - Community & State Indiana

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.

Idhifa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161232
Guideline Name	Idhifa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/25/2024	Updated initial auth criteria for AML based on NCCN recommendations; Minor cosmetic updates.

Igalmi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148844
Guideline Name	Igalmi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Igalmi	
Approval Length	5 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Bipolar I or II disorder
- Schizophrenia

AND

2 - Member is 18 years of age and older

AND

3 - Prescriber attests to both of the following:

3.1 Patient is currently or will be maintained on maintenance psychotropic therapy

AND

3.2 Medication will be administered under the supervision of a healthcare provider

AND

4 - Dose requested does not exceed 2 sublingual films per 30-day period

2 . Revision History

Date	Notes
6/26/2024	New guideline

Imbruvica

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164469
Guideline Name	Imbruvica
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/29/2025	Added rituximab to RHyperCVAD and minor formatting changes

Immunoglobulin A Nephropathy (IgAN) Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-141428
Guideline Name	Immunoglobulin A Nephropathy (IgAN) Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

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

Approval Criteria

1 - The patient is 18 years of age or older

AND

2 - Diagnosis of proteinuria associated with immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy (must submit evidence of biopsy)

AND

3 - Documentation supporting ONE of the following must be submitted:

3.1 Proteinuria greater than or equal to 1 g/day (gram per day)

OR

3.2 Urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g (grams per gram)

AND

4 - ONE of the following:

4.1 The patient has had a trial and failure of at least 90 days of drug therapy with an ACE inhibitor or ARB agent

OR

4.2 Prescriber has submitted valid medical justification for the use of Filspari (sparsentan) over ACE inhibitors and/or ARB agents

AND

5 - The patient is enrolled in the Filspari (sparsentan) REMS program and prescriber is monitoring in accordance with REMS requirements

AND

6 - The patient will not be using concomitantly with any of the following: ACE inhibitors, ARB agents, endothelin receptor antagonists (ERAs), aliskiren

AND

7 - Requested quantity does not exceed 1 tablet/day (200 mg or 400 mg strength tablets)

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

Approval Criteria

1 - History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - The patient will not be using concomitantly with any of the following: ACE inhibitors, ARB agents, endothelin receptor antagonists (ERAs), aliskiren

AND

3 - Requested quantity does not exceed 1 tablet/day (200 mg or 400 mg strength tablets)

Product Name:Tarpeyo	
Approval Length	Up to a maximum of 9 months
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient is 18 years of age or older

AND

2 - Diagnosis of proteinuria associated with immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy (must submit evidence of biopsy)

AND

3 - Documentation supporting ONE of the following must be submitted:

3.1 Proteinuria greater than or equal to 1 g/day (gram per day)

OR

3.2 Urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g (grams per gram)

AND

4 - ONE of the following:

4.1 The patient has had a trial and failure of at least 90 days of drug therapy with an ACE inhibitor or ARB agent

OR

4.2 Prescriber has submitted valid medical justification for the use of Tarpeyo (budesonide) over ACE inhibitors and/or ARB agents

AND

5 - Requested quantity does not exceed 4 capsules/day

AND

6 - Requested length of therapy does not exceed 9 months total

2 . Revision History

Date	Notes
2/12/2024	New guideline

Inbrija

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147441
Guideline Name	Inbrija
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/15/2024	Revised initial authorization to 12 months.

Injectable and Transdermal Antipsychotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161614
Guideline Name	Injectable and Transdermal Antipsychotics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:(All Antipsychotics) Abilify Asimtufii, Abilify Maintena, Aristada, Aristada Initio, Brand Zyprexa inj, generic olanzapine inj, Zyprexa Relprevv, Erzofri, Invega Sustenna, prochlorperazine inj, Brand Risperdal Consta, generic risperidone ER inj, Rykindo, Perseris, Uzedy, Secuado, chlorpromazine inj, fluphenazine inj, fluphenazine decanoate, Brand Haldol decanoate, Generic haloperidol decanoate, haloperidol lactate inj, Generic ziprasidone mesylate injection, Brand Geodon injection, Invega Trinza, Invega Hafyera	
Diagnosis	Duplicate Therapy with Another Antipsychotic
Therapy Stage	Initial Authorization
Guideline Type	Drug Utilization Review
Approval Criteria	

1 - ONE of the following:

1.1 The patient has had metabolic monitoring labs obtained within the past 12 months (with a 6-months grace period), confirmed by claims/medical history or chart documentation

OR

1.2 The patient is new to antipsychotic therapy and will be obtaining baseline metabolic labs within 4 months of initiating therapy *

AND

2 - One of the following:

2.1 The patient will be utilizing the requested antipsychotic as monotherapy

OR

2.2 The patient will be utilizing the requested antipsychotic agent as part of a duplicate antipsychotic regimen and ONE of the following:

2.2.1 Evidence of duplication of therapy with the requested antipsychotic agents for 90 of the past 120 days, confirmed by claims history or chart documentation

OR

2.2.2 All of the following:

- Diagnosis of psychosis
- Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist
- History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics
- History of at least 4 weeks of therapy with clozapine (unless contraindication, allergy, or intolerance to clozapine therapy)

OR

2.3 All of the following:

2.3.1 Diagnosis of depressed mood disorder

AND

2.3.2 BOTH of the following:

- At least one of the antipsychotics in the duplicate therapy regimen has an indication for depressed mood disorder
- The patient will be utilizing an antidepressant concurrently with the requested antipsychotic regimen

AND

2.3.3 Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist

AND

2.3.4 History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics

OR

2.4 ALL of the following:

2.4.1 Diagnosis of ONE of the following:

- Bipolar affective disorder
- Unspecified episodic mood disorder

AND

2.4.2 Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist

AND

2.4.3 History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics

OR

2.5 The agents involved in the therapeutic duplication are being cross tapered *

AND

3 - Patient is not utilizing more than 2 antipsychotics concurrently

Notes	*Approval Length – 90 days for cross taper, 4 months for patients new to antipsychotic therapy, 6 months for initial approval and not new to antipsychotic therapy

Product Name:(All Antipsychotics) Abilify Asimtufii, Abilify Maintena, Aristada, Aristada Initio, Brand Zyprexa inj, generic olanzapine inj, Zyprexa Relprevv, Erzofri, Invega Sustenna, prochlorperazine inj, Brand Risperdal Consta, generic risperidone ER inj, Rykindo, Perseris, Uzedy, Secuado, chlorpromazine inj, fluphenazine inj, fluphenazine decanoate, Brand Haldol decanoate, Generic haloperidol decanoate, haloperidol lactate inj, Generic ziprasidone mesylate injection, Brand Geodon injection, Invega Trinza, Invega Hafyera	
Diagnosis	Duplicate Therapy with Another Antipsychotic
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Drug Utilization Review

Approval Criteria

1 - History of the requested agent(s) for 90 of the past 120 days

AND

2 - The patient has had metabolic monitoring labs obtained within the past 12 months (with a 6-months grace period), confirmed by claims/medical history or chart documentation

AND

3 - One of the following:

3.1 The patient will be utilizing the requested antipsychotic as monotherapy

OR

3.2 The patient will be utilizing the requested antipsychotic agent as part of a duplicate antipsychotic regimen and there is evidence of duplication of therapy with the requested antipsychotic agents for 90 of the past 120 days, confirmed by claims history or chart documentation

AND

4 - Patient is not utilizing more than 2 antipsychotics concurrently

Product Name:(All Antipsychotics) Abilify Asimtufii, Abilify Maintena, Aristada, Aristada Initio, Brand Zyprexa inj, generic olanzapine inj, Zyprexa Relprevv, Erzofri, Invega Sustenna, prochlorperazine inj, Brand Risperdal Consta, generic risperidone ER inj, Rykindo, Perseris, Uzedy, Secuado, chlorpromazine inj, fluphenazine inj, fluphenazine decanoate, Brand Haldol decanoate, Generic haloperidol decanoate, haloperidol lactate inj, Generic ziprasidone mesylate injection, Brand Geodon injection, Invega Trinza, Invega Hafyera

Diagnosis	Age Limit Exception*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been

tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e. clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - All of the following:

2.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 ONE of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient
- The request is for continuation of therapy from another plan or following inpatient therapy

AND **3.3** One of the following: **3.3.1** Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition **OR** **3.3.2** The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits **AND** **3.4** If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	*These criteria come from the Non- Drug Specific PA policy

2 . Background

Benefit/Coverage/Program Information
Table 1 - Adequate Dose

Description	Adequate Dose
ARIPIPRAZOLE	>/=5 mg/day
ASENAPINE	>/= 10 mg/day
BREXPIPRAZOLE	>= 2 mg/day
CARIPRAZINE	>/= 1.5 mg/day
CHLORPROMAZINE HCL	>/= 30 mg/day
CLOZAPINE	>/=300 mg/day
FLUPHENAZINE HCL	>/= 1 mg/day
HALOPERIDOL	>/= 1 mg/day
HALOPERIDOL LACTATE	>/= 1 mg/day
ILOPERIDONE	>/= 12 mg/day
LOXAPINE SUCCINATE	>/= 20 mg/day
LUMATEPERONE	>/= 42 mg/day
LURASIDONE HCL	>/= 40 mg/day
MOLINDONE	>/= 15 mg/day
OLANZAPINE	>/= 10 mg/day
OLANZAPINE + FLUOXETINE	>/= 6/25 mg/day
OLANZAPINE + SAMIDORPHAN	>/= 10/10 mg/day
PALIPERIDONE	>/=3 mg/day
PERPHENAZINE	>/= 12 mg/day
PERPHENAZINE/AMITRIPTYLINE	>/= 12 mg/day (perphenazine component)
PIMOZIDE	>/= 1 mg/day
PROCHLORPERAZINE EDISYLATE/MALEATE	>/= 15 mg/day
QUETIAPINE	>/= 300 mg/day

RISPERIDONE	>/=2 mg/day
THIORIDAZINE HCL	>/= 150 mg/day
THIOTHIXENE	>/= 6 mg/day
TRIFLUOPERAZINE HCL	>/= 2 mg/day
ZIPRASIDONE	>/= 80 mg/day

3 . Revision History

Date	Notes
12/3/2024	Added Erzofri. Updated note language in Age Limit Exception section .

Inlyta

Prior Authorization Guideline

Guideline ID	GL-161159
Guideline Name	Inlyta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/21/2024	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-123560
Guideline Name	Inqovi
Formulary	• Medicaid - Community & State Indiana

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

Inrebic

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-117342
Guideline Name	Inrebic
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2023

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
11/28/2022	Copy NY

Insulin Pen Needles and Syringes

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161982
Guideline Name	Insulin Pen Needles and Syringes
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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 link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

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 . Revision History

Date	Notes
12/12/2024	Updated GPIs

Iqirvo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161349
Guideline Name	Iqirvo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/26/2024	New program.

Iressa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136328
Guideline Name	Iressa
Formulary	• Medicaid - Community & State Indiana

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

Iron Chelators

Prior Authorization Guideline

Guideline ID	GL-109711
Guideline Name	Iron Chelators
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2022

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
7/22/2022	Updated coverage criteria for Ferriprox per changes to the FDA appr oved label. Added generic deferiprone 1000 mg tablet. Clarified listin g of generics throughout guideline.

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

Isturisa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-109317
Guideline Name	Isturisa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2022

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

Itovebi

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-147140
Guideline Name	Iwilfin
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/7/2024	New guideline

Jakafi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164483
Guideline Name	Jakafi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/29/2025	Multiple criteria updates, including new criteria for Myeloproliferative Neoplasms. Updated auth length for multiple dx.

Jaypirca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147445
Guideline Name	Jaypirca
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/16/2024	Added criteria for CLL/SLL.

Jesduvroq (daprodustat)

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137548
Guideline Name	Jesduvroq (daprodustat)
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Jesduvroq	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chronic kidney disease

AND

2 - Patient has been receiving dialysis for at least four months

AND

3 - Patient is 18 years of age or older

AND

4 - ONE of the following

- Patient has tried and failed one erythropoiesis-stimulating agent (ESA) (e.g., Aranesp, Epogen, Retacrit, Mircera, Procrit), confirmed by claims history or chart documentation
- Prescriber has submitted valid medical justification for the use of Jesduvroq (daprodustat) over all ESA agents listed above

AND

5 - Documentation patient has a pretreatment hemoglobin of less than 11 grams per deciliter (g/dL)

AND

6 - Prescribed by, or in consultation with, a nephrologist

AND

7 - Prescriber attests that patient will not be utilizing Jesduvroq (daprodustat) concomitantly with an ESA agent (e.g., Aranesp, Epogen, Retacrit, Mircera, Procrit)

Product Name:Jesduvroq	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Patient has tried and failed an erythropoiesis-stimulating agent (ESA) (e.g., Aranesp, Epogen, Retacrit, Mircera, Procrit), confirmed by claims history or chart documentation
- Prescriber has submitted valid medical justification for the use of Jesduvroq (daprodustat) over all ESA agents listed above

AND

3 - Prescriber attests that patient is not/will not be utilizing Jesduvroq (daprodustat) concomitantly with an ESA agent (e.g., Aranesp, Epogen, Retacrit, Mircera, Procrit)

2 . Revision History

Date	Notes
12/11/2023	Updated patient to prescriber in second bullet of step 4 initial authorization.

Joenja

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151234
Guideline Name	Joenja
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/8/2024	Updated initial authorization duration to 12 months.

Jynarque

Prior Authorization Guideline

Guideline ID	GL-81962
Guideline Name	Jynarque
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Keveyis

Prior Authorization Guideline

Guideline ID	GL-123510
Guideline Name	Keveyis
Formulary	• Medicaid - Community & State Indiana

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

Kisqali

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164490
Guideline Name	Kisqali
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/29/2025	Updated criteria for new indication.

Kisqali Femara Co-Pack

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164515
Guideline Name	Kisqali Femara Co-Pack
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	Updated criteria for new indication

Korlym

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147299
Guideline Name	Korlym
Formulary	• Medicaid - Community & State Indiana

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

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161161
Guideline Name	Koselugo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/21/2024	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-156451
Guideline Name	Krazati
Formulary	• Medicaid - Community & State Indiana

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-93265
Guideline Name	Kuvan
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2021

1 . Criteria

Product Name:Brand Kuvan, generic sapropterin	
Diagnosis	Phenylketonuria (PKU)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of phenylketonuria (PKU)	

2 . Revision History

Date	Notes
9/8/2021	Updated GPI's and product name list

Lampit

Prior Authorization Guideline

Guideline ID	GL-164745
Guideline Name	Lampit
Formulary	• Medicaid - Community & State Arizona • 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.

Laxatives and Cathartics

Prior Authorization Guideline

Guideline ID	GL-210189
Guideline Name	Laxatives and Cathartics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/6/2025

1 . Criteria

Product Name:Brand Amitiza, generic lubiprostone, Linzess	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient had a trial of ONE of the following:

- Lactulose
- Sorbitol
- Polyethylene glycol

Product Name:Ibsrela, Brand Motegrity, generic prucalopride, Trulance	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient had a trial of lubiprostone and Linzess

OR

1.2 BOTH of the following:

1.2.1 Patient had a trial of ONE of the following:

- Lactulose
- Sorbitol
- Polyethylene glycol

AND

1.2.2 There is medical justification for use over the preferred* medications

AND

2 - If the request is for generic prucalopride, there is a reason for the generic requirement

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

Product Name:Movantik, Relistor tabs, Symproic	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient had a trial of ONE of the following:

- Lactulose
- Sorbitol
- Polyethylene glycol

AND

2 - Diagnosis of opioid-induced constipation

AND

3 - There is medical justification for use over the preferred* medications

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

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

Approval Criteria

1 - Patient had a trial of ONE of the following:

- Lactulose
- Sorbitol
- Polyethylene glycol

AND

2 - Diagnosis of opioid-induced constipation

2 . Revision History

Date	Notes
3/6/2025	Clarified and's/or's of second criteria box.

Lazcluze

Prior Authorization Guideline

Guideline ID	GL-164519
Guideline Name	Lazcluze
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	New program

Lenvima

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147448
Guideline Name	Lenvima
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/16/2024	Updated thyroid cancer criteria based on label and NCCN. Updated hepatobiliary and thymic cancer based on NCCN recommendations.

Leukotriene Receptor Antagonists

Prior Authorization Guideline

Guideline ID	GL-125086
Guideline Name	Leukotriene Receptor Antagonists
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Singulair granules, generic montelukast granules	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation indicating tablet formulations are unsuitable for use	

2 . Revision History

Date	Notes
4/27/2023	New

Lipotropics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157631
Guideline Name	Lipotropics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

Product Name:Brand Vytorin, generic ezetimibe/simvastatin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Trial history of a single-agent HMG-CoA (3-Hydroxy-3-Methylglutaryl Coenzyme A) reductase inhibitor for 90 days of the past 120 days	

Product Name:Nexletol	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has tried and failed two statin agents

OR

1.2 Patient has tried and failed a statin in combination with ezetimibe

OR

1.3 Medical justification for use

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

Approval Criteria

1 - One of the following:

1.1 Patient has tried and failed a statin in combination with ezetimibe

OR

1.2 Medical justification for use

2 . Revision History

Date	Notes
10/17/2024	Removed Brand Vascepa and generic icosapent ethyl

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

Livmarli

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161268
Guideline Name	Livmarli
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/25/2024	Updated examples of conventional treatment within initial authorizati on criteria for both PFIC and ALGS. Corrected spelling of pruritus.

Livtencity

Prior Authorization Guideline

Guideline ID	GL-123296
Guideline Name	Livtencity
Formulary	• Medicaid - Community & State Indiana

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

Livtencity

Prior Authorization Guideline

Guideline ID	GL-104785
Guideline Name	Livtencity
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	5/1/2022

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 be utilizing the requested medication in combination with ganciclovir or valganciclovir.

Lonsurf

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150901
Guideline Name	Lonsurf
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/2/2024

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
8/2/2024	Updated background for FDA indications and NCCN recommendations. Updated diagnostic criteria for colorectal cancer. Updated gastric/ gastroesophageal junction adenocarcinoma diagnostic criteria.

Lorbrena

Prior Authorization Guideline

Guideline ID	GL-147457
Guideline Name	Lorbrena
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/16/2024	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-120242
Guideline Name	Lovenox
Formulary	• Medicaid - Community & State Indiana

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.

Lucemyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-126584
Guideline Name	Lucemyra
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Lucemyra	
Diagnosis	First Course of Therapy (Less than or equal to 14 days of therapy within 180 days)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has a history of trial and failure of a guideline-accepted alpha-2 adrenergic agonist agent, confirmed by claims history or chart documentation

OR

1.2 Prescriber has provided valid medical rational for use of Lucemyra over other guideline-accepted alpha-2 adrenergic agonist agents

AND

2 - The request does not exceed the plan limitation maximum of 14 days supply (two separate 7 day fills) within 180 days

Product Name:Lucemyra	
Diagnosis	Subsequent Course of therapy (Greater than 14 days of therapy within 180 days)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber has provided valid medical rationale for continued use of Lucemyra

AND

2 - The request does not exceed the plan limitation maximum of 14 days supply (two separate 7 day fills)

2 . Revision History

Date	Notes
6/14/2023	Added T/F language and plan limitations (Two 7-day supplies in 180 days)

Lumakras

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156452
Guideline Name	Lumakras
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/30/2024	Added criteria for ampullary adenocarcinoma, colon cancer, and rect al cancer

Lynparza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156454
Guideline Name	Lynparza
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/30/2024	Updated formatting for ovarian cancer without change in clinical inten t.

Lytgobi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164521
Guideline Name	Lytgobi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	Updated cholangiocarcinoma initial criteria

Macrolides

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144304
Guideline Name	Macrolides
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:generic erythromycin ethylsuccinate susp	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must be under 12 years of age

OR

2 - Patient must be unable to swallow tablets/capsules

Product Name:Brand Eryped susp, Brand E.E.S. Granules	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient must have tried and failed generic erythromycin ethylsuccinate suspension in the past 90 days

OR

2 - BOTH of the following:

2.1 ONE of the following:

2.1.1 Patient must be under 12 years of age

OR

2.1.2 Patient must be unable to swallow tablets/capsules

AND

2.2 There is medical justification for use over the preferred* medications

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

2 . Revision History

Date	Notes
3/13/2024	Updated the NP criteria.

MASH-MASLD

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154944
Guideline Name	MASH-MASLD
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

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) with moderate (F2) to advanced (F3) liver fibrosis, confirmed by submission of both of the following:

1.1 One of the following tests indicating member has a diagnosis of steatohepatitis:

- FibroScan-aspartate aminotransferase (FAST)
- FibroScan controlled attenuation parameter (CAP)
- Liver biopsy
- MRI - protein density fat fraction (MRI-P DFF)
- MRI - aspartate aminotransferase (MAST)

AND

1.2 One of the following tests indicating member has moderate (F2) or advanced (F3) liver fibrosis:

- Enhance Liver Fibrosis (ELF)
- FibroScan
- Fibrosis-4 index (FIB-4) - for those 35 years of age or older
- Magnetic Resonance Elastography (MRE)
- Vibration-Controlled Transity Elastography (VCTE)

AND

2 - Patient is 18 years of age or older

AND

3 - Prescriber attests the patient does not have decompensated MASH cirrhosis

AND

4 - Prescribed by, or in consultation with, an endocrinologist, gastroenterologist, or hepatologist

AND

5 - The dose requested does not exceed 100 mg/day (milligrams per day)

AND

6 - The dose requested does not exceed one of the following:

- 60 mg strength - max of 1 tablet/day
- 80 mg strength - max of 1 tablet/day
- 100 mg strength - max of 1 tablet/day

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

Approval Criteria

1 - Submission of both of the following:

1.1 One of the following tests indicating improvement or stabilization of steatohepatitis:

- FibroScan-aspartate aminotransferase (FAST)
- FibroScan controlled attenuation parameter (CAP)
- Liver biopsy
- MRI - protein density fat fraction (MRI-P DFF)
- MRI - aspartate aminotransferase (MAST)

AND

1.2 One of the following tests indicating improvement or stabilization of fibrosis:

- Enhance Liver Fibrosis (ELF)
- FibroScan
- Fibrosis-4 index (FIB-4) - for those 35 years of age or older
- Magnetic Resonance Elastography (MRE)
- Vibration-Controlled Transity Elastography (VCTE)

AND

2 - Prescriber attests both of the following:

- Patient does not have decompensated metabolic dysfunction-associated steatohepatitis (MASH) cirrhosis
- Member continues to have signs of MASH and/or contributing metabolic dysfunction factors (e.g., hyperlipidemia, hypertension, insulin resistance, obesity)

AND

3 - The dose requested does not exceed 100 mg/day (milligrams per day)

AND

4 - The dose requested does not exceed one of the following:

- 60 mg strength - max of 1 tablet/day
- 80 mg strength - max of 1 tablet/day
- 100 mg strength - max of 1 tablet/day

2 . Revision History

Date	Notes
9/13/2024	Added FibroScan controlled attenuation parameter (CAP) as an optio n for testing

Mekinist

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151758
Guideline Name	Mekinist
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	Added criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Mektovi

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-98050
Guideline Name	Mepron
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

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

Approval Criteria

1 - ALL of the following:

1.1 Prophylaxis or treatment of Pneumocystis jirovecii pneumonia (PCP, PJP)

AND

1.2 ONE of the following:

1.2.1 Previous trial and failure of sulfamethoxazole/trimethoprim

OR

1.2.2 Prescriber has provided valid medical justification for the use of atovaquone over sulfamethoxazole/trimethoprim

OR

2 - BOTH of the following:

2.1 Diagnosis of babesiosis

AND

2.2 Patient will be using atovaquone concurrently with azithromycin

OR

3 - Prophylaxis or treatment of toxoplasma encephalitis in an HIV (human immunodeficiency virus)-infected patient

OR

4 - Treatment for ocular toxoplasmosis in an immunocompetent patient

Product Name:Brand Mepron, generic atovaquone	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has history of the requested medication within the past 90 days

AND

2 - Documentation from prescriber indicating improvement (including stabilization) in current clinical status

2 . Revision History

Date	Notes
11/5/2021	Updated all criteria to match state policy.

Migranal, Trudhesa

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-192191
Guideline Name	Migranal, Trudhesa
Formulary	• Medicaid - Community & State Indiana

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) 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) (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 prov ider. ***Requires a prior authorization.

2 . Revision History

Date	Notes
2/24/2025	Updated step therapy language. Updated list of prophylactic therapy

Miotics-Intraocular Pressure Reducers

Prior Authorization Guideline

Guideline ID	GL-137663
Guideline Name	Miotics-Intraocular Pressure Reducers
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Simbrinza	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation that separate components are not suitable for use	

Product Name:Iyuzeh	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure of latanoprost

OR

2 - Prescriber has provided medical justification for use of Iyuzeh over latanoprost

2 . Revision History

Date	Notes
12/12/2023	Added Iyuzeh and criteria.

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

Miscellaneous Oral Antidiabetic Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137614
Guideline Name	Miscellaneous Oral Antidiabetic Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:glipizide/metformin, glyburide/metformin, generic pioglitazone	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has tried metformin	

Product Name:Brand Riomet, generic metformin solution	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - BOTH of the following:

1.1 Patient is 10 years of age or older

AND

1.2 Patient is less than 12 years of age

OR

2 - Patient is unable to swallow tablets

Product Name:Brand Duetact, generic pioglitazone/glimepiride, Brand Actoplus Met, generic pioglitazone/metformin	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation that the separate components are unsuitable for use

2 . Revision History

Date	Notes
12/11/2023	Updated GPI and product name lists, updated metformin soln criteria .

Movement Disorder Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161816
Guideline Name	Movement Disorder Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Austedo, Austedo Patient Titration Kit, Austedo XR, Austedo XR Patient Titration Kit	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of chorea associated with Huntington's disease and both of the following:

1.1.1 Patient is 18 years of age or older

AND

1.1.2 Dose does not exceed 48 mg/day

OR

1.2 Diagnosis of tardive dyskinesia and all of the following:

1.2.1 Patient is 18 years of age or older

AND

1.2.2 One of the following:

1.2.2.1 Causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) has been removed from the patient's medication profile

OR

1.2.2.2 Medical rationale was provided as to why the causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) cannot be removed from the patient's medication profile

AND

1.2.3 Dose does not exceed 48 mg/day

Product Name:Austedo, Austedo Patient Titration Kit, Austedo XR, Austedo XR Patient Titration Kit	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Dose does not exceed 48 mg/day

Product Name:Ingrezza	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of chorea associated with Huntington disease

AND

1.2 Patient is 18 years of age or older

AND

1.3 Dose does not exceed 80 mg/day

OR

2 - ALL of the following:

2.1 Diagnosis of tardive dyskinesia

AND

2.2 Patient is 18 years of age or older

AND

2.3 One of the following:

2.3.1 Causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) has been removed from the patient's medication profile

OR

2.3.2 Medical rationale was provided as to why the causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) cannot be removed from the patient's medication profile

AND

2.4 Dose does not exceed 80 mg/day

Product Name:Ingrezza	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - One of the following:

2.1 Diagnosis of chorea associated with Huntington disease

OR

2.2 Diagnosis of tardive dyskinesia

AND

3 - Dose does not exceed 80 mg/day

Product Name:generic tetrabenazine, Brand Xenazine	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of chorea associated with Huntington's disease and both of the following:

1.1.1 Patient is 18 years of age or older

AND

1.1.2 Dose does not exceed 100 mg/day

OR

1.2 Diagnosis of tardive dyskinesia and all of the following:

1.2.1 Patient is 18 years of age or older

AND

1.2.2 One of the following:

1.2.2.1 Causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) has been removed from the patient's medication profile

OR

1.2.2.2 Medical rationale was provided as to why the causative agent (e.g., antipsychotic, dopamine receptor blocking drug, etc.) cannot be removed from the patient's medication profile

AND

1.2.3 Dose does not exceed 200 mg/day

OR

1.3 Both of the following:

1.3.1 Diagnosis of Tourette's syndrome

AND

1.3.2 Dose does not exceed 150 mg/day

OR

1.4 Diagnosis of other hyperkinetic movement disorder (e.g., hemiballismus, senile chorea, tic disorder) and both of the following:

1.4.1 Patient is 18 years of age or older

AND

1.4.2 Dose does not exceed 200 mg/day

Product Name:generic tetrabenazine, Brand Xenazine	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Both of the following:

2.1.1 Diagnosis of chorea associated with Huntington's disease

AND

2.1.2 Dose does not exceed 100 mg/day

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of one of the following:

- Tardive dyskinesia
- Hyperkinetic movement disorder (e.g., hemiballismus, senile chorea, tic disorder)

AND

2.2.2 Dose does not exceed 200 mg/day

OR

2.3 Both of the following:

2.3.1 Diagnosis of Tourette's syndrome

AND

2.3.2 Dose does not exceed 150 mg/day

2 . Revision History

Date	Notes
12/10/2024	Updated GPIs. Removed Tourette's syndrome indication from Austedo criteria. Combined Austedo and Austedo XR criteria

Mozobil

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147564
Guideline Name	Mozobil
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/21/2024	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.

Mulpleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-116812
Guideline Name	Mulpleta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2023

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

Multaq

Prior Authorization Guideline

Guideline ID	GL-82110
Guideline Name	Multaq
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

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

Approval Criteria

1 - ONE of the following:

1.1 All of the following:

1.1.1 Diagnosis of ONE of the following:

- Paroxysmal Atrial Fibrillation (AF)

- Persistent AF defined as AF less than 6 months duration

AND

1.1.2 ONE of the following:

- Patient is in sinus rhythm
- Patient is planned to undergo cardioversion to sinus rhythm

AND

1.1.3 Patient does not have New York Heart Association (NYHA) Class IV heart failure

AND

1.1.4 Patient does not have symptomatic heart failure with recent decompensation requiring hospitalization

OR

1.2 For continuation of current therapy

2 . Revision History

Date	Notes
3/5/2021	Bulk Load

Multiple Sclerosis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154797
Guideline Name	Multiple Sclerosis
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:generic teriflunomide, Brand Aubagio, generic fingolimod, Brand Gilenya, generic dimethyl fumarate, Brand Tecfidera, Avonex, Betaseron, generic glatiramer, Glatopa, Brand Copaxone, Rebif, Rebif Rebidose	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of multiple sclerosis	

Product Name:generic dalfampridine ER, Brand Ampyra	
Approval Length	100 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

Product Name:generic dalfampridine ER, Brand Ampyra	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation from a neurologist indicating improvement (including stabilization) in gait

Product Name:Bafiertam	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 Previous trial and failure of at least 28 days of therapy with dimethyl fumarate

OR

2.2 Medical justification for use of the requested medication over dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Kesimpta	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 Patient’s multiple sclerosis is secondary progressive

OR

2.2 Patient has had a trial of at least 28 days of therapy with ONE preferred* agent (excluding Ampyra)

OR

2.3 Medical justification for use of Kesimpta over ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Plegridy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 BOTH of the following:

- Trial and failure of Avonex within the past 180 days
- Patient has had a trial of at least 28 days of therapy with ONE different preferred* agent (excluding Ampyra)

OR

2.2 Medical justification for use of Plegridy over ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Tascenso ODT	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - ONE of the following:

3.1 Patient is 10 years of age or older, and less than 18 years of age

OR

3.2 Patient is 18 years of age or older and cannot swallow oral capsules [e.g., Gilenya (fingolimod) capsules]

Product Name:Tascenso ODT	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication in the past 90 days

AND

2 - ONE of the following:

- Patient is less than 18 years of age
- Patient is 18 years of age or older and cannot swallow oral capsules [e.g., Gilenya (fingolimod) capsules]

Product Name:Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 Patient has had a trial of at least 28 days of therapy with ONE preferred* agent (excluding Ampyra)

OR

2.2 Medical justification for use of Zeposia over ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe ulcerative colitis

AND

2 - ONE of the following:

2.1 Trial and failure of at least one targeted immunomodulator agent with an ulcerative colitis indication (adalimumab, infliximab, golimumab, tofacitinib, upadacitinib, ustekinumab, vedolizumab)

OR

2.2 Medical rationale supporting the use of the requested medication over all targeted immunomodulator agents

Product Name:Extavia	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 If the patient has secondary progressive multiple sclerosis (SPMS), trial of Betaseron

OR

2.2 BOTH of the following:

2.2.1 Patient has had a trial of at least 28 days of therapy with Betaseron (interferon beta-1b) within the past 180 days

AND

2.2.2 Patient has had a trial of at least 28 days of therapy with ONE other preferred* agent (excluding Ampyra)

OR

2.3 Medical justification for use of Extavia over Betaseron (interferon beta-1b) and ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Mavenclad	
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis or secondary progressive multiple sclerosis

AND

2 - Prescribed by, or in consultation with, a neurologist

AND

3 - One of the following:

3.1 Patient has had trials of at least 28 days of therapy with TWO different preferred* agents (excluding Ampyra)

OR

3.2 Medical justification for use of Mavenclad over ALL preferred* agents

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Mavenclad	
Approval Length	4 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication

AND

2 - Both of the following: *

- Patient has only received one initial treatment course
- 43 weeks have elapsed following completion of the first treatment course

Notes	*Mavenclad will be granted one reauthorization no earlier than 43 weeks following completion of first treatment course

Product Name:Mayzent	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 Patient's multiple sclerosis is secondary progressive

OR

2.2 Patient has had trials of at least 28 days of therapy with TWO different preferred* agents (excluding Ampyra)

OR

2.3 Medical justification for use of Mayzent over ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Ponvory	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 Patient's multiple sclerosis is secondary progressive

OR

2.2 Patient has had trials of at least 28 days of therapy with TWO different preferred* agents (excluding Ampyra)

OR

2.3 Medical justification for use of Ponvory over ALL preferred* agents

AND

3 - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Vumerity	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple sclerosis

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Trial and failure of at least 28 days of therapy with dimethyl fumarate (generic of Tecfidera)

AND

2.1.2 Trial and failure of at least 28 days of therapy with ONE other preferred* agent (excluding Ampyra)

OR

2.2 Medical justification for use of Vumerity over dimethyl fumarate (generic of Tecfidera) and ALL preferred* agents **AND** **3** - Prescribed by or in consultation with a neurologist

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:generic teriflunomide, Brand Aubagio, generic fingolimod, Brand Gilenya, Gilenya, generic dimethyl fumarate, Brand Tecfidera, Avonex, Betaseron, generic glatiramer, Glatopa, Brand Copaxone, Rebif, Rebif Rebidose, Kesimpta, Plegridy, Vumerity, Zeposia, Bafiertam, Extavia, Mayzent, Ponvory	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - History of the requested medication in the past 90 days	

2 . Revision History

Date	Notes
9/12/2024	Updated criteria for Plegridy (moved to NP). Removed list of alts throughout the guideline, and updated criteria to reference PDL.

Muscular Dystrophy Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124412
Guideline Name	Muscular Dystrophy Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Emflaza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing

AND

2 - Patient is 2 years of age or older

AND

3 - Requested dose does not exceed 0.9mg/kg/day, rounded up to the nearest possible tablet dose or nearest tenth of a milliliter of oral suspension once daily (document weight)

AND

4 - Prescriber must provide documentation of current clinical status to compare upon re-evaluations of therapy (e.g. Brooke Score, 6 minute walk test, etc.)

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

Approval Criteria

1 - History of the requested agent within the past 90 days

AND

2 - Documentation from prescriber indicating improvement (including stabilization) in current clinical status (e.g. Brooke Score, 6 minute walk test, etc.)

AND

3 - Requested dose does not exceed 0.9mg/kg/day, rounded up to the nearest possible tablet dose or nearest tenth of a milliliter of oral suspension once daily (document weight)

2 . Revision History

Date	Notes
4/10/2023	Updated daily dose requirement to be per day to match policy. Updated examples to match policy

Myalept

Prior Authorization Guideline

Guideline ID	GL-108459
Guideline Name	Myalept
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2022

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

Mytesi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82111
Guideline Name	Mytesi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Narcolepsy Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154894
Guideline Name	Narcolepsy Agents
Formulary	• Medicaid - Community & State Indiana • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Brand Nuvigil, generic armodafinil	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 18 years of age or older	

AND

2 - Patient has ONE of the following diagnoses:

- Bipolar depression in conjunction with appropriate medical intervention(s)
- Narcolepsy with excessive daytime sleepiness
- Obstructive sleep apnea/hypopnea syndrome with residual excessive daytime sleepiness in conjunction with appropriate medical intervention(s)
- Shift work sleep disorder

Product Name:Brand Provigil, generic modafinil	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 6 years of age or older and ONE of the following diagnoses:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Narcolepsy with excessive daytime sleepiness

OR

1.2 Patient is 18 years of age or older and ONE of the following diagnoses:

- Depression-related fatigue in conjunction with appropriate medical intervention(s)
- Idiopathic hypersomnia
- Obstructive sleep apnea/hypopnea syndrome with residual excessive daytime sleepiness in conjunction with appropriate medical intervention(s)
- Shift work sleep disorder
- Sleep deprivation
- Steinert Myotonic Dystrophy Syndrome

- Unipolar depression or bipolar depression in conjunction with appropriate medical intervention(s)

Product Name:Sunosi	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - ONE of the following:

2.1 Patient has a diagnosis of narcolepsy with excessive daytime sleepiness

OR

2.2 BOTH of the following:

2.2.1 Patient has a diagnosis of obstructive sleep apnea/hypopnea syndrome with residual excessive daytime sleepiness in conjunction with appropriate medical intervention(s)

AND

2.2.2 ONE of the following:

- Previous trial and failure of modafinil or armodafinil
- Prescriber has provided valid medical justification for the use of Sunosi (solriamfetol) over modafinil and armodafinil

Product Name:Wakix

Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - The patient meets the appropriate age requirement:

- Narcolepsy with cataplexy or excessive daytime sleepiness: 6 years of age or older
- Obstructive sleep apnea/hypopnea syndrome with residual excessive daytime sleepiness: 18 years of age or older

AND

2 - ONE of the following:

2.1 Patient has a diagnosis of narcolepsy with cataplexy or excessive daytime sleepiness

OR

2.2 BOTH of the following:

2.2.1 Patient has a diagnosis of obstructive sleep apnea/hypopnea syndrome with residual excessive daytime sleepiness in conjunction with appropriate medical intervention(s)

AND

2.2.2 ONE of the following:

- Previous trial and failure of modafinil or armodafinil
- Prescriber has provided valid medical justification for the use of Wakix (pitolisant) over modafinil and armodafinil

Product Name:Brand Nuvigil, generic armodafinil, Brand Provigil, generic modafinil, Sunosi, Wakix	
Approval Length	1 year(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication within the past 90 days

Product Name:Brand Xyrem, generic sodium oxybate	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 7 years of age or older and BOTH of the following:

1.1.1 Patient has a diagnosis of narcolepsy with cataplexy or excessive daytime sleepiness

AND

1.1.2 The requested dose does NOT exceed ONE of the following:

- 12 milliliters per day for patients weighing 20 kilograms (kg) to less than 30 kg
- 15 milliliters per day for patients weighing 30 kg to less than 45 kg
- 18 milliliters per day for patients weighing at least 45 kg

OR

1.2 Patient is 18 years of age or older and ALL of the following:

1.2.1 Diagnosis of fibromyalgia

AND

1.2.2 ONE of the following:

1.2.2.1 Greater than or equal to 90 days of medication therapy with ONE of the following*:

- Amitriptyline
- SNRI (Serotonin–norepinephrine reuptake inhibitor)
- SSRI (Selective serotonin reuptake inhibitor)
- Anticonvulsant (e.g., gabapentin, pregabalin)
- NSAID (non-steroidal anti-inflammatory drug)
- Acetaminophen

OR

1.2.2.2 Prescriber has provided valid medical justification for the use of sodium oxybate over therapy with amitriptyline, SNRI, SSRI, anticonvulsant (gabapentin/pregabalin), NSAID, AND acetaminophen

AND

1.2.3 Requested dose does NOT exceed 12 milliliters per day

Notes	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Xywav	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Patient is 7 years of age or older and BOTH of the following:

1.1.1 Diagnosis of narcolepsy with cataplexy or excessive daytime sleepiness

AND

1.1.2 Requested dose does NOT exceed ONE of the following:

- 12 milliliters per day for patients weighing 20 kilograms (kg) to less than 30 kg
- 15 milliliters per day for patients weighing 30 kg to less than 45 kg
- 18 milliliters per day for patients weighing at least 45 kg

OR

1.2 Patient is 18 years of age or older and BOTH of the following:

1.2.1 Diagnosis of idiopathic hypersomnia

AND

1.2.2 Requested dose does not exceed 18 milliliters per day

Product Name:Brand Xyrem, generic sodium oxybate, Xywav	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication within the past 90 days

AND

2 - Documented attempt to decrease dose or trial and failure of an alternative therapy within the past year

AND **3** - Documentation from prescriber indicating continued benefit from the medication (reduction in frequency of cataplexy, reduction in symptoms of excessive daytime sleepiness, etc.) without significant adverse events

2 . Revision History

Date	Notes
9/13/2024	Updated Wakix age requirements.

Natpara

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161410
Guideline Name	Natpara
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

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

Approval Criteria

1 - Diagnosis of hypocalcemia resulting from chronic hypoparathyroidism

AND

2 - Patient is currently on adequate supplemental calcium and active vitamin D (e.g., calcitriol) therapy as evidenced by serum calcium (albumin corrected) greater than 7.5 mg/dL

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

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

Approval Criteria

1 - Documentation of positive clinical response [e.g., total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 8.5 mg/dL)]

AND

2 - Patient continues to take concomitant calcium supplementation that is sufficient to meet daily requirements

AND

3 - Prescribed by ONE of the following:

- Endocrinologist
- Nephrologist

2 . Revision History

Date	Notes
12/9/2024	Updated initial authorization criteria.

Nerlynx

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156471
Guideline Name	Nerlynx
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/30/2024	Updated formatting, no changes to criteria

Nexavar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161361
Guideline Name	Nexavar
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/26/2024	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.

Ninlaro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151701
Guideline Name	Ninlaro
Formulary	• Medicaid - Community & State Indiana

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

Prior Authorization Guideline

Guideline ID	GL-81981
Guideline Name	Nityr
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Nocdurna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147461
Guideline Name	Nocdurna
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/17/2024	Increased initial authorization to 12 months.

Non-Preferred Drugs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-108436
Guideline Name	Non-Preferred Drugs
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2022

1 . Criteria

Product Name:Non-Preferred Drugs	
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:

- 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.
- 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.

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 generic equivalent of the 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 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 **2.3** 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	*PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-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.

2 . Revision History

Date	Notes
6/20/2022	Copy NY

Northera

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150035
Guideline Name	Northera
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

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
7/19/2024	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-115268
Guideline Name	Nubeqa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	12/1/2022

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

Nuedexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-81266
Guideline Name	Nuedexta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

Product Name:Nuedexta (dextromethorphan/quinidine)	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pseudobulbar affect (PBA)

AND

2 - Prescribed by or in consultation with a psychiatrist or neurologist

AND

3 - Patient does not have ONE of the following:

- Lupus-like syndrome
- Thrombocytopenia or bone marrow suppression
- Heart failure, QT prolongation, AV block or history of AV block, or on other medications that can lead to QT prolongation
- Currently utilizing MAOI therapy (or within past 14 days)
- Hepatitis induced by dextromethorphan/quinidine, quinine, mefloquine, or quinidine

2 . Revision History

Date	Notes
2/18/2021	IN 4/1 implementation

Nuzyra

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147577
Guideline Name	Nuzyra
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/21/2024	Updated product name section to specify Nuzyra "tablets". No changes to clinical criteria.

Ocaliva

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-164533
Guideline Name	Odomzo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	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.

Ojemda

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151312
Guideline Name	Ojemda
Formulary	• Medicaid - Community & State Indiana

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-164618
Guideline Name	Ojjaara
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/3/2025	Updated clinical criteria.

Omnipod 5

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165075
Guideline Name	Omnipod 5
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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

2/12/2025	Updated GPIs. Updated product name and note of QL section.

Ophthalmic Antibiotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-144311
Guideline Name	Ophthalmic Antibiotics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Brand Vigamox, generic moxifloxacin ophth soln	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 30 years of age or older

OR

2 - Patient has tried at least ONE preferred* medication within the past 30 days

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

2 . Revision History

Date	Notes
3/13/2024	Removed Moxeza.

Opiates

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-199187
Guideline Name	Opiates
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2025

1 . Criteria

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

Approval Criteria

1 - Diagnosis of pain

AND

2 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding

buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

3 - The patient is not using concurrently with a carisoprodol-containing product

AND

4 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

5 - One of the following:

5.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

5.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

5.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

5.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

5.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

5.4.2 Documentation of previous therapies attempted for the given indications

AND

5.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

6 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

7 - ONE of the following:

7.1 BOTH of the following:

7.1.1 Patient is a current utilizer of opioid therapy (at least 90 days of therapy in the past 120 days)

AND

7.1.2 Patient is not utilizing more than one long-acting opioid agent

OR

7.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

8 - ONE of the following:

- History of the requested agent for 90 of the past 105 days (stable therapy)
- History of a 14-day trial of Butrans (buprenorphine) patches within the past 90 days
- Prescriber has provided valid medical rationale as to why Butrans (buprenorphine patches) are unsuitable for use

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

Product Name:fentanyl patch	
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 Patient is a current utilizer of opioid therapy (at least 90 days of therapy in the past 120 days)

AND

1.1.2 Patient is not utilizing more than one long-acting agent

OR

1.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

2 - One of the following:

- History of the requested agent for 90 of the past 105 days (stable therapy)
- History of dysphagia
- Submission of medical records showing patient has a history of NPO (nothing-by-mouth) within the past 6 months
- Active cancer diagnosis
- History of 1 preferred long-acting opioid agent in the past 120 days

AND

3 - The patient is not using concurrently with a carisoprodol-containing product

AND

4 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

5 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

6 - One of the following:

6.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

6.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

6.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

6.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

6.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

6.4.2 Documentation of previous therapies attempted for the given indications

AND

6.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks

- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

7 - Fewer than 5 different prescribers of opiates in the past 60 days

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

Product Name:brand Hysingla ER, generic hydrocodone ER tab, Oxymorphone ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable

- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - ONE of the following:

6.1 BOTH of the following:

6.1.1 Patient is a current utilizer of opioid therapy (at least 90 days of therapy in the past 120 days)

AND

6.1.2 Patient is not utilizing more than one long-acting agent

OR

6.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

7 - One of the following:

7.1 History of the requested agent for 90 of the past 105 days (stable therapy)

OR

7.2 BOTH of the following:

- History of trial with 2 different preferred long acting medications (2 different ingredients) in the past 90 days
- History of trial with 2 different non-preferred long acting medications (2 different ingredients) in the past 90 days

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Qdolo, tramadol oral soln, Seglentis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable

- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - ONE of the following:

6.1 BOTH of the following:

6.1.1 Patient is a current utilizer of opioid therapy (at least 90 days of therapy in the past 120 days)

AND

6.1.2 Patient is not utilizing more than one short-acting agent

OR

6.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

7 - BOTH of the following:

- History of the requested agent for 90 of the past 105 days (stable therapy)
- For tramadol oral solution, the prescriber has provided rationale as to why the tablets are not suitable for use
- For Seglentis, the prescriber has provided valid rationale as to why separate components are unsuitable for use

AND

8 - The patient is 18 years of age or older (if less than 18 years of age, please see Age Limit criteria)

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

Product Name:Conzip, tramadol ER cap, tramadol ER tab, tramadol ER biphasic ER tab	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - ONE of the following:

6.1 BOTH of the following:

6.1.1 Patient is a current utilizer of opioid therapy (at least 90 days of therapy in the past 120 days)

AND

6.1.2 Patient is not utilizing more than one Long-acting agent

OR

6.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

7 - ONE of the following:

- History of the requested agent for 90 of the past 105 days (stable therapy)
- History of immediate release tramadol for 90 of the past 120 days

AND

8 - The patient is 18 years of age or older (if less than 18 years of age, please see Age Limit criteria)

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

Product Name:Long-Acting Opioids: brand Butrans, generic buprenorphine patch, brand MS Contin, generic morphine sulfate ER, generic morphine sulfate CR, Oxycontin, Oxycodone ER, hydromorphone ER, methadone (tab, conc, soln, intensol, tab for oral susp, inj), methadose (conc, SF conc and tab for oral susp), generic hydrocodone ER caps	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - One of the following:

6.1 BOTH of the following:

6.1.1 Patient is a current utilizer (at least 90 days of therapy in the past 120 days)

AND

6.1.2 Patient is not utilizing more than one long-acting opioid agent

OR

6.2 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

AND

7 - If the request is for a non-preferred medication ONE of the following:

- History of at least 2 different preferred long-acting opioid products (2 different ingredients) in the past 90 days
- History of the requested agent for 90 of the past 105 days (stable therapy)

AND

8 - If the request is for a methadone product, the patient does not have a diagnosis of opioid use disorder (OUD) **

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

	**Methadone for the diagnosis of opioid use disorder (OUD) is not per missible for reimbursement through the pharmacy benefit. By law, onl y a SAMHSA-certified opioid treatment program (OTP) can dispense methadone for the treatment of OUD, as governed by 42 CFR 8. Patie nts taking methadone to treat OUD must receive the medication under the supervision of a practitioner at an OTP facility. The Indiana Health Coverage Programs (IHCP) requires providers to enroll under the Ad diction Services/OTP provider type and to bill services as outlined in t he Indiana Health Coverage Programs provider bulletin BT201755. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/in diana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:belladonna/Opium suppositories	
Approval Length	For diagnosis of pain associated with ureteral spasm: 4 weeks; All other diagnoses:12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - One of the following:

6.1 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

OR

6.2 Both of the following:

- The requested dose does not exceed 60 morphine milligram equivalents (MME) per day
- The patient has filled up to a 7-day supply of initial opioid therapy in the past 120 days

OR

6.3 The patient has a diagnosis of pain associated with ureteral spasm

AND

7 - If the request is for a non-preferred medication, one of the following:

- History of at least 2 different preferred short-acting opioid products (2 different ingredients) in the past 6 months
- History of the requested medication for 90 of the past 105 days

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

	IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Opium tincture	
Approval Length	For patients with non-cancer treatment-related diarrhea: 4 weeks; For patients with cancer treatment-related diarrhea: 6 month(s); All other diagnoses: 12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less

- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - One of the following:

6.1 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

OR

6.2 Both of the following:

- The requested dose does not exceed 60 morphine milligram equivalents (MME) per day
- The patient has filled up to a 7-day supply of initial opioid therapy in the past 120 days

OR

6.3 The patient has a diagnosis of diarrhea and diarrhea is one of the following:

- Non-cancer treatment related
- Cancer treatment related

AND

7 - If the request is for a non-preferred medication, one of the following:

- History of at least 2 different preferred short-acting opioid products (2 different ingredients) in the past 6 months
- History of the requested medication for 90 of the past 105 days

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber.

	IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Antitussives: Brand Hycodan, Hydromet, hydrocodone/homatropine syrup, hydrocodone/homatropine tabs, Tuzistra XR, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, M-Clear WC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Virtussin AC/ALC, Maxi-Tuss AC, Coditussin DAC, Virtussin DAC, Tuxarin ER, Tusnel C	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - One of the following

6.1 One of the following diagnoses:

- Cancer
- Palliative care
- Other terminal diagnosis with concomitant irretractable cough

OR

6.2 Both of the following:

- The requested dose does not exceed 60 morphine milligram equivalents (MME) per day
- The patient has filled up to a 7-day supply of initial opioid therapy in the past 120 days

AND

7 - If the request is for a non-preferred medication, one of the following:

- History of 2 different preferred antitussive products (2 different ingredients) in the past 6 months
- History of the requested medication for 90 of the past 105 days

AND

8 - The patient is 18 years of age or older (if less than 18 years of age, please see Age Limit criteria)

Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Short-Acting Opioids: butorphanol, acetaminophen/codeine (soln and tabs), brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine/codeine, ascomp/codeine, butalbital/aspirin/caffeine/codeine, Apadaz, Benzhydrocodone/acetaminophen, morphine sulfate (tab, soln and supp), codeine sulfate, brand Lortab, generic hydrocodone/acetaminophen soln, brand Xodol, generic hydrocodone/acetaminophen tab, hydrocodone/ibuprofen, brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, brand dilaudid, generic hydromorphone, oxycodone cap, brand Roxicodone, brand Oxaydo, generic oxycodone tab, oxycodone conc, oxycodone soln, brand Percocet, Nalocet, Endocet, Prolate (tab and soln), Oxycodone/acetaminophen (tab and soln), generic oxycodone/acetaminophen tab, levorphanol, meperidine (tab and soln), oxymorphone, pentazocine/naloxone, brand Ultram, generic tramadol, brand Ultracet, generic tramadol/acetaminophen, Synapryn	
Diagnosis	Prior Authorization/Opioid Naive (days supply limit)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - No concurrent claims for buprenorphine/naloxone or buprenorphine therapy, excluding buprenorphine patches (Butrans) and sublingual buprenorphine indicated for the treatment of pain (Belbuca), exceeding a 7-day supply every 180 days*

AND

2 - The patient is not using concurrently with a carisoprodol-containing product

AND

3 - No concurrent claims for Lybalvi (olanzapine/samidorphan) within the past 45 days

AND

4 - One of the following:

4.1 Patient is not using the requested medication concurrently with a benzodiazepine (claim within the past 30 days)

OR

4.2 BOTH of the following:

- Days' supply for the requested opioid is 7 days or less
- Including the days' supply for the requested agent, the patient will not exceed 7 days of concurrent opiate/benzodiazepine therapy in the past 180 days

OR

4.3 Patient has utilized concurrent benzodiazepine/opiate therapy, including any cross-tapered or discontinued agents, for at least 90 of the past 120 days

OR

4.4 All of the following for concurrent opiate/benzodiazepine therapy exceeding 7 days in the past 180 days:

4.4.1 Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)

AND

4.4.2 Documentation of previous therapies attempted for the given indications

AND

4.4.3 Prescriber attests to ALL of the following:

- The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis
- The patient has been educated in regard to the risks of concurrent utilization of opioid and benzodiazepine therapy, and the patient accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the patient, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization

AND

5 - Fewer than 5 different prescribers of opiates in the past 60 days

AND

6 - One of the following:

6.1 The patient has one of the following indications for long-term opioid use:

- Cancer
- Sickle cell disease
- Palliative care
- Other terminal diagnosis associated with significant pain

OR

6.2 Both of the following:

- The requested dose does not exceed 60 morphine milligram equivalents (MME) per day
- The patient has filled up to a 7-day supply of initial opioid therapy in the past 120 days

OR

6.3 Both of the following:

- Patient is a current utilizer (at least 90 days of therapy in the past 120 days)
- Patient is not using more than one short-acting opioid agent

AND

7 - If the request is for a non-preferred medication, one of the following:

- History of at least 2 different preferred short-acting opioid products (2 different ingredients) in the past 6 months
- History of the requested medication for 90 of the past 105 days

AND

8 - If the request is for a codeine-containing or tramadol-containing product, the patient is 18 years of age or older (if less than 18 years of age, please see Age Limit criteria)	
Notes	*Unless faxed documentation has been received from the opioid prescriber with approval for opioid therapy from the buprenorphine or buprenorphine/naloxone prescriber. IN PDL Link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:fentanyl patch, brand Butrans, generic buprenorphine patch, brand MS Contin, generic morphine sulfate ER, generic morphine sulfate CR, Oxycontin, Oxycodone ER, hydromorphone ER, brand Hysingla ER, generic hydrocodone ER tab, Oxymorphone ER, brand Zohydro ER, generic hydrocodone ER cap, Conzip, tramadol ER cap, tramadol ER tab, tramadol ER biphasic ER tab, butorphanol, acetaminophen/codeine (soln and tabs), brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine/codeine, ascomp/codeine, butalbital/aspirin/caffeine/codeine, Apadaz, Benzhydrocodone/acetaminophen, morphine sulfate (tab, soln and supp), codeine sulfate, brand Lortab, generic hydrocodone/acetaminophen soln, brand Xodol, generic hydrocodone/acetaminophen tab, hydrocodone/ibuprofen, brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, brand dilaudid, generic hydromorphone, oxycodone cap, brand Roxicodone, brand Oxaydo, generic oxycodone tab, oxycodone conc, oxycodone soln, brand Percocet, Nalocet, Endocet, Prolate (tab and soln), Oxycodone/acetaminophen (tab and soln), generic oxycodone/acetaminophen tab, levorphanol, meperidine (tab and soln), methadone (tab, conc, soln, intensol, tab for oral susp, inj), methadose (conc, SF conc and tab for oral susp), oxymorphone, pentazocine/naloxone, brand Ultram, generic tramadol, brand Ultracet, generic tramadol/acetaminophen, Synapryn, Qdolo, tramadol oral soln, belladonna/Opium, Opium, Seglentis, Roxybond, Oxycodone abuse deterrent tabs, Brand Hycodan, Hydromet, hydrocodone/homatropine syrup, hydrocodone/homatropine tabs, Tuzistra XR, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, M-Clear WC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Virtussin AC/ALC, Maxi-Tuss AC, Coditussin DAC, Virtussin DAC, Tuxarin ER, Tusnel C *	
Guideline Type	Morphine Milligram Equivalents (MME)**

Approval Criteria

1 - Diagnosis of cancer, sickle cell disease, palliative care, other terminal diagnosis associated with significant pain

OR

2 - Provider has submitted a taper plan with specific doses and durations

OR

3 - The patient has attempted a dose reduction of their opioid therapy within the past 12 months and all of the following:

- Attempt at MME reduction can be identified by chart notes or claims history
- Provider has submitted chart notes demonstrating adverse outcomes experienced with attempted taper

Notes	*Authorization will be issued for 12 months for Cancer, sickle cell disease, palliative care, and terminal diagnosis associated with significant 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. Authorization for when member has attempted a dose reduction of their opioid therapy within the past 12 months will be granted for 12 months. Authorization for when a provider has submitted a taper plan with specific doses and durations will be granted for 6 months. These authorizations should be entered for the requested MME. **Reference Table 1 in background for MME Limits.

Product Name:acetaminophen/codeine (soln and tabs), brand Fioricet/codeine, generic butalbital/acetaminophen/caffeine/codeine, ascomp/codeine, butalbital/aspirin/caffeine/codeine, codeine sulfate, brand Trezix, generic acetaminophen/caffeine/dihydrocodeine, brand Ultram, generic tramadol, brand Ultracet, generic tramadol/acetaminophen, Qdolo, tramadol oral soln, Seglentis, Conzip, tramadol ER cap, tramadol ER tab, tramadol ER biphasic ER tab, Tuzistra XR, hydrocodone polst/chlorpheniramine polst ER susp, M-END PE, Poly-Tussin AC, Capcof, Pro-Red AC, Histex-AC, Maxi-Tuss CD, promethazine w/codeine, Promethazine VC/codeine, promethazine-phenylephrine-codeine, Rydex, Mar-Cof BP, Ninjacof-XG, Coditussin AC, Mar-Cof GG, Trymine CG, M-Clear WC, Codeine/Guaifenesin, G Tussin AC, Guaiatussin AC, Guaifenesin AC, Guaifenesin/Codeine, Virtussin A/C, Virtussin AC/ALC, Maxi-Tuss AC, Coditussin DAC, Virtussin DAC, Tuxarin ER, Tusnel C, butorphanol	
Diagnosis	Age Limit
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the member is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - All of the following:

2.1 History of requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 ONE of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient
- The request is for continuation of therapy from another plan or following inpatient therapy

AND

3.3 One of the following:

3.3.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

OR

3.3.2 The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits

AND

3.4 If the member is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	These criteria are from the Non-Drug-Specific Prior Authorization Criteria policy

Product Name:All Opioid Products	
Diagnosis	DDI: Lybalvi + Opioid
Approval Length	12 month(s)
Guideline Type	Drug Utilization Review

Approval Criteria

1 - The patient has not used Lybalvi (olanzapine/samidorphan) within the past 45 days

2 . Background

Benefit/Coverage/Program Information

Table 1: Planned Taper Schedule for MME Limit Reduction

Date of Reduction	MME Daily Limit
April 1, 2025	375
July 1, 2025	350
October 1, 2025	325
January 1, 2026	300
April 1, 2026	275
July 1, 2026	250
October 1, 2026	225

3 . Revision History

Date	Notes
2/25/2025	Added oxycodone abuse deterrent 10mg tab GPI. Updated Oxycontin GPIs. Updated MME table in background.

Oral Antipsychotics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158410
Guideline Name	Oral Antipsychotics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

Product Name:Prochlorperazine*	
Diagnosis	Nausea and Vomiting
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Nausea and Vomiting	
Notes	*For all psychiatry-based diagnoses utilize applicable criteria (e.g., Duplicate Therapy, Age Limit Exception)

Product Name:Lybalvi *	
Diagnosis	DDI: Lybalvi + Opioid
Approval Length	12 month(s)
Guideline Type	Drug Utilization Review

Approval Criteria

1 - ALL of the following:

- Patient is not using opiate agonists (including buprenorphine) concurrently with Lybalvi
- Patient has not used short-acting opiates within the past 7 days prior to initiating Lybalvi therapy
- Patient has not used long-acting opiates within the past 14 days prior to initiating Lybalvi therapy

Notes	*Additional criteria may apply (e.g., Duplicate Therapy, Age Limit Exception)

Product Name:Brand Abilify, Generic aripiprazole (tabs, oral solution, ODT), Abilify Mycite, Generic asenapine, Brand Saphris, Vraylar, Generic clozapine (tab, ODT), Brand Clozaril, Brand Latuda, Generic lurasidone, Brand Zyprexa, Generic olanzapine, Brand Zyprexa Zydis, Generic olanzapine ODT, Generic paliperidone ER, Brand Invega, Brand Seroquel, Generic quetiapine, Brand Seroquel XR, Generic quetiapine ER, Brand Risperdal, Generic risperidone (tabs, ODT), Brand Geodon, Generic ziprasidone, Caplyta, chlorpromazine (tabs, oral conc), fluphenazine (tabs, oral conc, elixir), haloperidol (tabs, oral conc), loxapine, molindone, perphenazine, perphenazine/amitriptyline, pimozide, thioridazine, thiothixene, trifluoperazine, Fanapt, Generic olanzapine/fluoxetine, Brand Symbyax, Rexulti, Lybalvi, prochlorperazine *	
Diagnosis	Duplicate Therapy with Another Antipsychotic
Therapy Stage	Initial Authorization
Guideline Type	Drug Utilization Review

Approval Criteria

1 - ONE of the following:

1.1 The patient has had metabolic monitoring labs (e.g. HbA1c test, Lipids test, Glucose test) obtained within the past 12 months (with a 6-months grace period) (Please document date metabolic monitoring was performed)

OR

1.2 The patient is new to antipsychotic therapy and will be obtaining baseline metabolic labs within 4 months of initiating therapy *

AND

2 - One of the following:

2.1 The patient will be utilizing the requested antipsychotic as monotherapy

OR

2.2 The patient will be utilizing the requested antipsychotic agent as part of a duplicate antipsychotic regimen and ONE of the following:

2.2.1 Evidence of duplication of therapy with the requested antipsychotic agents for 90 of the past 120 days, confirmed by claims history or chart documentation

OR

2.2.2 All of the following:

- Diagnosis of psychosis
- Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist
- History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics
- History of at least 4 weeks of therapy with clozapine (unless contraindication, allergy, or intolerance to clozapine therapy)

OR

2.3 All of the following:

2.3.1 Diagnosis of depressed mood disorder

AND

2.3.2 BOTH of the following:

- At least one of the antipsychotics in the duplicate therapy regimen has an indication for depressed mood disorder
- The patient will be utilizing an antidepressant concurrently with the requested antipsychotic regimen

AND

2.3.3 Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist

AND

2.3.4 History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics

OR

2.4 ALL of the following:

2.4.1 Diagnosis of ONE of the following:

- Bipolar affective disorder
- Unspecified episodic mood disorder

AND

2.4.2 Both antipsychotics involved in the therapeutic duplication are prescribed by or in consultation with a psychiatrist or psychiatric specialist

AND

2.4.3 History of at least 4 weeks of single-agent therapy at an adequate dose (See Table 1) for 2 different antipsychotics

OR

2.5 The agents involved in the therapeutic duplication are being cross tapered *

AND

3 - Patient is not utilizing more than 2 antipsychotics concurrently

Notes	*Approval Length – 90 days for cross taper, 4 months for patients new to antipsychotic therapy, 6 months for initial approval and not new to antipsychotic therapy

Product Name:Brand Abilify, Generic aripiprazole (tabs, oral solution, ODT), Abilify Mycite, Generic asenapine, Brand Saphris, Vraylar, Generic clozapine (tab, ODT), Brand Clozaril, Brand Latuda, Generic lurasidone, Brand Zyprexa, Generic olanzapine, Brand Zyprexa Zydis, Generic olanzapine ODT, Generic paliperidone ER, Brand Invega, Brand Seroquel, Generic quetiapine, Brand Seroquel XR, Generic quetiapine ER, Brand Risperdal, Generic risperidone (tabs, ODT), Brand Geodon, Generic ziprasidone, Caplyta, chlorpromazine (tabs, oral conc), fluphenazine (tabs, oral conc, elixir), haloperidol (tabs, oral conc), loxapine, molindone, perphenazine, perphenazine/amitriptyline, pimozide, thioridazine, thiothixene, trifluoperazine, Fanapt, Generic olanzapine/fluoxetine, Brand Symbyax, Rexulti, Lybalvi, prochlorperazine	
Diagnosis	Duplicate Therapy with Another Antipsychotic
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Drug Utilization Review

Approval Criteria

1 - History of the requested agent(s) for 90 of the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of therapy administration

AND

2 - The patient has had metabolic monitoring labs (e.g. HbA1c test, Lipids test, Glucose test) obtained within the past 12 months (with a 6-months grace period) (Please document date metabolic monitoring was performed)

AND

3 - One of the following:

3.1 The patient will be utilizing the requested antipsychotic as monotherapy

OR

3.2 The patient will be utilizing the requested antipsychotic agent as part of a duplicate antipsychotic regimen and there is evidence of duplication of therapy with the requested antipsychotic agents for 90 of the past 120 days, confirmed by claims history or chart documentation

AND

4 - Patient is not utilizing more than 2 antipsychotics concurrently

Product Name:(ALL Antipsychotics), Brand Abilify, Generic aripiprazole (tabs, oral solution, ODT), Abilify Mycite, Generic asenapine, Brand Saphris, Vraylar, Generic clozapine (tab, ODT), Brand Clozaril, Cobenfy, Brand Latuda, Generic lurasidone, Brand Zyprexa, Generic olanzapine, Brand Zyprexa Zydis, Generic olanzapine ODT, Generic paliperidone ER, Brand Invega, Brand Seroquel, Generic quetiapine, Brand Seroquel XR, Generic quetiapine ER, Brand Risperdal, Generic risperidone (tabs, ODT), Brand Geodon, Generic ziprasidone, Caplyta, chlorpromazine (tabs, oral conc), fluphenazine (tabs, oral conc, elixir), haloperidol (tabs, oral conc), loxapine, molindone, perphenazine, perphenazine/amitriptyline, pimozide, thioridazine, thiothixene, trifluoperazine, Fanapt, Generic olanzapine/fluoxetine, Brand Symbyax, Rexulti, Lybalvi, prochlorperazine	
Diagnosis	Age Limit Exception*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e. clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - All of the following:

2.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 ONE of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient

- The request is for continuation of therapy from another plan or following inpatient therapy

AND

3.3 One of the following:

3.3.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

OR

3.3.2 The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits

AND

3.4 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	*This criteria applies to the Non- Drug Specific PA policy

Product Name:Brand Symbyax, Generic olanzapine/fluoxetine	
Diagnosis	Duplicate Therapy with Another SSRI/SNRI*
Therapy Stage	Initial Authorization
Guideline Type	Drug Utilization Review

Approval Criteria

1 - Agents involved in therapeutic duplication are being cross tapered**

OR

2 - The SSRI/SNRI agent in the patient's history is being discontinued or there are plans to discontinue** **OR** **3** - Medical rationale supporting duplication of therapy**	
Notes	*This criteria applies to the SSRI and SNRI Duplicate Therapy Policy **Approval Duration – Cross-taper or discontinuation: 90 days; Initial approval: 6 months

Product Name:Brand Symbyax, Generic olanzapine/fluoxetine	
Diagnosis	Duplicate Therapy with Another SSRI/SNRI*
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Drug Utilization Review
Approval Criteria **1** - Evidence of duplication of therapy with the requested SSRI/SNRI agents for 90 of the past 120 days	
Notes	*This criteria applies to the SSRI and SNRI Duplicate Therapy Policy

Product Name:Cobenfy	
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of schizophrenia **AND**	

2 - One of the following:

2.1 Cobenfy (xanomeline and trospium chloride) will be used as single-agent antipsychotic therapy

OR

2.2 Patient will be cross-tapering from a different antipsychotic agent to Cobenfy (xanomeline and trospium chloride) as single-agent antipsychotic therapy*

AND

3 - Prescriber attests that member does NOT have any one of the following:

- Gastric retention
- Hepatic impairment (Child-Pugh Class B or C)
- Untreated narrow-angle glaucoma
- Urinary retention

Notes	*Approval Length - 90 days for cross-taper from a different antipsychotic agent; otherwise, 6 months

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

Approval Criteria

1 - History of requested agent for 90 days in the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of therapy administration

AND

2 - Prescriber attests patient has been and will continue to use Cobenfy (xanomeline and trospium chloride) as single-agent antipsychotic therapy

AND

3 - Prescriber attests that member does NOT have any one of the following:

- Gastric retention
- Hepatic impairment (Child-Pugh Class B or C)
- Untreated narrow-angle glaucoma
- Urinary retention

2 . Background

Benefit/Coverage/Program Information
Table 1 - Adequate Dose

Description	Adequate Dose
ARIPIPRAZOLE	>/=5 mg/day
ASENAPINE	>/= 10 mg/day
BREXPIPRAZOLE	>= 2 mg/day
CARIPRAZINE	>/= 1.5 mg/day
CHLORPROMAZINE HCL	>/= 30 mg/day
CLOZAPINE	>/=300 mg/day
FLUPHENAZINE HCL	>/= 1 mg/day
HALOPERIDOL	>/= 1 mg/day
HALOPERIDOL LACTATE	>/= 1 mg/day
ILOPERIDONE	>/= 12 mg/day
LOXAPINE SUCCINATE	>/= 20 mg/day
LUMATEPERONE	= 42 mg/day
LURASIDONE HCL	>/= 40 mg/day
MOLINDONE	>/= 15 mg/day
OLANZAPINE	>/= 10 mg/day
OLANZAPINE + FLUOXETINE	>/= 6/25 mg/day
OLANZAPINE + SAMIDORPHAN	>/= 10/10 mg/day
PALIPERIDONE	>/=3 mg/day
PERPHENAZINE	>/= 12 mg/day
PERPHENAZINE/AMITRIPTYLINE	>/= 12 mg/day (perphenazine component)
PIMOZIDE	>/= 1 mg/day
PROCHLORPERAZINE EDISYLATE/MALEATE	>/= 15 mg/day
QUETIAPINE	>/= 300 mg/day

RISPERIDONE	>/=2 mg/day
THIORIDAZINE HCL	>/= 150 mg/day
THIOTHIXENE	>/= 6 mg/day
TRIFLUOPERAZINE HCL	>/= 2 mg/day
ZIPRASIDONE	>/= 80 mg/day

3 . Revision History

Date	Notes
11/5/2024	Updated reauth for Duplicate Therapy with Another Antipsychotic. Add ded Cobenfy to age limit and added Cobenfy specific section (update d product name of Duplicate Therapy with Another Antipsychotic sect ions to remove all antipsychotics from heading). Updated Lumateper one adequate dose in Table 1 of background.

Orfadin

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127398
Guideline Name	Orfadin
Formulary	• Medicaid - Community & State Indiana

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

Orladeyo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147206
Guideline Name	Orladeyo
Formulary	• Medicaid - Community & State Indiana

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-147249
Guideline Name	Orserdu
Formulary	• Medicaid - Community & State Indiana

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-124497
Guideline Name	Osphena
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2023

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

Oxervate

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-98032
Guideline Name	Oxervate
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

Product Name:Oxervate	
Diagnosis	Neurotrophic keratitis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 2 years of age or older

AND

2 - Diagnosis of neurotrophic keratitis

AND

3 - Prescribed by, or in consultation with, an ophthalmologist

AND

4 - Patient has not received 8 weeks or more of prior cenegermin (Oxervate) treatment for the affected eye

2 . Revision History

Date	Notes
11/4/2021	Updated all criteria to match state policy.

Palynziq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156821
Guideline Name	Palynziq
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
10/1/2024	Updated authorization durations to 12 months

Pancreatic Enzymes

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125017
Guideline Name	Pancreatic Enzymes
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Pertzye, Viokace	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has utilized 30 cumulative days of preferred* agent therapy in the past 180 days	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
4/25/2023	New

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.

PCSK9 Inhibitors and Select Lipotropics

Prior Authorization Guideline

Guideline ID	GL-154997
Guideline Name	PCSK9 Inhibitors and Select Lipotropics
Formulary	• Medicaid - Community & State Indiana • Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient is enrolled in the Juxtapid REMS (Risk Evaluation and Mitigation Strategy) program and prescriber is monitoring in accordance with REMS requirements

AND

2 - The patient is 18 years of age or older

AND

3 - Prescribed by, or in consultation with, a cardiologist or endocrinologist

AND

4 - One of the following:

4.1 Trial and failure of Praluent or Repatha

OR

4.2 BOTH of the following:

- Medical rationale for use of Juxtapid over Praluent or Repatha
- Patient has had trial and failure of at least 90 days of high dose rosuvastatin (20 mg/40 mg) or atorvastatin (40 mg/80 mg, if rosuvastatin intolerant) therapy concurrently with ezetimibe (or documented intolerance/contraindication to statins/ezetimibe)

AND

5 - For those of childbearing potential, documentation of a negative pregnancy test in the past 30 days and prescriber has counseled member on risks associated with conceiving while utilizing Juxtapid and appropriate methods of contraception

AND

6 - One of the following:

6.1 The patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Juxtapid

OR

6.2 Documented intolerance to statin and/or ezetimibe therapy

OR

6.3 Medical rationale against use of statin or ezetimibe therapy

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

Approval Criteria

1 - History of Juxtapid for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - One of the following:

2.1 Prior history of at least one preferred PCSK9 inhibitor*

OR

2.2 Valid medical rationale for the use of Juxtapid over preferred PCSK9 inhibitors*

AND

3 - One of the following:

3.1 Continued concurrent use of maximally tolerated statin therapy with or without ezetimibe

OR

3.2 Documented intolerance to statin and/or ezetimibe therapy

OR

3.3 Medical rationale against use of statin or ezetimibe therapy

AND

4 - One of the following:

4.1 Reduction in LDL-C (low-density lipoprotein-cholesterol) from baseline

OR

4.2 Maintenance of goal LDL-C

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

Product Name:Niacin ER (generic Niaspan)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe hypertriglyceridemia [baseline triglycerides greater than or equal to 500 mg/dL (milligrams per deciliter)] and one of the following:

1.1 Concurrent therapy with ALL of the following for at least 90 days:

- Omega-3 fatty acid (omega-3-acid ethyl esters or icosapent ethyl)
- Fibric acid derivative
- Statin therapy

OR

1.2 Documented intolerance of omega-3 fatty acid, fibric acid derivative, AND statin therapy

OR

1.3 Medical rationale against the use of omega-3 fatty acid, fibric acid derivatives, AND statin therapy

AND

2 - Patient is 17 years of age or older

Product Name:Niacin ER (generic Niaspan)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

Product Name:Praluent	
Diagnosis	ASCVD (Atherosclerotic Cardiovascular Disease)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clinical ASCVD (atherosclerotic cardiovascular disease)

AND

2 - ONE of the following:

2.1 Patient at very high risk of future ASCVD events* requiring therapy for secondary prevention and one of the following:

2.1.1 Persistently elevated LDL-C (low-density lipoprotein cholesterol) (greater than or equal to 55 mg/dL) despite treatment with one of the following:

2.1.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.1.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.1.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

OR

2.2 Patient is NOT at very high risk of future ASCVD events* requiring therapy for secondary prevention and one of the following:

2.2.1 Persistently elevated LDL-C (greater than or equal to 70 mg/dL) despite treatment with one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.2.2 Documented intolerance of both rosuvastatin and atorvastatin and/or ezetimibe

OR

2.2.3 Medical rationale against the use of statin therapy and/or ezetimibe therapy

OR

2.3 Patient with a baseline LDL-C greater than or equal to 190 mg/dL not due to secondary causes (see Table 3), without clinical or genetic diagnosis of familial hypercholesterolemia, requiring therapy for secondary prevention and one of the following:

2.3.1 Persistently elevated LDL-C (greater than or equal to 70 mg/dL) despite treatment with one of the following:

2.3.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.3.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.3.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

OR

2.4 Patient at very high risk of future ASCVD events* with a baseline LDL-C greater than or equal to 190 mg/dL not due to secondary causes (see Table 3), a diagnosis of familial hypercholesterolemia, and requiring treatment for secondary prevention and one of the following:

2.4.1 Persistently elevated LDL-C (greater than or equal to 55 mg/dL) despite treatment with one of the following:

2.4.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.4.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.4.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

AND

3 - The patient is 18 years of age or older

AND

4 - One of the following:

4.1 The patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Praluent

OR

4.2 Documented intolerance to statin and/or ezetimibe therapy

OR

4.3 Medical rationale against use of statin or ezetimibe therapy

AND

5 - One of the following:

5.1 The dose requested is 75 mg every 2 weeks

OR

5.2 The dose requested is 300 mg every 4 weeks

OR

5.3 The dose requested is 150 mg every 2 weeks and one of the following:

- Patient has homozygous familial hypercholesterolemia
- Patient has heterozygous familial hypercholesterolemia and is undergoing LDL apheresis
- Patient has not achieved clinically meaningful response after at least 4 weeks of dosing at 75 mg every 2 weeks or 300 mg every 4 weeks

Notes	*Very High Risk of future ASCVD events is defined as: multiple (2 or more) major ASCVD events from Table 1 OR 1 major ASCVD event fr om Table 1 and multiple (2 or more) high risk conditions from Table 2

Product Name:Praluent	
Diagnosis	Primary hyperlipidemia, without clinical ASCVD (Atherosclerotic Cardiovascular Disease)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperlipidemia, without clinical ASCVD (atherosclerotic cardiovascular disease)

AND

2 - Baseline LDL-C (low-density lipoprotein cholesterol) greater than or equal to 190 mg/dL (milligrams per deciliter) not due to secondary causes (see Table 3), with or without concomitant ASCVD risk factors, requiring therapy for primary prevention

AND

3 - One of the following:

3.1 Persistently elevated LDL-C (greater than or equal to 100 mg/dL) despite treatment with one of the following:

3.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

3.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

3.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

AND

4 - The patient is 18 years of age or older

AND

5 - One of the following:

5.1 Patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Praluent

OR

5.2 Documented intolerance to statin and/or ezetimibe therapy

OR

5.3 Medical rationale against use of statin or ezetimibe therapy

AND

6 - One of the following:

6.1 The dose requested is 75 mg every 2 weeks

OR

6.2 The dose requested is 300 mg every 4 weeks

OR

6.3 The dose requested is 150 mg every 2 weeks and one of the following:

- Patient has homozygous familial hypercholesterolemia
- Patient has heterozygous familial hypercholesterolemia and is undergoing LDL apheresis
- Patient has not achieved clinically meaningful response after at least 4 weeks of dosing at 75 mg every 2 weeks or 300 mg every 4 weeks

Product Name:Praluent	
Diagnosis	HoFH (Homozygous Familial Hypercholesterolemia), HeFH (Heterozygous Familial Hypercholesterolemia)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) OR heterozygous familial hypercholesterolemia (HeFH)

AND

2 - One of the following:

2.1 Persistently elevated LDL-C (low-density lipoprotein cholesterol) (greater than or equal to 70 mg/dL) despite treatment with one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy concurrently with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy concurrently with ezetimibe

OR

2.2 Documented intolerance of both rosuvastatin and atorvastatin and/or ezetimibe

OR

2.3 Medical rationale against the use of statin and/or ezetimibe therapy

AND

3 - One of the following:

- If for a diagnosis of HeFH, patient is 8 years of age or older
- If for a diagnosis of HoFH, patient is 18 years of age or older

AND

4 - One of the following:

4.1 Patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Praluent

OR

4.2 Documented intolerance to statin and/or ezetimibe therapy

OR

4.3 Medical rationale against use of statin or ezetimibe therapy

AND

5 - One of the following:

5.1 The dose requested is 75 mg every 2 weeks

OR

5.2 The dose requested is 300 mg every 4 weeks

OR

5.3 The dose requested is 150 mg every 2 weeks and one of the following:

- Patient has homozygous familial hypercholesterolemia
- Patient has heterozygous familial hypercholesterolemia and is undergoing LDL apheresis
- Patient has not achieved clinically meaningful response after at least 4 weeks of dosing at 75 mg every 2 weeks or 300 mg every 4 weeks

OR

5.4 The dose requested is 150 mg every 4 weeks and both of the following:

- Patient has heterozygous familial hypercholesterolemia
- Patient is under 18 years of age and weighs less than 50 kg

Product Name:Praluent

Diagnosis	ASCVD (Atherosclerotic Cardiovascular Disease), Primary hyperlipidemia, without clinical ASCVD, HoFH (Homozygous Familial Hypercholesterolemia), HeFH (Heterozygous Familial Hypercholesterolemia)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Praluent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

- Continued concurrent use of maximally tolerated statin therapy with or without ezetimibe
- Documented intolerance to statin and/or ezetimibe therapy OR medical rationale against the use of statin and/or ezetimibe therapy

AND

3 - One of the following:

3.1 The dose requested is 75 mg every 2 weeks

OR

3.2 The dose requested is 300 mg every 4 weeks

OR

3.3 The dose requested is 150 mg every 2 weeks and one of the following:

- Patient has homozygous familial hypercholesterolemia

- Patient has heterozygous familial hypercholesterolemia and is undergoing LDL (low-density lipoprotein) apheresis
- Patient has not achieved clinically meaningful response after at least 4 weeks of dosing at 75 mg every 2 weeks or 300 mg every 4 weeks

OR

3.4 The dose requested is 150 mg every 4 weeks and both of the following:

- Patient has heterozygous familial hypercholesterolemia
- Patient is under 18 years of age and weighs less than 50 kg

AND

4 - One of the following:

4.1 Reduction in LDL-C from baseline

OR

4.2 Maintenance of goal LDL-C

Product Name:Repatha	
Diagnosis	ASCVD (Atherosclerotic Cardiovascular Disease)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clinical ASCVD (atherosclerotic cardiovascular disease)

AND

2 - ONE of the following:

2.1 Patient is at very high risk of future ASCVD events* requiring therapy for secondary prevention and one of the following:

2.1.1 Persistently elevated LDL-C (low-density lipoprotein cholesterol) (greater than or equal to 55 mg/dL) despite treatment with one of the following:

2.1.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.1.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.1.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

OR

2.2 Patient is NOT at very high risk of future ASCVD events* requiring therapy for secondary prevention and one of the following:

2.2.1 Persistently elevated LDL-C (greater than or equal to 70 mg/dL) despite treatment with one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.2.2 Documented intolerance of both rosuvastatin and atorvastatin and/or ezetimibe

OR

2.2.3 Medical rationale against the use of statin therapy and/or ezetimibe therapy

OR

2.3 Patient with a baseline LDL-C greater than or equal to 190 mg/dL not due to secondary causes (see Table 3), without clinical or genetic diagnosis of familial hypercholesterolemia, requiring therapy for secondary prevention and one of the following:

2.3.1 Persistently elevated LDL-C (greater than or equal to 70 mg/dL) despite treatment with one of the following:

2.3.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.3.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.3.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

OR

2.4 Patient is at very high risk of future ASCVD events* with a baseline LDL-C greater than or equal to 190 mg/dL not due to secondary causes (see Table 3), a diagnosis of familial hypercholesterolemia, and requiring treatment for secondary prevention and one of the following:

2.4.1 Persistently elevated LDL-C (greater than or equal to 55 mg/dL) despite treatment with one of the following:

2.4.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

2.4.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

2.4.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

AND

3 - The patient is 18 years of age or older

AND

4 - One of the following:

4.1 Patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Repatha

OR

4.2 Documented intolerance to statin and/or ezetimibe therapy

OR

4.3 Medical rationale against use of statin or ezetimibe therapy

AND

5 - One of the following:

5.1 The dose requested is 140 mg every 2 weeks

OR

5.2 The dose requested is 420 mg once monthly

OR

5.3 Dose requested is 420 mg every 2 weeks and the patient is receiving lipid apheresis

Notes	*Very High Risk of future ASCVD events is defined as: multiple (2 or more) major ASCVD events from Table 1 OR 1 major ASCVD event fr om Table 1 and multiple (2 or more) high risk conditions from Table 2

Product Name:Repatha	
Diagnosis	Primary hyperlipidemia, without clinical ASCVD (Atherosclerotic Cardiovascular Disease)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperlipidemia, without clinical ASCVD (atherosclerotic cardiovascular disease)

AND

2 - Patient with a baseline LDL-C (low-density lipoprotein cholesterol) greater than or equal to 190 mg/dL (milligrams per deciliter) not due to secondary causes (see Table 3), with or without concomitant ASCVD risk factors, requiring therapy for primary prevention

AND

3 - One of the following:

3.1 Persistently elevated LDL-C (greater than or equal to 100 mg/dL) despite treatment with one of the following:

3.1.1 For patient requiring greater than 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy

OR

3.1.2 For patient requiring less than or equal to 25% additional lowering, one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy with ezetimibe

OR

3.2 Documented intolerance of both rosuvastatin and atorvastatin with or without ezetimibe OR medical rationale against the use of statin therapy with or without ezetimibe therapy

AND

4 - The patient is 18 years of age or older

AND

5 - One of the following:

5.1 Patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Repatha

OR

5.2 Documented intolerance to statin and/or ezetimibe therapy

OR

5.3 Medical rationale against use of statin or ezetimibe therapy

AND

6 - One of the following:

6.1 The dose requested is 140 mg every 2 weeks

OR

6.2 The dose requested is 420 mg once monthly

OR

6.3 The dose requested is 420 mg every 2 weeks and patient is receiving lipid apheresis

Product Name:Repatha	
Diagnosis	HoFH (Homozygous Familial Hypercholesterolemia), HeFH (Heterozygous Familial Hypercholesterolemia)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) or heterozygous familial hypercholesterolemia (HeFH)

AND

2 - One of the following:

2.1 Persistently elevated LDL-C (low-density lipoprotein cholesterol) (greater than or equal to 70 mg/dL) despite treatment with one of the following:

- At least 90 days of therapy with high intensity rosuvastatin (20 mg/40 mg) therapy concurrently with ezetimibe
- For those intolerant to rosuvastatin, at least 90 days of therapy with high intensity atorvastatin (40 mg/80 mg) therapy concurrently with ezetimibe

OR

2.2 Documented intolerance of both rosuvastatin and atorvastatin and/or ezetimibe

OR

2.3 Medical rationale against the use of statin and/or ezetimibe therapy

AND

3 - The patient is 10 years of age or older

AND

4 - One of the following:

4.1 Patient will be utilizing maximally tolerated statin therapy with or without ezetimibe concurrently with Repatha

OR

4.2 Documented intolerance to statin and/or ezetimibe therapy

OR

4.3 Medical rationale against use of statin or ezetimibe therapy

AND

5 - One of the following:

5.1 If the patient has a diagnosis of HoFH, one of the following:

5.1.1 The dose requested is 420 mg once monthly

OR

5.1.2 The dose requested is 420 mg every 2 weeks and one of the following:

- Patient has not achieved clinically meaningful response after at least 12 weeks at 420 mg once monthly dosing
- Patient is receiving lipid apheresis

OR

5.2 If the patient has a diagnosis of HeFH, one of the following:

5.2.1 The dose requested is 140 mg every 2 weeks

OR

5.2.2 The dose requested is 420 mg once monthly

OR

5.2.3 The dose requested is 420 mg every 2 weeks and patient is receiving lipid apheresis

Product Name:Repatha	
Diagnosis	ASCVD (Atherosclerotic Cardiovascular Disease), Primary hyperlipidemia, without clinical ASCVD, HoFH (Homozygous Familial Hypercholesterolemia), HeFH (Heterozygous Familial Hypercholesterolemia)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Repatha for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - One of the following:

- Continued concurrent use of maximally tolerated statin therapy with or without ezetimibe
- Documented intolerance to statin and/or ezetimibe therapy OR medical rationale against use of statin or ezetimibe therapy

AND

3 - One of the following:

3.1 If the patient has a diagnosis of HoFH (homozygous familial hypercholesterolemia), one of the following:

3.1.1 The dose requested is 420 mg once monthly

OR

3.1.2 The dose requested is 420 mg every 2 weeks and one of the following:

- Patient has not achieved clinically meaningful response after at least 12 weeks at 420 mg once monthly dosing
- Patient is receiving lipid apheresis

OR

3.2 For all other diagnoses, one of the following:

3.2.1 The dose requested is 140 mg every 2 weeks

OR

3.2.2 The dose requested is 420 mg once monthly

OR

3.2.3 The dose requested is 420 mg every 2 weeks and patient is receiving lipid apheresis

AND

4 - One of the following:

4.1 Reduction in LDL-C from baseline

OR

4.2 Maintenance of goal LDL-C

2 . Background

Benefit/Coverage/Program Information

Table 1. Major ASCVD Events

Acute Coronary Syndrome (ACS) within the past 12 months
History of myocardial infarction (other than recent ACS event listed above)
History of ischemic stroke
Peripheral artery disease (PAD) with history of claudication with ABI <0.85
PAD with history of previous revascularization or amputation

Table 2. High-Risk Conditions

Age >/= 65 years
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery outside of major ASCVD event
History of prior percutaneous coronary intervention outside of major ASCVD event
Diabetes mellitus
Hypertension
Chronic kidney disease (eGFR 15-59 mL/min/1.73m^2)
Current smoker
Persistently elevated LDL-C (>/= 100 mg/dL) despite maximally tolerated statin therapy plus ezetimibe
Congestive heart failure

Table 3. Secondary Causes of Dyslipidemia

Cholestatic Liver Disease

Chronic Renal Disease
Cigarette Smoking
Diabetes Mellitus
Excessive Alcohol Consumption
Extreme Dietary Patterns (e.g., anorexia nervosa)
Hypothyroidism
Medications (e.g., thiazide diuretics, beta blockers, oral estrogens)
Nephrotic Syndrome
Obesity

3 . Revision History

Date	Notes
9/16/2024	Updated Juxtapid pregnancy test language and Praluent HeFH min a ge and quantity limits. Corrected typo in step 2.2.1 of Repatha ASCV D section.

Pemazyre

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164548
Guideline Name	Pemazyre
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/30/2025	Updated criteria for cholangiocarcinoma

Phosphodiesterase Inhibitors for COPD

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-159180
Guideline Name	Phosphodiesterase Inhibitors for COPD
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	12/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient has severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis

AND

2 - Chart documentation shows patient has a history of exacerbations

AND

3 - Chart documentation shows patient has an FEV-1 that is less than or equal to 50% predicted

AND

4 - One of the following:

4.1 Patient is utilizing a combination long-acting beta-agonist (LABA)/long-acting muscarinic antagonist (LAMA)/inhaled corticosteroid (ICS) therapy for at least 90 days in the past 120 days

OR

4.2 BOTH of the following:

4.2.1 Prescriber has provided medical rationale for the use of Daliresp (roflumilast) over combination LAMA/LABA/ICS therapy

AND

4.2.2 One of the following:

- Member is utilizing combination LABA/LAMA therapy for at least 90 days in the past 120 days
- Prescriber has provided medical rationale for the use of Daliresp (roflumilast) over combination LABA/LAMA therapy

AND

5 - One of the following:

5.1 Prescriber attests patient will continue to utilize appropriate adjunct therapy while on Daliresp (roflumilast)

OR

5.2 Prescriber has provided medical rationale for discontinuing use of adjunct therapy (please document)

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

Approval Criteria

1 - Patient has diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2 - Chart documentation shows patient has an FEV-1/FVC ratio of less than 0.7 measured by spirometry

AND

3 - Chart documentation shows patient has a Modified Medical Research Council (mMRC) dyspnea score of greater than or equal to 2

AND

4 - One of the following:

4.1 Patient is utilizing a combination long-acting beta-agonist (LABA)/long-acting muscarinic antagonist (LAMA)/inhaled corticosteroid (ICS) therapy for at least 90 days in the past 120 days

OR

4.2 BOTH of the following:

4.2.1 Prescriber has provided medical rationale for the use of Ohtuvayre (ensifentrine) over combination LAMA/LABA/ICS therapy

AND

4.2.2 One of the following:

- Member is utilizing combination LABA/LAMA therapy for at least 90 days in the past 120 days
- Prescriber has provided medical rationale for the use of Ohtuvayre (ensifentrine) over combination LABA/LAMA therapy

AND

5 - One of the following:

5.1 Prescriber attests patient will continue to utilize appropriate adjunct therapy while on Ohtuvayre (ensifentrine)

OR

5.2 Prescriber has provided medical rationale for discontinuing use of adjunct therapy (please document)

Product Name:Brand Daliresp, generic roflumilast, Ohtuvayre	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

2 - One of the following:

2.1 Patient is continuing to utilize adjunct therapy, as applicable

OR

2.2 Medical rationale has been provided for not continuing adjunct therapy (please document)

2 . Revision History

Date	Notes
11/4/2024	New

Piqray

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147148
Guideline Name	Piqray
Formulary	• Medicaid - Community & State Indiana

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 ova rian ablation/suppression, or male under BC initial auth section; Mino

	r verbiage update to NCCN Recommended Regimens initial auth sec tion (with no changes to clinical intent).

Pomalyst

Prior Authorization Guideline

Guideline ID	GL-151385
Guideline Name	Pomalyst
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/13/2024	Updated criteria for multiple myeloma and Kaposi sarcoma.

Pompe Disease Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154706
Guideline Name	Pompe Disease Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Opfolda	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease confirmed by ONE of the following (submission of documentation required):

1.1 Deficiency of acid alpha-glucosidase (GAA) enzyme

OR

1.2 GAA genotyping or gene sequencing

AND

2 - Patient is 18 years of age or older

AND

3 - Patient weighs greater than or equal to 40 kilograms

AND

4 - Prescriber attests that patient will be using Opfolda (miglustat) and Pombiliti (cipaglucosidase alfa) concurrently

AND

5 - Prescriber attests that patient will NOT be using Opfolda (miglustat) concurrently with Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase alfa)

AND

6 - Prescribed by, or in consultation with, a geneticist, metabolic disorder specialist or neurologist

AND

7 - For those of childbearing potential, documentation of a negative pregnancy test from within the past 30 days and prescriber has counseled patient on risks associated with conceiving while utilizing Pombiliti/Opfolda and medically appropriate methods of contraception

AND

8 - Dose requested does not exceed 260 milligrams every other week (8 capsules/28 days)

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

Approval Criteria

1 - History of requested agent within the past 90 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

2 - Prescriber attests to ALL of the following:

2.1 Opfolda (miglustat) will continue to be used in conjunction with Pombiliti (cipaglucosidase alfa)

AND

2.2 For those of childbearing potential, patient is not currently pregnant and prescriber has counseled patient regarding medically appropriate methods of contraception

AND

2.3 Patient will NOT be using Opfolda (miglustat) concurrently with Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase alfa)

AND

3 - Prescriber has submitted documentation supporting improvement or stabilization in disease state (e.g., forced vital capacity, six-minute walk test) **AND** **4** - Dose requested does not exceed 260 milligrams every other week (8 capsules/28 days)

2 . Revision History

Date	Notes
9/10/2024	Criteria added to not use Opfolda with Lumizyme or Nexviazyme.

Preferred Non-Solid Dosage Forms

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-122060
Guideline Name	Preferred Non-Solid Dosage Forms
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/16/2023

1 . Criteria

Diagnosis	Requests for 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 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 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 History of failure, contraindication, or intolerance to at least THREE preferred* solid oral dosage forms (Prior trials of formulary/PDL (preferred drug list) alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request. NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to ALL of the preferred products.)

OR

3.1.2.2 There are no preferred formulary 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 medication 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	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Presbyopia Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123777
Guideline Name	Presbyopia Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Vuity	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of presbyopia

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by, or in consultation with, an optometrist or ophthalmologist

AND

4 - Previous trial/failure/intolerance of corrective lenses (e.g., eyeglasses, contact lenses)

Product Name:Vuity	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - History of the requested agent in the past 90 days	
Notes	*If patient does not meet history requirement for reauthorization criteri a, please refer to initial authorization criteria

2 . Revision History

Date	Notes
4/11/2023	SPDL eff 7.1.23

Prevymis

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129062
Guideline Name	Prevymis
Formulary	• Medicaid - Community & State Indiana

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

Procysbi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-109261
Guideline Name	Procysbi
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2022

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

Progesterone – Non-Oral

Prior Authorization Guideline

Guideline ID	GL-147395
Guideline Name	Progesterone – Non-Oral
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name: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
5/14/2024	New

Promacta, Alvaiz

Prior Authorization Guideline

Guideline ID	GL-160752
Guideline Name	Promacta, Alvaiz
Formulary	• Medicaid - Community & State Indiana

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
11/18/2024	Added non-solid dosage form questions for Promacta packets

Proton Pump Inhibitors

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150081
Guideline Name	Proton Pump Inhibitors
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:(All Rx and OTC Products per label name included) generic omeprazole tabs, Brand Prilosec tabs, Brand Protonix tabs, Brand Prevacid caps, Nexium caps, generic rabeprazole tabs, Brand Aciphex tabs, generic dexlansoprazole caps, generic omeprazole/sodium bicarb caps, Brand Zegerid caps, omeprazole 20.6 mg caps, omeprazole ODT, generic esomeprazole 24HR, Brand Nexium 24HR	
Diagnosis	Non-Preferred Products - NOT exceeding 90 days PPI therapy within past 180 days
Approval Length	90 Days*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following**:

1.1 Trial and failure history of two different (chemical entities) preferred agents within the same subclass for a total duration of 4 weeks (supported by chart documentation or claims history)

OR

1.2 Prescriber has submitted medical justification for use of the requested non-preferred agent over ALL preferred agents within the same subclass

Notes	*Approval duration should not allow member to exceed 90 days of PPI therapy within 180 days **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:(All Rx and OTC Products per label name included) generic omeprazole tabs, Brand Prilosec tabs, Brand Protonix tabs, Brand Prevacid caps, Nexium caps, generic rabeprazole tabs, Brand Aciphex tabs, generic dexlansoprazole caps, generic omeprazole/sodium bicarb caps, Brand Zegerid caps, omeprazole 20.6 mg caps, omeprazole ODT, generic esomeprazole 24HR, Brand Nexium 24HR	
Diagnosis	Non-Preferred Products - NOT exceeding 90 days PPI therapy within past 180 days
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 365 days

Product Name:(All Rx and OTC Products per label name included) generic omeprazole caps, Brand Prilosec tabs, generic omeprazole tabs, generic pantoprazole tabs, Brand Protonix tabs, generic lansoprazole caps, Brand Prevacid caps, generic esomeprazole magnesium caps, Brand Nexium caps, generic rabeprazole tabs, Brand Aciphex tabs, generic dexlansoprazole caps, Brand Dexilant caps, generic omeprazole/sodium bicarb caps, Brand Zegerid caps, omeprazole 20.6 mg caps, omeprazole ODT, generic esomeprazole 24HR, Brand Nexium 24HR	
Diagnosis	Exceeding 90 days PPI therapy within past 180 days

Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has one of the following diagnoses:

- Barrett's esophagus
- Abnormality of secretion of gastrin
- Zollinger-Ellison syndrome
- Any disease leading to hypersecretion

OR

1.2 Diagnosis of duodenal/gastric/peptic ulcer that has not healed* (see notes)

OR

1.3 Patient is on continuous drug therapy requiring gastroprotection (e.g. anticoagulants, corticosteroids, antiplatelet agents, NSAIDS, etc.)

OR

1.4 Both of the following:

1.4.1 Diagnosis of one of the following:

- Erosive esophagitis
- Gastroesophageal reflux disease (GERD)

AND

1.4.2 One of the following:

- Previous trial and failure of intermittent PPI therapy (patient has experienced discontinuation of PPI therapy)
- Previous trial and failure of H2 antagonist therapy
- Previous trial and failure of antacid therapy

AND

2 - If the request is non-preferred one of the following**:

2.1 Trial and failure history of two different (chemical entities) preferred agents within the same subclass for a total duration of 4 weeks (supported by chart documentation or claims history)

OR

2.2 Prescriber has submitted medical justification for use of the requested non-preferred agent over ALL preferred agents within the same subclass

Notes	*Diagnosis of duodenal/gastric/peptic ulcer that has not healed: Approve only 4 additional weeks beyond patient's previous 90 days of use (permit a total of 118 days of therapy per 180 days). **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:(All Rx and OTC Products per label name included) Brand Prilosec susp packet, generic lansoprazole ODT, Brand Prevacid Solutab, Rabeprazole sprinkle, generic esomeprazole susp packet, generic pantoprazole susp packet, generic omeprazole/sodium bicarb powd pack, Brand Zegerid powd pack, Konvomep	
Diagnosis	Non-Preferred Non-Solid Dosage Forms - NOT exceeding 90 days PPI therapy within past 180 days
Approval Length	90 Days*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is unable to swallow tablet/capsule formulation

AND

2 - One of the following:

2.1 Trial and failure of both Brand Nexium Packets and Brand Protonix Pak for a total duration of 4 weeks (supported by chart documentation or claims history)

OR

2.2 Prescriber has submitted medical justification for use of the requested non-preferred agent over both Brand Nexium Packets and Brand Protonix Pak

Notes	*Approval duration should not allow member to exceed 90 days of PPI therapy within 180 days

Product Name:(All Rx and OTC Products per label name included) Brand Prilosec susp packet, generic lansoprazole ODT, Brand Prevacid Solutab, Rabeprazole sprinkle, generic esomeprazole susp packet, generic pantoprazole susp packet, generic omeprazole/sodium bicarb powd pack, Brand Zegerid powd pack, Konvomep	
Diagnosis	Non-Preferred Non-Solid Dosage Forms - NOT exceeding 90 days PPI therapy within past 180 days
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 365 days

Product Name:(All Rx and OTC Products per label name included) Brand Prilosec susp packet, generic lansoprazole ODT, Brand Prevacid Solutab, Rabeprazole sprinkle, generic esomeprazole susp packet, Brand Nexium packet, generic pantoprazole susp packet, Brand Protonix packet, generic omeprazole/sodium bicarb powd pack, Brand Zegerid powd pack, Konvomep	
Diagnosis	Non-Solid Dosage Forms - Exceeding 90 days PPI therapy within past 180 days

Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has one of the following diagnoses:

- Barrett's esophagus
- Abnormality of secretion of gastrin
- Zollinger-Ellison syndrome
- Any disease leading to hypersecretion

OR

1.2 Diagnosis of duodenal/gastric/peptic ulcer that has not healed* (see notes)

OR

1.3 Patient is on continuous drug therapy requiring gastroprotection (e.g. anticoagulants, corticosteroids, antiplatelet agents, NSAIDS, etc.)

OR

1.4 Both of the following:

1.4.1 Diagnosis of one of the following:

- Erosive esophagitis
- Gastroesophageal reflux disease (GERD)

AND

1.4.2 One of the following:

- Previous trial and failure of intermittent PPI therapy (patient has experienced discontinuation of PPI therapy)
- Previous trial and failure of H2 antagonist therapy
- Previous trial and failure of antacid therapy

AND

2 - If the request is non-preferred, both of the following:

2.1 Patient is unable to swallow tablet/capsule formulation

AND

2.2 One of the following:

2.2.1 Trial and failure of both Brand Nexium Packets and Brand Protonix Pak for a total duration of 4 weeks (supported by chart documentation or claims history)

OR

2.2.2 Prescriber has submitted medical justification for use of the requested non-preferred agent over both Brand Nexium Packets and Brand Protonix Pak

Notes	*Diagnosis of duodenal/gastric/peptic ulcer that has not healed: Approve only 4 additional weeks beyond patient's previous 90 days of use (permit a total of 118 days of therapy per 180 days).

Product Name:(All Rx and OTC Products per label name included) generic omeprazole caps, Brand Prilosec tabs, generic omeprazole tabs, generic pantoprazole tabs, Brand Protonix tabs and susp packet, generic lansoprazole caps, Brand Prevacid caps, generic esomeprazole magnesium caps, Brand Nexium caps and susp packet, generic rabeprazole tabs, Brand Aciphex tabs, generic dexlansoprazole caps, Brand Dexilant caps, generic omeprazole/sodium bicarb caps, Brand Zegerid caps, Brand Prilosec susp packet, generic lansoprazole ODT, Brand Prevacid Solutab, Rabeprazole sprinkle, generic esomeprazole susp packet, generic pantoprazole susp packet, generic omeprazole/sodium bicarb powd pack, Brand Zegerid powd pack, Konvomep, omeprazole 20.6 mg caps, omeprazole ODT, generic esomeprazole 24HR, Brand Nexium 24HR	
Diagnosis	Quantity Limit
Approval Length	90 Days*
Guideline Type	Quantity Limit (Max Daily Dose)

Approval Criteria

1 - One of the following:

1.1 The requested drug must be used for an 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 - The drug is being prescribed within the manufacturer's published dosing guidelines or 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.

Notes	These criteria are from the Quantity Limits policy. *May approve UP T O 1 year if member meets drug-specific criteria for PPI therapy in exc ess of 90 days per 180 days; otherwise, approval should not exceed 9 0 days of therapy within 180 days.

Product Name:(All Rx and OTC Products per label name included) generic omeprazole caps, Brand Prilosec tabs, generic omeprazole tabs, generic pantoprazole tabs, Brand Protonix tabs and susp packet, generic lansoprazole caps, Brand Prevacid caps, generic esomeprazole magnesium caps, Brand Nexium caps and susp packet, generic rabeprazole tabs, Brand Aciphex tabs, generic dexlansoprazole caps, Brand Dexilant caps, generic omeprazole/sodium bicarb caps, Brand Zegerid caps, Brand Prilosec susp packet, generic lansoprazole ODT, Brand Prevacid Solutab, Rabeprazole sprinkle, generic esomeprazole susp packet, generic pantoprazole susp packet, generic omeprazole/sodium bicarb powd pack, Brand Zegerid powd pack, Konvomep, omeprazole 20.6 mg caps, omeprazole ODT, generic esomeprazole 24HR, Brand Nexium 24HR	
Diagnosis	Exceeding 90 days PPI therapy within past 180 days; Non-Solid Dosage Forms - Exceeding 90 days PPI therapy within past 180 days
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has one of the following diagnoses:

- Barrett's esophagus
- Abnormality of secretion of gastrin
- Zollinger-Ellison syndrome
- Any disease leading to hypersecretion

OR

2 - Diagnosis of duodenal/gastric/peptic ulcer that has not healed* (see notes)

OR

3 - Patient is on continuous drug therapy requiring gastroprotection (e.g. anticoagulants, corticosteroids, antiplatelet agents, NSAIDS, etc.)

OR **4** - Both of the following: **4.1** Diagnosis of erosive esophagitis or Gastroesophageal reflux disease (GERD) **AND** **4.2** Previous trial and failure of intermittent PPI therapy (member has trialed discontinuation of PPI therapy within the previous approval timeframe)

Notes	*Diagnosis of duodenal/gastric/peptic ulcer that has not healed: Approve only 4 additional weeks

2 . Revision History

Date	Notes
7/22/2024	Removed age limits for non-solid dosage forms. Updated T/F language for non-solid dosage forms. Updated required value from ALL to 1 in step 1.4.1 pf Non-Solid Dosage Forms - Exceeding 90 days PPI therapy within past 180 days section.

Pulmonary Antihypertensives

Prior Authorization Guideline

Guideline ID	GL-150849
Guideline Name	Pulmonary Antihypertensives
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/2/2024

1 . Criteria

Product Name:Winrevair	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (WHO Group 1)

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Patient has previous trial and failure of at least 60 days of therapy with any agent from two of the following subcategories:

- Endothelin receptor antagonists
- Phosphodiesterase 5-inhibitors
- Prostacyclin receptor modulators
- Soluble guanylate cyclase stimulator

OR

4.2 Prescriber has provided valid medical justification for the use of Winrevair (sotatercept-csrk) over all agents within all of the following subcategories:

- Endothelin receptor antagonists
- Phosphodiesterase 5-inhibitors
- Prostacyclin receptor modulators
- Soluble guanylate cyclase stimulator

AND

5 - Prescriber attests to all of the following:

- Prescriber has obtained baseline hemoglobin (Hgb) and platelet count prior to initiating therapy
- Baseline platelet count is 50,000/mm3 (50 x 109/L) or greater
- Prescriber will continue to monitor Hgb and platelet count and adjust dosing per the prescribing information

AND

6 - Requested dose does not exceed 0.7 milligrams per kilogram (actual body weight) every 3 weeks

Product Name:Winrevair	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Prescriber has submitted documentation (e.g., current and previous chart notes) explicitly supporting improvement or stabilization in disease state (e.g., WHO Functional Class classification, 6-minute walk test, etc.)

AND

3 - Requested dose does not exceed 0.7 milligrams per kilogram (actual body weight) every 3 weeks

Product Name:Opsynvi	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (WHO Group 1)

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - One of the following:

- Previous trial and failure of separate components
- Prescriber has provided valid medical rationale for the use of macitentan/tadalafil combination over separate components

AND

4 - Requested dose does not exceed 10 milligrams/40 milligrams per day

AND

5 - For those of childbearing potential, submission of documentation of a negative pregnancy test obtained within the past 30 days

AND

6 - For female patients, patient is enrolled in the Opsynvi (macitentan/tadalafil) REMS (Risk Evaluation and Mitigation Strategy) program

AND

7 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor (other than the one being requested)

- Adempas (riociguat)

Product Name:Opsynvi	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 10 milligrams/40 milligrams per day

AND

3 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor (other than the one being requested)
- Adempas (riociguat)

Product Name:Brand Letairis, generic ambrisentan	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - ONE of the following:

- Previous trial and failure of bosentan
- Prescriber has provided valid medical rationale of ambrisentan over bosentan

AND

4 - Requested dose does not exceed one of the following:

- 10 mg (milligrams)/day
- 5 mg/day if on concomitant cyclosporine therapy

AND

5 - For those of childbearing potential, submission of documentation of a negative pregnancy test obtained within the past 30 days

AND

6 - Patient is enrolled in the Ambrisentan or PS-Ambrisentan REMS program (female patients only)

Product Name:Brand Letairis, generic ambrisentan	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed one of the following:

- 10 mg/day
- 5 mg/day if on concomitant cyclosporine therapy

Product Name:Opsumit	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - ONE of the following:

- Previous trial and failure of bosentan
- Prescriber has provided valid medical rationale for the use of macitentan over bosentan

AND

4 - Requested dose does not exceed 10 mg/day

AND

5 - For those of childbearing potential, submission of documentation of a negative pregnancy test obtained within the past 30 days

AND

6 - Patient is enrolled in the Opsumit/macitentan REMS program (female patients only)

Product Name:Opsumit	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 10 mg/day

Product Name:Brand Tracleer, generic bosentan, Tracleer	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - ONE of the following:

3.1 For adult patients (tablet formulation), ONE of the following:

3.1.1 Requested dose does not exceed 250 mg/day for patients weighing greater than 40 kg (kilograms)

OR

3.1.2 Requested dose does not exceed 125 mg/day for patients weighing less than or equal to 40 kg

OR

3.2 For pediatric patients 12 years of age or older (tablet formulation), ONE of the following:

3.2.1 Requested dose does not exceed 250 mg/day for patients weighing greater than 40 kg

OR

3.2.2 Requested dose does not exceed 125 mg/day for patients weighing less than or equal to 40 kg

OR

3.3 For pediatric patients less than or equal to 12 years of age (dispersible tablet formulation), ONE of the following:

3.3.1 Requested dose does not exceed 32 mg/day (1 dispersible tablet/day) for patients weighing 4 kg to 8 kg

OR

3.3.2 Requested dose does not exceed 64 mg/day (2 dispersible tablets/day) for patients weighing greater than 8 kg to 16 kg

OR

3.3.3 Requested dose does not exceed 96 mg/day (3 dispersible tablets/day) for patients weighing greater than 16 kg to 24 kg

OR

3.3.4 Requested dose does not exceed 128 mg/day (4 dispersible tablets/day) for patients weighing greater than 24 kg to 40 kg

AND

4 - Patient does not have active claims for cyclosporine-A or glyburide

AND

5 - For those of childbearing potential, submission of documentation of a negative pregnancy test obtained within the past 30 days

AND

6 - Patient is enrolled in the Tracleer/bosentan REMS program

Product Name:Brand Tracleer, generic bosentan, Tracleer	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Patient does not have active claims for cyclosporine-A or glyburide

AND

3 - ONE of the following:

3.1 For adult patients (tablet formulation), ONE of the following:

3.1.1 Requested dose does not exceed 250 mg/day for patients weighing greater than 40 kg (kilograms)

OR

3.1.2 Requested dose does not exceed 125 mg/day for patients weighing less than or equal to 40 kg

OR

3.2 For pediatric patients 12 years of age or older (tablet formulation), ONE of the following:

3.2.1 Requested dose does not exceed 250 mg/day for patients weighing greater than 40 kg

OR

3.2.2 Requested dose does not exceed 125 mg/day for patients weighing less than or equal to 40 kg

OR

3.3 For pediatric patients less than or equal to 12 years of age (dispersible tablet formulation), ONE of the following:

3.3.1 Requested dose does not exceed 32 mg/day (1 dispersible tablet/day) for patients weighing 4 kg to 8 kg

OR

3.3.2 Requested dose does not exceed 64 mg/day (2 dispersible tablets/day) for patients weighing greater than 8 kg to 16 kg

OR

3.3.3 Requested dose does not exceed 96 mg/day (3 dispersible tablets/day) for patients weighing greater than 16 kg to 24 kg

OR

3.3.4 Requested dose does not exceed 128 mg/day (4 dispersible tablets/day) for patients weighing greater than 24 kg to 40 kg

Product Name:Liqrev	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Requested dose does not exceed 60 mg/day

AND

4 - Patient is 18 years of age or older

AND

5 - Patient is unable to swallow tablet formulation of sildenafil

AND

6 - ONE of the following:

6.1 Patient has previous trial and failure of Revatio suspension

OR

6.2 Provider has submitted medical rationale for use of Liqrev suspension over Revatio suspension

AND

7 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- Adempas (riociguat)

- Reyataz (atazanavir)
- Prezista (darunavir)
- Lexiva (fosamprenavir)
- Crixivan (indinavir)
- Kaletra (lopinavir/ritonavir)
- Viracept (nelfinavir)
- Norvir (ritonavir)
- Invirase (saquinavir)
- Aptivus (tipranavir)
- PDE-5 inhibitor (other than the one being requested)

Product Name:Liqrev	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Patient is unable to swallow tablet formulation of sildenafil

AND

3 - ONE of the following:

3.1 Patient has previous trial and failure of Revatio suspension

OR

3.2 Provider has submitted medical rationale for use of Liqrev suspension over Revatio suspension

AND

4 - Requested dose does not exceed 60 mg/day

AND

5 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- Adempas (riociguat)
- Reyataz (atazanavir)
- Prezista (darunavir)
- Lexiva (fosamprenavir)
- Crixivan (indinavir)
- Kaletra (lopinavir/ritonavir)
- Viracept (nelfinavir)
- Norvir (ritonavir)
- Invirase (saquinavir)
- Aptivus (tipranavir)
- PDE-5 inhibitor (other than the one being requested)

Product Name:Brand Revatio, generic sildenafil	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Requested dose does not exceed 60 mg/day

AND

4 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- Adempas (riociguat)
- Reyataz (atazanavir)
- Prezista (darunavir)
- Lexiva (fosamprenavir)
- Crixivan (indinavir)
- Kaletra (lopinavir/ritonavir)
- Viracept (nelfinavir)
- Norvir (ritonavir)
- Invirase (saquinavir)
- Aptivus (tipranavir)
- PDE-5 inhibitor (other than the one being requested)

AND

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

- Patient is under 12 years of age
- Patient is 12 years of age or older and unable to swallow tablet formulation of sildenafil

Product Name:Brand Revatio, generic sildenafil	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 60 mg/day

AND

3 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- Adempas (riociguat)
- Reyataz (atazanavir)
- Prezista (darunavir)
- Lexiva (fosamprenavir)
- Crixivan (indinavir)
- Kaletra (lopinavir/ritonavir)
- Viracept (nelfinavir)
- Norvir (ritonavir)
- Invirase (saquinavir)
- Aptivus (tipranavir)
- PDE-5 inhibitor (other than the one being requested)

AND

4 - If the request is for Revatio suspension, ONE of the following:

- Patient is under 12 years of age
- Patient is 12 years of age or older and unable to swallow tablet formulation of sildenafil

Product Name:Brand Adcirca, generic tadalafil, Alyq	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Requested dose does not exceed 40 mg/day

AND

4 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE5 inhibitor (other than the one being requested)
- Adempas (riociguat)

AND

5 - If the request is for Alyq, the patient has a trial and failure of generic tadalafil or medical justification for use

Product Name:Brand Adcirca, generic tadalafil, Alyq	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 40 mg/day

AND

3 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor (other than the one being requested)
- Adempas (riociguat)

Product Name:Tadliq	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - ONE of the following:

- Previous trial and failure of Revatio suspension

- Prescriber has provided valid medical rationale for the use of Tadliq over Revatio suspension

AND

4 - Requested dose does not exceed 40 mg/day

AND

5 - ONE of the following:

- Patient is under 12 years of age
- Patient is 12 years of age or older and unable to swallow tablet formulation of tadalafil

AND

6 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor (other than the one being requested)
- Adempas (riociguat)

Product Name:Tadliq	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 40 mg/day

AND

3 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor (other than the one being requested)
- Adempas (riociguat)

AND

4 - ONE of the following:

- Patient is under 12 years of age
- Patient is 12 years of age or older and unable to swallow tablet formulation of tadalafil

Product Name:Orenitram, Orenitram titration kit	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Patient does not have severe hepatic impairment (Child-Pugh class C)

Product Name:Orenitram, Orenitram titration kit	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Patient does not have severe hepatic impairment (Child-Pugh class C)

Product Name:Tyvaso, Tyvaso DPI	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension or pulmonary hypertension associated with interstitial lung disease

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

Product Name:Tyvaso, Tyvaso DPI	
Approval Length	1 year(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

Product Name:Uptravi, Uptravi Titration Pack	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Patient does not have an active claim for CYP2C8 (enzyme) inhibitor (e.g., gemfibrozil)

AND

4 - ONE of the following:

- Previous trial and failure of Orenitram
- Prescriber has submitted valid medical rationale for the use of Uptravi over Orenitram

Product Name:Uptravi, Uptravi Titration Pack

Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Patient does not have an active claim for CYP2C8 inhibitor (e.g., gemfibrozil)

Product Name:Ventavis	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of arterial pulmonary hypertension

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

Product Name:Ventavis	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

Product Name:Adempas	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of arterial pulmonary hypertension
- Diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)

AND

2 - Prescribed by, or in consultation with, a pulmonologist or cardiologist

AND

3 - Requested dose does not exceed 7.5 mg/day (patients who smoke may require further dosing evaluation)

AND

4 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor
- Non-specific PDE inhibitor (dipyridamole, theophylline, aminophylline)

- Verquvo (vericiguat)

AND

5 - For those of childbearing potential, submission of documentation of a negative pregnancy test obtained within the past 30 days

AND

6 - Patient is enrolled in the Adempas REMS program (female patients only)

Product Name:Adempas	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 60 days within the past 90 days, confirmed by claims history or submission of medical records

AND

2 - Requested dose does not exceed 7.5 mg/day (patients who smoke may require further dosing evaluation)

AND

3 - Patient does not have an active claim for any of the following:

- Nitrate therapy
- PDE-5 inhibitor
- Non-specific PDE inhibitor (dipyridamole, theophylline, aminophylline)
- Verquvo (vericiguat)

2 . Revision History

Date	Notes
8/2/2024	Updated Tyvaso DPI GPIs. Added Winrevair and Opsynvi. Updated d iagnosis to add arterial. Updated pregnancy test language.

Pulmozyme

Prior Authorization Guideline

Guideline ID	GL-147428
Guideline Name	Pulmozyme
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/15/2024	Updated generic name in GPI table. Removed dx header and minor cosmetic updates. No changes to clinical intent.

Qbrexza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-125831
Guideline Name	Qbrexza
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

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
5/16/2023	New

Qinlock

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156862
Guideline Name	Qinlock
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
10/1/2024	Updated disease type for GIST based on NCCN recommendations

Quantity Limits

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-128960
Guideline Name	Quantity Limits
Formulary	• Medicaid - Community & State Indiana

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 permitted

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-156416
Guideline Name	Radicava ORS
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
9/27/2024	Clarified criteria for existing prior authorization to be under the medic al benefit. Updated initial and reauth durations to 12 months.

Rayos

Prior Authorization Guideline

Guideline ID	GL-161328
Guideline Name	Rayos
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/26/2024	Minor updates to embedded step criterion (no changes to clinical inte nt).

Rectiv

Prior Authorization Guideline

Guideline ID	GL-165021
Guideline Name	Rectiv
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/11/2025	Added generic Nitroglycerin ointment.

Regranex

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82129
Guideline Name	Regranex
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Relyvrio

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.

Repository Corticotropins

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-114249
Guideline Name	Repository Corticotropins
Formulary	• Medicaid - Community & State Indiana

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 treatment 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

Respiratory and Allergy Biologics

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-155000
Guideline Name	Respiratory and Allergy Biologics
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Dupixent	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma (eosinophilic phenotype or corticosteroid-dependent)

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is utilizing ONE of the following inhaled asthma treatments for 90 of the past 120 days:

- High-dose inhaled corticosteroid (ICS) AND a long-acting beta 2 agonist (LABA) concurrently
- High-dose ICS/LABA combination product
- High-dose ICS/long acting antimuscarinic (LAMA)/LABA combination product

AND

4 - Dupixent will be used as adjunct therapy along with one of the above inhaled asthma treatments

AND

5 - Patient has inadequately controlled asthma as evidenced by ONE of the following:

- Greater than or equal to 3 canisters of a short-acting beta 2 agonist (SABA) in past 60 days
- Oral steroid use in the past 45 days
- ER (emergency room) visit with primary diagnosis of asthma in past 45 days

Product Name:Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 6 months of age or older

AND

3 - Patient has had greater than or equal to 45 days of topical drug therapy with ONE of the following:

- Pimecrolimus
- Tacrolimus
- Corticosteroids

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 1 year of age or older

AND

3 - Patient weighs 15 kg (kilograms) or more

AND

4 - One of the following:

4.1 Patient is 10 years of age or younger

OR

4.2 Patient has had a trial and failure of a 12-week course of Eohilia (budesonide) suspension

OR

4.3 Provider has documented valid medical justification for the use Dupixent (dupilumab) over Eohilia (budesonide) (please document)

Product Name:Dupixent	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has had greater than or equal to 90 days of therapy with an intranasal corticosteroid

AND

4 - Dupixent will be used as adjunct therapy along with an intranasal corticosteroid

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 is 18 years of age or older

AND

3 - Patient has had greater than or equal to 30 days of topical drug therapy with at least ONE of the following:

- Pimecrolimus
- Tacrolimus

- Corticosteroids

Product Name:Dupixent	
Diagnosis	Asthma, Atopic Dermatitis, Eosinophilic Esophagitis, Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), Prurigo Nodularis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of Dupixent within the past 90 days

AND

2 - ONE of the following:

- Patient is continuing to utilize adjunct therapy, if applicable
- Medical rationale has been provided for not continuing adjunct therapy

Product Name:Fasenra	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma (eosinophilic phenotype)

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is utilizing ONE of the following inhaled asthma treatments for 90 of the past 120 days:

- Concurrent high-dose inhaled corticosteroid (ICS) AND a long-acting beta 2 agonist (LABA)
- A high-dose ICS/LABA combination product
- A high-dose ICS/LAMA/LABA combination product

AND

4 - Fasenra will be used as adjunct therapy along with the above inhaled asthma treatment

AND

5 - Patient has inadequately controlled asthma as evidenced by ONE of the following:

- Greater than or equal to 3 canisters of a short-acting beta2 agonist (SABA) in past 60 days
- Oral steroid use in the past 45 days
- ER visit with primary diagnosis of asthma in past 45 days

Product Name:Fasenra	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of Fasenra within the past 90 days

AND

2 - ONE of the following:

- Patient is continuing to utilize adjunct therapy, if applicable
- Medical rationale has been provided for not continuing adjunct therapy

Product Name:Nucala	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma (eosinophilic phenotype)

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is utilizing ONE of the following inhaled asthma treatments for 90 of the past 120 days:

- Concurrent high-dose inhaled corticosteroid (ICS) AND a long-acting beta 2 agonist (LABA)

- A high-dose ICS/LABA combination product
- A high-dose ICS/LAMA/LABA combination product

AND

4 - Nucala will be used as adjunct therapy along with the above inhaled asthma treatment

AND

5 - Patient has inadequately controlled asthma as evidenced by ONE of the following:

- Greater than or equal to 3 canisters of a short-acting beta 2 agonist (SABA) in past 60 days
- Oral steroid use in the past 45 days
- ER visit with primary diagnosis of asthma in past 45 days

Product Name:Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss syndrome)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss Syndrome)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has had greater than or equal to 90 days of drug therapy with ONE of the following:

- Systemic glucocorticoid
- Azathioprine
- Methotrexate
- Cyclophosphamide
- Mycophenolate

Product Name:Nucala	
Diagnosis	Hypereosinophilic syndrome (HES)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient is 12 years of age or older

Product Name:Nucala	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has had greater than or equal to 90 days of therapy with an intranasal corticosteroid

AND

4 - Nucala will be used as adjunct therapy along with an intranasal corticosteroid

Product Name:Nucala	
Diagnosis	Asthma, Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss syndrome), Hypereosinophilic syndrome (HES), Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Nucala within the past 90 days

AND

2 - ONE of the following:

- Patient is continuing to utilize adjunct therapy, if applicable
- Medical rationale has been provided for not continuing adjunct therapy

Product Name:Tezspire auto injector	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma

AND

2 - Patient is 12 years of age or older

AND

3 - Patient is utilizing ONE of the following inhaled asthma treatments for 90 of the past 120 days:

- Concurrent high-dose inhaled corticosteroid (ICS) AND a long-acting beta 2 agonist (LABA)
- A high-dose ICS/LABA combination product
- A high-dose ICS/LAMA/LABA combination product

AND

4 - Tezspire will be used as adjunct therapy along with one of the above inhaled asthma treatments

AND

5 - Patient has inadequately controlled asthma as evidenced by ONE of the following:

- Greater than or equal to 3 canisters of a short-acting beta2 agonist (SABA) in past 60 days
- Oral steroid use in the past 45 days

- ER visit with primary diagnosis of asthma in past 45 days

Product Name:Tezspire auto injector	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Tezspire within the past 90 days

AND

2 - ONE of the following:

- Patient is continuing to utilize adjunct therapy, if applicable
- Medical rationale has been provided for not continuing adjunct therapy

Product Name:Xolair	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of asthma (severe allergic asthma or nonallergic eosinophilic asthma)

AND

2 - Documentation of ONE of the following:

- A positive percutaneous allergy skin test
- In vitro reactivity to a perennial aeroallergen within the past year

AND

3 - Patient is 6 years of age or older

AND

4 - Patient is utilizing ONE of the following inhaled asthma treatments for 90 of the past 120 days:

- Concurrent high-dose inhaled corticosteroid (ICS) AND a long-acting beta 2 agonist (LABA)
- A high-dose ICS/LABA combination product
- A high-dose ICS/LAMA/LABA combination product

AND

5 - Xolair will be used as adjunct therapy along with one of the above inhaled asthma treatments

AND

6 - Patient has inadequately controlled asthma as evidenced by ONE of the following:

- Greater than or equal to 3 canisters of a short-acting beta 2 agonist (SABA) in past 60 days
- Oral steroid use in the past 45 days
- ER visit with primary diagnosis of asthma in past 45 days

Product Name:Xolair	
Diagnosis	Chronic Idiopathic Urticaria
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic idiopathic urticaria

AND

2 - Documentation of at least 6 weeks of symptoms

AND

3 - Patient is 12 years of age or older

AND

4 - The patient has had at least 14 days of drug therapy with a histamine 1 (H1)-receptor antagonist

Product Name:Xolair	
Diagnosis	Nasal Polyps
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inadequately controlled nasal polyps

AND

2 - Patient is 18 years of age or older

AND

3 - The patient has had at least 90 days of therapy with an intranasal corticosteroid

AND

4 - Xolair will be used as adjunct therapy along with an intranasal corticosteroid

Product Name:Xolair	
Diagnosis	IgE-Mediated Food Allergy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of an IgE-mediated (Type 1) allergic reaction to one or more food allergens (submission of chart notes explicitly stating suspected food allergen and respective reaction experienced required)

AND

2 - Submission of documentation (chart notes, laboratory tests/values, assessments, etc.) of one of the following:

- Positive skin prick test (SPT) (greater than or equal to 4 millimeter wheal) to identified foods
- Positive IgE screening (greater than or equal to 6 kUA/L) to identified foods

AND

3 - Patient is at least 1 year of age or older

AND

4 - Prescribed by, or in consultation with, an allergist or immunologist

AND

5 - Prescriber attests that member has been counseled to continue food allergen avoidance while utilizing Xolair (omalizumab)

Product Name:Xolair	
Diagnosis	Asthma, Chronic Idiopathic Urticaria, Nasal Polyps, IgE-Mediated Food Allergy
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of Xolair within the past 90 days

AND

2 - ONE of the following:

- Patient is continuing to utilize adjunct therapy, if applicable
- Medical rationale has been provided for not continuing adjunct therapy

2 . Revision History

Date	Notes

9/16/2024	Updated criteria for eosinophilic esophagitis. GPI updated.

Retevmo

Prior Authorization Guideline

Guideline ID	GL-165073
Guideline Name	Retevmo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/12/2025	Updated GPIs

Revlimid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151757
Guideline Name	Revlimid
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	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.

Rezlidhia

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-123358
Guideline Name	Rezlidhia
Formulary	• Medicaid - Community & State Indiana

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

Rezurock

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161237
Guideline Name	Rezurock
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/25/2024	Removed age requirement in initial auth section.

Rivfloza

Prior Authorization Guideline

Guideline ID	GL-150940
Guideline Name	Rivfloza
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/5/2024

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 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
8/5/2024	New program.

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-125947
Guideline Name	Rubraca
Formulary	• Medicaid - Community & State Indiana

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	Copy NY

Ruconest

Prior Authorization Guideline

Guideline ID	GL-150096
Guideline Name	Ruconest
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

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
7/22/2024	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-109388
Guideline Name	Rydapt
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2022

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 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
7/14/2022	Added myeloid/lymphoid neoplasms criteria per NCCN guideline update.

Samsca

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127874
Guideline Name	Samsca
Formulary	• Medicaid - Community & State Indiana

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

Scemblix

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.

Sedative-Hypnotics and Benzodiazepines

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161871
Guideline Name	Sedative-Hypnotics and Benzodiazepines
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Ambien CR; Generic zolpidem ER; Amytal; Edluar; Generic zolpidem; Brand Lunesta; Generic eszopiclone; meprobamate; zaleplon; Brand Ambien; Generic zolpidem; Zolpimist; Brand Nembutal; Generic Pentobarbital; alprazolam ODT; Generic alprazolam; Brand Xanax; Generic alprazolam ER; Brand Xanax XR; alprazolam intensol; chlordiazepoxide; chlordiazepoxide/amitriptyline; Generic clonazepam; Brand Klonopin; clonazepam ODT; Generic clorazepate dipotassium; Brand Tranxene T; Generic diazepam; Brand Valium; diazepam intensol; Brand Doral; Generic quazepam; estazolam; flurazepam; Brand Ativan; Generic lorazepam; lorazepam intensol; Loreev XR; midazolam; oxazepam; Brand Restoril; Generic temazepam; Brand Halcion; Generic triazolam; Belsomra; Quviviq; Dayvigo; zolpidem caps; Brand Librax; Generic chlordiazepoxide/clidinium; Brand Onfi; Generic clobazam; Sympazan	
Diagnosis	Duplicate Therapy
Approval Length	12 month(s)
Guideline Type	Drug Utilization Review

Approval Criteria

1 - If the request is a clobazam product, the patient has a seizure diagnosis

OR

2 - One of the following:

2.1 The medications involved in the therapeutic duplication are being cross-tapered

OR

2.2 The sedative-hypnotic or benzodiazepine in patient's history is being discontinued or there are plans to discontinue

OR

2.3 There is medical rationale supporting duplication of therapy

Product Name:alprazolam ODT; Generic alprazolam; Brand Xanax; Generic alprazolam ER; Brand Xanax XR; alprazolam intensol; chlordiazepoxide; chlordiazepoxide/amitriptyline; Generic clonazepam; Brand Klonopin; clonazepam ODT; Generic clorazepate dipotassium; Brand Tranxene T; Generic diazepam; Brand Valium; diazepam intensol; Brand Doral; Generic quazepam; estazolam; flurazepam; Brand Ativan; Generic lorazepam; lorazepam intensol; midazolam; oxazepam; Brand Restoril; Generic temazepam; Brand Halcion; Generic triazolam	
Diagnosis	(> 15 day supply and/or > 30 day supply within 90 days)
Approval Length	6 month(s) for catatonia, 12 month(s) for all other indications
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Patient has at least 90 days of benzodiazepine therapy in the past 180 days

OR

1.2 ONE of the following:

1.2.1 Diagnosis of cancer, seizure disorder, catatonia, intractable Meniere's disease, or other terminal illness

OR

1.2.2 Diagnosis of spasticity associated with a central neurological disorder (e.g. cerebral palsy, dystonia, paraplegia, etc.) and BOTH of the following:

1.2.2.1 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 Pharmacopeia-National Formulary (USP-NF)

AND

1.2.2.2 ONE of the following:

- Prescribed by, or in consultation with, a neurologist or physical medicine and rehabilitation specialist
- Previous trial and failure of at least two non-benzodiazepine muscle relaxants

OR

1.2.3 Diagnosis of akathisia and ONE of the following:

- Previous trial and failure of propranolol
- Prescriber has provided medical rationale for the use of a benzodiazepine over propranolol

OR

1.3 Documentation of valid medical justification to exceed plan limitation maximum for initiation of benzodiazepine therapy [15-day supply with a subsequent claim(s) not to exceed 15-day supply (for a total of 30 days of therapy) every 90 days]

Product Name:Loreev XR	
Diagnosis	(> 15 day supply and/or > 30 day supply within 90 days)
Approval Length	6 month(s) for catatonia, 12 month(s) for all other indications
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 The patient has current approval for long-term benzodiazepine therapy (1 year or greater)

OR

1.2 ONE of the following:

1.2.1 Patient has at least 90 days of benzodiazepine therapy in the past 180 days

OR

1.2.2 ONE of the following:

1.2.2.1 Diagnosis of cancer, seizure disorder, catatonia, intractable Meniere's disease, or other terminal illness

OR

1.2.2.2 Diagnosis of spasticity associated with a central neurological disorder (e.g. cerebral palsy, dystonia, paraplegia, etc.) and BOTH of the following:

1.2.2.2.1 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 Pharmacopeia-National Formulary (USP-NF)

AND

1.2.2.2.2 ONE of the following:

- Prescribed by, or in consultation with, a neurologist or physical medicine and rehabilitation specialist
- Previous trial and failure of at least two non-benzodiazepine muscle relaxants

OR

1.2.2.3 Diagnosis of akathisia and ONE of the following:

- Previous trial and failure of propranolol
- Prescriber has provided medical rationale for the use of a benzodiazepine over propranolol

OR

1.3 Documentation of valid medical justification to exceed plan limitation maximum for initiation of benzodiazepine therapy [15-day supply with a subsequent claim(s) not to exceed 15-day supply (for a total of 30 days of therapy) every 90 days]

AND

2 - BOTH of the following:

- History of lorazepam IR formulation for at least 90 of the past 180 days
- Documentation the patient has been utilizing lorazepam IR formulation at a consistent scheduled TID (three times per day) dose within the previous 30 days

2 . Revision History

Date	Notes
12/10/2024	Removed Diastat (diazepam) rectal gel

SGLT2 Inhibitors and Combinations

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124980
Guideline Name	SGLT2 Inhibitors and Combinations
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Glyxambi, Qtern, Steglujan, Trijardy XR	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed combination therapy with preferred* agents of the same classes

OR

2 - Medical justification for use	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
4/24/2023	New

Signifor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82006
Guideline Name	Signifor
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

1 . Criteria

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

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

AND

1.2 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
3/5/2021	Bulk Load

Sivextro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156864
Guideline Name	Sivextro
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
10/1/2024	Added “tablets” to product name to clarify that the policy is specific to oral tablets not IV form

Skeletal Muscle Relaxants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150092
Guideline Name	Skeletal Muscle Relaxants
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

1 . Criteria

Product Name:Lyvispah	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is unable to swallow tablets	

Product Name:Baclofen solution, Ozobax solution, Ozobax DS, Brand Fleqsuvy, generic baclofen suspension	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is unable to swallow tablets

AND

2 - ONE of the following:

- Trial and failure of Lyvispah
- Documentation of medical rationale for use

Product Name:Brand Amrix, generic cyclobenzaprine ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial of cyclobenzaprine (immediate release) within the past 30 days

AND

2 - One of the following:

2.1 History of failure to at least TWO additional preferred alternatives as confirmed by claims history or submission of medical records.*

OR

2.2 History of contraindication or intolerance to TWO additional preferred alternatives (please specify contraindication or intolerance).*

Notes	NOTE: In instances where there are fewer than three preferred altern atives, the patient must have a history of failure, contraindication or int olerance to all of the preferred products.

2 . Revision History

Date	Notes
7/22/2024	Removed age limits for baclofen products

Skyclarys

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127234
Guideline Name	Skyclarys
Formulary	• Medicaid - Community & State Indiana

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.

Smoking Deterrent Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137508
Guideline Name	Smoking Deterrent Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:nicotine transdermal patch, Nicoderm CQ, nicotine gum, Thrive, Nicorette, nicotine lozenge, Nicotrol NS, Nicotrol Inhaler	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 10 years of age or older **AND**	

2 - If the request is non-preferred*, the patient had a trial and failure of THREE preferred* medications within this drug class that are indicated for the patient's diagnosis (if applicable)	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:varenicline, Apo-varenicline	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is 18 years of age or older	

2 . Revision History

Date	Notes
12/11/2023	Updated GPI and product name lists, added NP criteria and PDL link in note.

Sohonos

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147561
Guideline Name	Sohonos
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/21/2024	New program.

Solaraze

Prior Authorization Guideline

Guideline ID	GL-124376
Guideline Name	Solaraze
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Solaraze, generic diclofenac 3% (actinic keratoses) gel	
Approval Length	1 year(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of actinic keratosis	

2 . Revision History

Date	Notes
4/7/2023	Updated GL type to PA

Somavert

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-129170
Guideline Name	Somavert
Formulary	• Medicaid - Community & State Indiana

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)

Soriatane

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-98051
Guideline Name	Soriatane
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

1 . Criteria

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

Approval Criteria

1 - Patient must meet ONE of the following indications for treatment:

- Hyperkeratotic dermatitis of the palms
- Lichen planus
- Palmoplantar pustulosis

- Prophylaxis of skin cancer in a high-risk kidney transplant recipient
- Psoriasis classified as severe
- Squamous cell carcinoma
- Subcorneal pustular dermatosis (SPD; Sneddon-Wilkinson disease)

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

Approval Criteria

1 - Patient must have a history of the requested medication within the past 90 days

2 . Revision History

Date	Notes
11/5/2021	Updated all criteria to match state policy.

Spravato

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157265
Guideline Name	Spravato
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Patient is taking an oral antidepressant

2 . Revision History

Date	Notes
10/9/2024	New guideline

Sprycel

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164573
Guideline Name	Sprycel
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/31/2025	Updated GPIs and product list to add generic. Updated criteria for GI ST

SSRI and SNRI

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124721
Guideline Name	SSRI and SNRI
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Brand Celexa, Generic citalopram, Drizalma, Brand Pristiq, Generic desvenlafaxine succinate ER, Desvenlafaxine ER, Brand Cymbalta, Generic duloxetine, Brand Lexapro, Generic escitalopram, Brand Prozac, Generic fluoxetine caps, Fluoxetine (tabs, soln, DR caps, PMDD tabs), fluvoxamine, Fetzima, Brand Zoloft, Generic sertraline tabs and oral conc, Sertraline caps, Savella, Venlafaxine Besylate 112.5mg ER tabs, Venlafaxine tabs, Brand Effexor XR, Generic venlafaxine ER caps, Venlafaxine ER tabs, Brand Viibryd, Generic vilazodone, Qelbree, Trintellix, Brand Strattera, Generic atomoxetine, Brand Paxil, Generic paroxetine tablets, Paroxetine oral susp, Brand Paxil CR, Generic paroxetine ER, Pexeva, paroxetine capsules	
Diagnosis	Duplicate Therapy with Another SSRI/SNRI
Therapy Stage	Initial Authorization
Guideline Type	Drug Utilization Review (DUR)

Approval Criteria

1 - Agents involved in therapeutic duplication are being cross tapered*

OR

2 - The SSRI/SNRI agent in the patient's history is being discontinued or there are plans to discontinue*

OR

3 - Medical rationale supporting duplication of therapy*

Notes	*Approval Duration – Cross-taper or discontinuation: 90 days; Initial approval: 6 months

Product Name:Brand Celexa, Generic citalopram, Drizalma, Brand Pristiq, Generic desvenlafaxine succinate ER, Desvenlafaxine ER, Brand Cymbalta, Generic duloxetine, Brand Lexapro, Generic escitalopram, Brand Prozac, Generic fluoxetine caps, Fluoxetine (tabs, soln, DR caps, PMDD tabs), fluvoxamine, Fetzima, Brand Zoloft, Generic sertraline tabs and oral conc, Sertraline caps, Savella, Venlafaxine Besylate 112.5mg ER tabs, Venlafaxine tabs, Brand Effexor XR, Generic venlafaxine ER caps, Venlafaxine ER tabs, Brand Viibryd, Generic vilazodone, Qelbree, Trintellix, Brand Strattera, Generic atomoxetine, Brand Paxil, Generic paroxetine tablets, Paroxetine oral susp, Brand Paxil CR, Generic paroxetine ER, Pexeva, paroxetine capsules	
Diagnosis	Duplicate Therapy with Another SSRI/SNRI
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Drug Utilization Review (DUR)

Approval Criteria

1 - Evidence of duplication of therapy with the requested SSRI/SNRI agents for 90 of the past 120 days

Product Name:Brand Celexa, Generic citalopram, Drizalma, Brand Pristiq, Generic desvenlafaxine succinate ER, Desvenlafaxine ER, Brand Cymbalta, Generic duloxetine, Brand Lexapro, Generic escitalopram, Brand Prozac, Generic fluoxetine caps, Fluoxetine (tabs, soln, DR caps, PMDD tabs), fluvoxamine, Fetzima, Brand Zoloft, Generic sertraline tabs and oral conc, Sertraline caps, Savella, Venlafaxine Besylate 112.5mg ER tabs, Venlafaxine tabs, Brand Effexor XR, Generic venlafaxine ER caps, Venlafaxine ER tabs, Brand Viibryd, Generic vilazodone, Qelbree, Trintellix, Brand Strattera, Generic atomoxetine, Brand Paxil, Generic paroxetine tablets, Paroxetine oral susp, Brand Paxil CR, Generic paroxetine ER, Pexeva, paroxetine capsules	
Diagnosis	Age Limit Exception*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e. clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - All of the following:

2.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 ONE of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient
- The request is for continuation of therapy from another plan or following inpatient therapy

AND

3.3 One of the following:

3.3.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

OR

3.3.2 The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits

AND

3.4 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	*This criteria applies to the Non- Drug Specific PA policy

2 . Revision History

Date	Notes
4/17/2023	Aligned criteria with with the policy and added the age limit criteria fro m the non-drug specific PA policy

Stimulants

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-124893
Guideline Name	Stimulants
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name:Adhansia XR, Adzenys ER, Adzenys XR-ODT, Generic amphetamine, Brand Evekeo, Generic amphetamine/dextroamphetamine, Brand Adderall, generic amphetamine/dextroamphetamine ER, Brand Adderall XR, Brand Aptensio XR, generic methylphenidate ER (XR) cap, Azstarys, Cotempla XR-ODT, Brand Daytrana, Generic methylphenidate patch, Generic dexmethylphenidate, Brand Focalin, Generic dexmethylphenidate ER, Brand Focalin XR, Dyanavel XR, Generic dextroamphetamine tabs, Brand Zenzedi, Generic dextroamphetamine ER, Brand Dexedrine ER, Generic dextroamphetamine soln, Brand Procentra, Evekeo ODT, Generic methamphetamine, Brand Desoxyn, Jornay PM, Generic methylphenidate tabs, Brand Ritalin, methylphenidate chew, methylphenidate ER tabs, Generic methylphenidate ER osmotic tabs, Brand Concerta, Brand Relexxii, Generic methylphenidate ER (LA) caps, Brand Ritalin LA, methylphenidate ER (CD) caps, methylphenidate ER (24 HR) tabs, Generic methylphenidate soln, Brand Methylin soln, Mydayis, Quillichew ER, Quillivant XR, Vyvanse, Vyvanse chew, Xelstrym*	
Diagnosis	Duplicate Therapy with Another Stimulant
Guideline Type	Drug Utilization Review (DUR)

Approval Criteria

1 - One of the following:

1.1 Patient is 19 years of age or younger

OR

1.2 Patient has a Food and Drug Administration (FDA)-labeled or approved compendia indication (See Table 1 in Background)

AND

2 - One of the following:

2.1 Evidence of duplication of therapy with the requested stimulant agents for 90 of the past 120 days

OR

2.2 The request is for immediate-release dextroamphetamine tablets or immediate-release amphetamine salts in combination with Vyvanse

OR

2.3 The medications involved in the therapeutic duplication are being cross tapered or discontinued

Notes	*Approval Length: 45 days for any request involving cross-tapering or discontinuation, 6 months for all others

Product Name:Adhansia XR, Adzenys ER, Adzenys XR-ODT, Generic amphetamine, Brand Evekeo, Generic amphetamine/dextroamphetamine, Brand Adderall, generic amphetamine/dextroamphetamine ER, Brand Adderall XR, Brand Aptensio XR, generic methylphenidate ER (XR) cap, Azstarys, Cotempla XR-ODT, Brand Daytrana, Generic methylphenidate patch, Generic dexmethylphenidate, Brand Focalin, Generic dexmethylphenidate ER, Brand Focalin XR, Dyanavel XR, Generic dextroamphetamine tabs,

Brand Zenzedi, Generic dextroamphetamine ER, Brand Dexedrine ER, Generic dextroamphetamine soln, Brand Procentra, Evekeo ODT, Generic methamphetamine, Brand Desoxyn, Jornay PM, Generic methylphenidate tabs, Brand Ritalin, methylphenidate chew, methylphenidate ER tabs, Generic methylphenidate ER osmotic tabs, Brand Concerta, Brand Relexxii, Generic methylphenidate ER (LA) caps, Brand Ritalin LA, methylphenidate ER (CD) caps, methylphenidate ER (24 HR) tabs, Generic methylphenidate soln, Brand Methylin soln, Mydayis, Quillichew ER, Quillivant XR, Vyvanse, Vyvanse chew, Xelstrym*	
Diagnosis	Single stimulant agent in adults (greater than 19 years of age)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a Food and Drug Administration (FDA)-labeled or approved compendia indication for the use of stimulant agents (See Table 1 in Background)

Product Name:Adhansia XR, Adzenys ER, Adzenys XR-ODT, Generic amphetamine, Brand Evekeo, Generic amphetamine/dextroamphetamine, Brand Adderall, generic amphetamine/dextroamphetamine ER, Brand Adderall XR, Brand Aptensio XR, generic methylphenidate ER (XR) cap, Azstarys, Cotempla XR-ODT, Brand Daytrana, Generic methylphenidate patch, Generic dexmethylphenidate, Brand Focalin, Generic dexmethylphenidate ER, Brand Focalin XR, Dyanavel XR, Generic dextroamphetamine tabs, Brand Zenzedi, Generic dextroamphetamine ER, Brand Dexedrine ER, Generic dextroamphetamine soln, Brand Procentra, Evekeo ODT, Generic methamphetamine, Brand Desoxyn, Jornay PM, Generic methylphenidate tabs, Brand Ritalin, methylphenidate chew, methylphenidate ER tabs, Generic methylphenidate ER osmotic tabs, Brand Concerta, Brand Relexxii, Generic methylphenidate ER (LA) caps, Brand Ritalin LA, methylphenidate ER (CD) caps, methylphenidate ER (24 HR) tabs, Generic methylphenidate soln, Brand Methylin soln, Mydayis, Quillichew ER, Quillivant XR, Vyvanse, Vyvanse chew, Xelstrym*	
Diagnosis	Age Limit Exception*
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition

AND

1.2 If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e. clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

OR

2 - All of the following:

2.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Patient previously received an authorization for age limit exception for the requested agent

OR

3 - All of the following:

3.1 History of the requested agent for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

3.2 ONE of the following:

- The requested agent has newly implemented age limits which did not previously apply to the patient
- The request is for continuation of therapy from another plan or following inpatient therapy

AND

3.3 One of the following: **3.3.1** Documentation that other age and diagnosis-appropriate agents available have been tried for an adequate period of time and been deemed ineffective in the treatment of the patient's disease or medical condition **OR** **3.3.2** The prescriber has provided valid medical justification for use of the requested agent outside of FDA or plan-established age limits over the use of other diagnosis-appropriate agents within FDA or plan-established age limits **AND** **3.4** If the patient is outside of FDA-established age limits, clinical support or rationale for safety and efficacy has been provided (i.e., clinical literature in conjunction with patient attributes and/or characteristics of the drug) for the requested drug and dose

Notes	*This criteria applies to the Non- Drug Specific PA policy

2 . Background

Benefit/Coverage/Program Information

Table 1:

FDA-Labeled Diagnoses or Approved Compendia Dlagnoses
ADHD
Narcolepsy
Binge Eating Disorder (lisdexamfetamine only)
Depression
Mania (dextroamphetamine only)
Cocaine Dependence (dextroamphetamine only)

Personality Disorder
Schizophrenia
Sleep Deprivation

3 . Revision History

Date	Notes
4/21/2023	Added Dyanavel XR Chews

Stivarga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152508
Guideline Name	Stivarga
Formulary	• Medicaid - Community & State Indiana

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

Strensiq

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-136413
Guideline Name	Strensiq
Formulary	• Medicaid - Community & State Indiana

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

Sucraid

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

Sutent

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147811
Guideline Name	Sutent
Formulary	• Medicaid - Community & State Indiana

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 provi der.

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 thyroi d carcinoma per NCCN recommendations.

Systemic Antifungals

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154915
Guideline Name	Systemic Antifungals
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Brand Sporanox soln, generic itraconazole soln, Brand Vfend susp, generic voriconazole susp	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has tried and failed ALL preferred agents* (i.e., each preferred chemical entity)

OR

1.2 Provider has provided medical justification as to why each preferred agent* is not appropriate for use (e.g., infection being treated is not susceptible to preferred agents)

AND

2 - One of the following:

2.1 Patient is 12 years of age or under

OR

2.2 Patient is unable to swallow tablets

Notes	*PDL: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Brand Noxafil, generic posaconazole DR tab, generic posaconazole susp	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- The requested agent is being used for the treatment of oropharyngeal candidiasis
- Patient has tried fluconazole

OR

2 - Both of the following:

2.1 Patient is severely immunocompromised

AND

2.2 The requested agent is being used as prophylaxis against ONE of the following:

- Invasive Aspergillus
- Candida Infections

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

Approval Criteria

1 - Member is 2 years of age or older AND less than 13 years of age

2 . Revision History

Date	Notes
9/13/2024	Updated Sporanox/Vfend Soln. criteria.

Tabrecta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-157150
Guideline Name	Tabrecta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	11/1/2024

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
10/7/2024	Minor update to NCCN Recommended Regimens initial auth section (no changes to clinical intent).

Tafinlar

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151316
Guideline Name	Tafinlar
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/12/2024	Added new criteria for hairy cell leukemia, salivary gland tumor, and GIST.

Tagrisso

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164609
Guideline Name	Tagrisso
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/3/2025	Updated clinical criteria.

Takhzyro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147194
Guideline Name	Takhzyro
Formulary	• Medicaid - Community & State Indiana

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.

Talzenna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-134182
Guideline Name	Talzenna
Formulary	• Medicaid - Community & State Indiana

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-165085
Guideline Name	Tarceva
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/12/2025	Updated GPI list.

Targeted Immunomodulators

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-158334
Guideline Name	Targeted Immunomodulators
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Actemra, Actemra Actpen	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Cytokine release syndrome

- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis
- Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

OR

1.2 Diagnosis of giant cell arteritis, and BOTH of the following:

1.2.1 At least 90 days of drug therapy with ONE of the following:

- Systemic glucocorticoid
- Azathioprine
- Methotrexate

AND

1.2.2 Patient will be using a systemic glucocorticoid concurrently with the requested medication

OR

1.3 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.3.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.3.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Adalimumab-FKJP, Hadlima, Humira, Simlandi	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Ulcerative colitis

OR

1.2 Diagnosis of Crohn's disease, and ONE of the following:

1.2.1 Diagnosis of Crohn’s disease classified as moderate, severe, or fistulizing

OR

1.2.2 Previous trial and failure of another targeted immunomodulator agent

OR

1.2.3 At least 90 days of drug therapy with at least ONE of the following:

- Azathioprine
- Mercaptopurine
- Mesalamine
- Methotrexate
- Systemic glucocorticoid

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of hidradenitis suppurativa

AND

1.3.2 At least 90 days of drug therapy with ONE of the following:

- Oral or topical antibiotic therapy
- Oral retinoid therapy
- Dapsone
- Acitretin

OR

1.4 BOTH of the following:

1.4.1 Diagnosis of non-infectious uveitis

AND

1.4.2 At least 90 days of drug therapy with ONE of the following:

- Oral or injectable steroid therapy
- Methotrexate
- Mycophenolate
- Azathioprine
- Cyclosporine
- Tacrolimus
- Cyclophosphamide

OR

1.5 Diagnosis of psoriasis, and ONE of the following:

1.5.1 Diagnosis of psoriasis classified as severe

OR

1.5.2 Diagnosis of psoriasis of the fingernail

OR

1.5.3 At least 90 days of topical drug therapy with ONE of the following:

- Calcipotriene
- Corticosteroids
- Tazarotene

OR

1.5.4 At least 90 days of systemic drug therapy with ONE of the following:

- Cyclosporine
- Methotrexate
- Acitretin

OR

1.5.5 Previous trial and failure of another targeted immunomodulator agent

OR

1.6 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.6.1 Previous trial and failure of another targeted immunomodulator agent

OR

1.6.2 At least 90 days of drug therapy with ONE of the following:

- Azathioprine

- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Adbry	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - ONE of the following:

3.1 At least 45 days of topical drug therapy with ONE of the following:

- Corticosteroids
- Pimecrolimus
- Tacrolimus

OR

3.2 Prescriber has provided valid medical justification for the use of Adbry over topical drug therapies

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Enbrel	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis (adult or juvenile)
- Ankylosing spondylitis

OR

1.2 Diagnosis of psoriasis, and ONE of the following:

1.2.1 Diagnosis of psoriasis classified as severe

OR

1.2.2 At least 90 days of topical drug therapy with ONE of the following:

- Calcipotriene
- Corticosteroids

- Tazarotene

OR

1.2.3 At least 90 days of systemic drug therapy with ONE of the following:

- Cyclosporine
- Methotrexate
- Acitretin

OR

1.2.4 Previous trial and failure of another targeted immunomodulator agent

OR

1.3 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.3.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.3.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Kineret	
Approval Length	1 year(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Neonatal onset multisystem inflammatory disease (NOMID)
- Deficiency of interleukin-1 receptor antagonist (DIRA)

OR

1.2 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.2.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.2.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Olumiant	
Approval Length	Rheumatoid arthritis - 12 months; Severe Alopecia Areata - 6 months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of rheumatoid arthritis, and BOTH of the following:

1.1.1 Previous trial and failure of at least ONE tumor necrosis factor (TNF) blocker

AND

1.1.2 Previous trial and failure of at least ONE other targeted immunomodulator agent

OR

1.2 Submission of chart notes showing a diagnosis of severe alopecia areata defined as greater than or equal to 50% of hair loss, and BOTH of the following:

1.2.1 Patient is 18 years of age or older

AND

1.2.2 Prescribed by, or in consultation with, a dermatologist

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

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

Approval Criteria

1 - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - If the request is for reauthorization for treatment of severe alopecia areata, documentation of patient status and response to therapy (Document status/response)

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Orencia	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis

OR

1.2 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.2.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.2.2 Previous trial and failure of another targeted immunomodulator agent

OR

1.3 Diagnosis of acute graft-versus host disease prophylaxis, and BOTH of the following:

1.3.1 Patient will be using Orencia concurrently with both methotrexate AND a calcineurin inhibitor

AND

1.3.2 Patient will be concurrently undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Otezla	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of psoriatic arthritis

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of oral ulcers associated with Behcet's disease in an adult (18 years of age and older)

AND

1.2.2 At least 90 days of drug therapy with colchicine

OR

1.3 Diagnosis of psoriasis, and ONE of the following:

1.3.1 Diagnosis of psoriasis classified as severe

OR

1.3.2 At least 90 days of topical drug therapy with ONE of the following:

- Calcipotriene
- Corticosteroids
- Tazarotene

OR

1.3.3 At least 90 days of systemic drug therapy with ONE of the following:

- Cyclosporine
- Methotrexate
- Acitretin

OR

1.3.4 Previous trial and failure of another targeted immunomodulator agent

Product Name:Simponi	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Ankylosing spondylitis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Ulcerative colitis

OR

1.2 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.2.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.2.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Taltz	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Ankylosing spondylitis
- Non-radiographic axial spondyloarthritis
- Psoriatic arthritis

OR

1.2 Diagnosis of psoriasis, and ONE of the following:

1.2.1 Diagnosis of psoriasis classified as severe

OR

1.2.2 At least 90 days of topical drug therapy with ONE of the following:

- Calcipotriene
- Corticosteroids
- Tazarotene

OR

1.2.3 At least 90 days of systemic drug therapy with ONE of the following:

- Cyclosporine
- Methotrexate
- Acitretin

OR

1.2.4 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Tyenne	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Polyarticular juvenile idiopathic arthritis
- Systemic juvenile idiopathic arthritis

OR

1.2 Diagnosis of giant cell arteritis, and BOTH of the following:

1.2.1 At least 90 days of drug therapy with ONE of the following:

- Systemic glucocorticoid
- Azathioprine
- Methotrexate

AND

1.2.2 Patient will be using a systemic glucocorticoid concurrently with the requested medication

OR

1.3 Diagnosis of rheumatoid arthritis, and ONE of the following:

1.3.1 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

OR

1.3.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Xeljanz tabs/oral soln	
Approval Length	1 year(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 diagnoses:

- Ankylosing spondylitis
- Psoriatic arthritis

AND

1.1.2 Previous trial and failure of at least ONE tumor necrosis factor (TNF) blocker

AND

1.1.3 Dose does not exceed 5 mg (milligrams) twice daily

OR

1.2 ALL of the following:

1.2.1 Diagnosis of polyarticular juvenile idiopathic arthritis

AND

1.2.2 Previous trial and failure of a TNF blocker with juvenile idiopathic arthritis indication [e.g., adalimumab agents, Enbrel (etanercept), or Simponi (golimumab)]

AND

1.2.3 Dose does not exceed 5 mg twice daily

OR

1.3 Diagnosis of rheumatoid arthritis, and BOTH of the following:

1.3.1 ONE of the following:

1.3.1.1 Previous trial and failure of at least ONE TNF blocker

OR

1.3.1.2 At least 90 days of drug therapy with ONE of the following:

- Azathioprine
- Hydroxychloroquine
- Leflunomide
- Methotrexate
- Sulfasalazine

AND

1.3.2 Dose does not exceed 5 mg twice daily

OR

1.4 ALL of the following:

1.4.1 Diagnosis of ulcerative colitis

AND

1.4.2 Previous trial and failure of a TNF blocker with an ulcerative colitis indication [e.g., adalimumab agents, Simponi (golimumab), or infliximab agents]

AND

1.4.3 ONE of the following:

1.4.3.1 Dose does not exceed 10 mg twice daily for the induction period up to 16 weeks

OR

1.4.3.2 Dose does not exceed 5 mg twice daily for the maintenance period

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

AND

3 - If the request is for Xeljanz oral solution, ONE of the following:

3.1 Both of the following:

- Patient is 2 years of age or older AND less than 18 years of age
- Patient weighs 10 kg or more AND less than 40kg

OR

3.2 Provider has submitted documentation supporting inability to swallow tablet formulation

Product Name:Xeljanz XR	
Approval Length	1 year(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 diagnoses:

- Ankylosing spondylitis
- Psoriatic arthritis
- Rheumatoid arthritis

AND

1.1.2 Previous trial and failure of a tumor necrosis factor (TNF) blocker or Xeljanz IR (immediate release)

AND

1.1.3 Dose does not exceed 11 mg once daily

OR

1.2 ALL of the following:

1.2.1 Diagnosis of ulcerative colitis

AND

1.2.2 Previous trial and failure of a TNF blocker with ulcerative colitis indication [e.g. adalimumab agents, Simponi (golimumab), or infliximab agents] or Xeljanz IR

AND

1.2.3 ONE of the following:

1.2.3.1 Dose does not exceed 22 mg once daily for the induction period up to 16 weeks

OR

1.2.3.2 Dose does not exceed 11 mg once daily for the maintenance period

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Xeljanz, Xeljanz XR	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - Dose requested does not exceed any of the established quantity limits for the indication:

2.1 For Xeljanz, ONE of the following:

2.1.1 For ankylosing spondylitis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, or rheumatoid arthritis, dose does not exceed 5 mg twice daily

OR

2.1.2 For ulcerative colitis, dose does not exceed 10 mg twice daily for the induction period up to 16 weeks, and dose does not exceed 5 mg twice daily for the maintenance period

OR

2.2 For Xeljanz XR, ONE of the following:

2.2.1 For ankylosing spondylitis, psoriatic arthritis, or rheumatoid arthritis, dose does not exceed 11 mg once daily

OR

2.2.2 For ulcerative colitis, dose does not exceed 22 mg once daily for the induction period up to 16 weeks, and dose does not exceed 11 mg once daily for the maintenance period

AND

3 - If the request is for Xeljanz oral solution, ONE of the following:

3.1 Both of the following

- Patient is 2 years of age or older AND less than 18 years of age
- Patient weighs 10 kg or more AND less than 40kg

OR

3.2 Provider has submitted documentation supporting inability to swallow tablet formulation

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Cimzia	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Ankylosing spondylitis
- Crohn's disease
- Non-radiographic axial spondyloarthritis
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis

AND

2 - Previous trial and failure of another targeted immunomodulator agent

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Cosentyx	
Approval Length	1 year(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 diagnoses:

- Ankylosing spondylitis
- Non-radiographic axial spondyloarthritis
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis

AND

1.1.2 Previous trial and failure of another targeted immunomodulator agent

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of hidradenitis suppurativa

AND

1.2.2 Previous trial and failure of a preferred adalimumab agent

OR

1.3 Diagnosis of enthesitis-related arthritis (ERA)

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Entyvio Pen	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Crohn's disease
- Ulcerative colitis

AND

2 - Previous trial and failure of another targeted immunomodulator agent

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Kevzara	
Approval Length	1 year(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 polyarticular juvenile idiopathic arthritis

AND

1.1.2 Previous trial and failure of another targeted immunomodulator agent

AND

1.1.3 Patient weighs at least 63 kilograms

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of polymyalgia rheumatica

AND

1.2.2 At least 90 days of drug therapy with oral corticosteroids or methotrexate

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of rheumatoid arthritis

AND

1.3.2 Previous trial and failure of another targeted immunomodulator agent

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Litfulo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of chart notes showing a diagnosis of severe alopecia areata defined as greater than or equal to 50% of hair loss

AND

2 - Patient is 12 years of age or older

AND

3 - Previous trial and failure of Olumiant

AND

4 - Prescribed by, or in consultation with, a dermatologist

AND

5 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

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

Approval Criteria

1 - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - Documentation of patient status and response to therapy (document status/response)

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Rinvoq ER tablets	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of atopic dermatitis, and ALL of the following:

1.1.1 Patient is at least 12 years of age AND weighs at least 40 kg (kilograms)

AND

1.1.2 ONE of the following:

1.1.2.1 Patient has tried and failed ONE systemic agent with an atopic dermatitis indication

OR

1.1.2.2 If patient was unable to utilize a systemic agent, patient has trialed at least 45 days of topical drug therapy with ONE of the following (documentation required):

- Pimecrolimus
- Tacrolimus
- Corticosteroids

OR

1.1.2.3 Prescriber has provided valid medical justification for the use of the requested medication over topical corticosteroids and/or topical immunomodulator agents

AND

1.1.3 For patients 65 years of age or older, requested dose does not exceed 15 mg (milligrams) daily

OR

1.2 ALL of the following:

1.2.1 Diagnosis of ONE of the following:

- Ankylosing spondylitis
- Non-radiographic axial spondyloarthritis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis

AND

1.2.2 Previous trial and failure of at least ONE tumor necrosis factor (TNF) blocker

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of Crohn's disease

AND

1.3.2 Previous trial and failure of at least ONE TNF blocker with Crohn’s disease indication (adalimumab agents, Cimzia (certolizumab), infliximab agents)

OR

1.4 BOTH of the following:

1.4.1 Diagnosis of ulcerative colitis

AND

1.4.2 Previous trial and failure of at least ONE TNF blocker with ulcerative colitis indication (e.g. adalimumab agents, infliximab agents, Simponi (golimumab))

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Rinvoq LQ	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

- Psoriatic arthritis
- Polyarticular juvenile idiopathic arthritis

AND

2 - Previous trial and failure of at least ONE TNF blocker

AND

3 - Patient is at least 2 years of age AND weighs at least 10 kilograms

AND

4 - ONE of the following:

4.1 Patient is less than 18 years of age AND weighs less than 30 kilograms

OR

4.2 Provider has submitted documentation supporting inability to swallow tablet formulation

AND

5 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Rinvoq LQ	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - One of the following:

2.1 Patient is less than 18 years of age AND weighs less than 30 kilograms

OR

2.2 Provider has submitted documentation supporting inability to swallow tablet formulation

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Siliq	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of psoriasis

AND

2 - Previous trial and failure of another targeted immunomodulator agent

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Abrilada, Adalimumab-AACF, Idacio, Adalimumab-ADAZ, Hyrimoz, Adalimumab-ADBM, Cyltezo, Adalimumab-RYVK, Amjevita, Hulio, Adalimumab-AATY, Yuflyma, Yusimry	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Ankylosing spondylitis
- Crohn's disease
- Hidradenitis suppurativa
- Non-infectious uveitis
- Polyarticular juvenile idiopathic arthritis
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

AND

2 - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not adalimumab

AND

3 - Both of the following:

- Previous trial of ALL preferred adalimumab product(s)
- Prescriber has provided valid medical rationale for the use of the requested non-preferred adalimumab product over ALL of the preferred adalimumab product(s)

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Abrilada, Adalimumab-AACF, Idacio, Adalimumab-ADAZ, Hyrimoz, Adalimumab-ADBM, Cyltezo, Adalimumab-RYVK, Amjevita, Hulio, Adalimumab-AATY, Yuflyma, Yusimry	
Approval Length	1 year(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - Both of the following:

- Previous trial of ALL preferred adalimumab product(s)
- Prescriber has provided valid medical rationale for the use of the requested non-preferred adalimumab product over ALL of the preferred adalimumab product(s)

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Arcalyst	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of Cryopyrin-Associated Periodic Syndrome (CAPS) [including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)]

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of recurrent pericarditis (RP)

AND

1.2.2 At least 90 days of drug therapy with ONE of the following:

- Colchicine
- Systemic glucocorticoids

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

AND

1.3.2 Previous trial and failure of Kineret (anakinra)

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Bimzelx	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of psoriasis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Cibinqo	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is at least 12 years of age

AND

3 - ONE of the following:

3.1 BOTH of the following:

- At least 60 days of therapy with Dupixent (dupilumab)
- At least 120 days of therapy with Adbry (tralokinumab-ldrm)

OR

3.2 At least 60 days of therapy with Rinvoq (upadacitinib)

OR

3.3 Prescriber has provided valid medical justification for the use of the requested medication over Dupixent (dupilumab), Adbry (tralokinumab-ldrm), and Rinvoq (upadacitinib)

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Ilaris	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 ONE of the following diagnoses:

- Cryopyrin-Associated Periodic Syndrome (CAPS) [including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)]
- Systemic juvenile idiopathic arthritis
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD)

OR

1.2 BOTH of the following:

1.2.1 Diagnosis of adult-onset Still's disease

AND

1.2.2 At least 90 days of drug therapy with ONE of the following:

- Corticosteroids
- Methotrexate
- NSAIDs (non-steroidal anti-inflammatory drugs)

OR

1.3 BOTH of the following:

1.3.1 Diagnosis of familial Mediterranean fever (FMF)

AND

1.3.2 At least 90 days of drug therapy with colchicine

OR

1.4 BOTH of the following:

1.4.1 Diagnosis of gout flares

AND

1.4.2 ONE of the following:

1.4.2.1 Both of the following:

- Previous trial and failure of colchicine, corticosteroids, AND NSAIDs (non-steroidal anti-inflammatory drugs) in the past 30 days
- Prescriber has submitted chart documentation illustrating inadequate response

OR

1.4.2.2 Prescriber has submitted chart documentation supporting contraindication to colchicine, NSAIDs, AND prolonged corticosteroid use

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Ilumya	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of psoriasis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Omvoh	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ulcerative colitis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Skyrizi	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Crohn's disease
- Psoriasis
- Psoriatic arthritis
- Ulcerative colitis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Sotyktu	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age and older

AND

2 - Diagnosis of psoriasis

AND

3 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Spevigo syringe	
Approval Length	1 year(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) flare

AND

2 - Patient is at least 12 years of age AND weighs at least 40 kilograms

AND

3 - Prescribed by, or in consultation with, a dermatologist or rheumatologist

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Stelara	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Crohn's disease
- Psoriasis
- Psoriatic arthritis
- Ulcerative colitis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Tremfya	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following diagnoses:

- Psoriasis
- Psoriatic arthritis

AND

2 - Previous trial and failure of at least TWO other targeted immunomodulator agents

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Velsipity	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ulcerative colitis

AND

2 - Previous trial and failure of BOTH of the following:

- Zeposia (ozanimod)
- At least ONE other targeted immunomodulator agent

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Actemra, Adalimumab-FKJP, Adbry, Arcalyst, Cibinqo, Cimzia, Cosentyx, Enbrel, Entyvio Pen, Hadlima, Humira, Ilaris, Ilumya, Kevzara, Kineret, Orencia, Otezla, Rinvoq ER tablets, Siliq, Simlandi, Simponi, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Tyenne, Bimzelx, Omvoh, Velsipity	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Zymfentra	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe Crohn's disease or ulcerative colitis

AND

2 - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not infliximab

AND

3 - Both of the following:

- Previous trial of preferred infliximab product(s)
- Prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

AND

4 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Product Name:Zymfentra	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

AND

2 - Both of the following:

- Previous trial of preferred infliximab product(s)
- Prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

AND

3 - Patient does not have a history of a targeted immunomodulator [except Otezla (apremilast)] other than the one on the incoming claim in the past 30 days

Targretin (bexarotene)

Prior Authorization Guideline

Guideline ID	GL-138786
Guideline Name	Targretin (bexarotene)
Formulary	• Medicaid - Community & State Indiana

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; Minor cosmetic/formatting cleanup of criteria; Removed reference to "Targretin" in reauthorization criterion for NCCN Recommended Regimens section. No changes to clinical intent.

Tasigna

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138880
Guideline Name	Tasigna
Formulary	• Medicaid - Community & State Indiana

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-124763
Guideline Name	Tasmar
Formulary	• Medicaid - Community & State Indiana

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

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 • 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-147185
Guideline Name	Tazverik
Formulary	• Medicaid - Community & State Indiana

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

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-138862
Guideline Name	Tegsedi
Formulary	• Medicaid - Community & State Indiana

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

Prior Authorization Guideline

Guideline ID	GL-106490
Guideline Name	Tepmetko
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2022

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

Test Strips

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127170
Guideline Name	Test Strips
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name:Non-preferred Test Strip Products	
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 of ALL of the following as confirmed by claims history or submitted medical records:

- Accu-Chek Guide Retail Test Strips
- True Metrix Test Strips
- ReliOn Rx TMX Test Strips

OR

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

- Accu-Chek Guide Retail Test Strips
- True Metrix Test Strips
- ReliOn Rx TMX Test Strips

AND

1.2 Documentation provided from the prescriber of the medical necessity rationale for the non-preferred test strips

OR

2 - Patient is on an insulin pump

Product Name:Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 For Insulin Dependent or Pregnant patients, 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

1.2 For Non-Insulin Dependent Patients, ONE the following: **1.2.1** The patient is experiencing or is prone to hypoglycemia or hyperglycemia and requires additional testing to achieve glycemic control **OR** **1.2.2** The patient's physician is adjusting medications and the patient requires additional blood glucose testing during this time **OR** **1.2.3** The patient's physician is adjusting MNT (medical nutrition therapy) and the patient requires additional blood glucose testing during this time **OR** **1.2.4** The patient requires additional testing due to fluctuations in blood glucose due to physical activity or exercise **OR** **1.2.5** 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	NOTE: The quantity limit for insulin-dependent and pregnant patients i s 6 test strips/day. The quantity limit for non-insulin dependent and no n-pregnant patients is 2 test strips/day.

2 . Revision History

Date	Notes
6/27/2023	Added new GPIs to market since last update. Changed from a step t hrough one to a step through all preferred products. Updated IN pref erred products.

Testosterones

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161869
Guideline Name	Testosterones
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Depo-Testosterone, generic testosterone cypionate, Testosterone cypionate	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 Diagnosis of delayed puberty

OR

1.2 Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Pregnancy
- Prostate cancer

Notes	*If patient has had history with injectable/topical product within the pas t 120 days, confirmed by claims history, and switching formulations to preferred injectable formulation, use reauthorization criteria.

Product Name:Brand Depo-Testosterone, generic testosterone cypionate, Testosterone cypionate	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of injectable or topical testosterone agent(s) within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Submission of documentation of total testosterone level less than or equal to 1000 ng/dL within the past 6 months

AND

3 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, pregnancy, prostate cancer)

Product Name:testosterone enanthate	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

1.1 ONE of the following:

- Diagnosis of delayed puberty
- Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

1.2 ONE of the following:

- Previous trial and failure of ALL preferred** injectable testosterone agents, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred** injectable testosterone agents

AND

1.3 Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Pregnancy
- Prostate cancer

OR

2 - BOTH of the following:

2.1 Palliative treatment of metastatic breast cancer

AND

2.2 Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Pregnancy
- Prostate cancer

Notes	*If patient has had history with injectable/topical product within the pas t 120 days, confirmed by claims history, and are switching formulation s to nonpreferred injectable formulation, use reauthorization criteria. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indi ana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:testosterone enanthate	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

OR

1.2 Patient has had history with injectable/topical product within the past 120 days, confirmed by claims history, and are switching formulations to the requested agent

AND

2 - Submission of documentation of total testosterone level less than or equal to 1000 ng/dL within the past 6 months

AND

3 - ONE of the following: (not required for palliative treatment of breast cancer)

- Previous trial and failure of at least one preferred* injectable testosterone agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred* injectable testosterone agents

AND

4 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, pregnancy, prostate cancer)

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

Product Name:Aveed, Testopel, Xyosted	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

- Diagnosis of delayed puberty
- Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

2 - ONE of the following:

- Previous trial and failure of ALL preferred** injectable testosterone agents, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred** injectable testosterone agents

AND

3 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Hypogonadal conditions not associated with structural or genetic etiologies (Xyosted ONLY)
- Pregnancy
- Prostate cancer

Notes	*If patient has had history with injectable/topical product within the pas t 120 days, confirmed by claims history, and are switching formulation s to nonpreferred injectable formulation, use reauthorization criteria. **PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indi ana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Aveed, Testopel, Xyosted	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

OR

1.2 Patient has had history with injectable/topical product within the past 120 days, confirmed by claims history, and are switching formulations to the requested agent

AND

2 - Submission of documentation of total testosterone level less than or equal to 1000 ng/dL within the past 6 months

AND

3 - ONE of the following:

- Previous trial and failure of at least one preferred* injectable testosterone agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred* injectable testosterone agents

AND

4 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, hypogonadal conditions not associated with structural or genetic etiologies [Xyosted ONLY], pregnancy, prostate cancer)

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

Product Name:Androderm, generic testosterone gel, Brand Androgel, Brand Testim, Brand Vogelxo, testosterone topical soln, Brand Fortesta, Natesto	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization*
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 16 years of age or older

AND

2 - Submission of documentation of total testosterone level is less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

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

- Previous trial and failure of ALL preferred** topical testosterone agents, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred** topical testosterone agents

AND

4 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Pregnancy
- Prostate cancer

Notes	*If patient has had history with injectable/topical product within the pas t 120 days, confirmed by claims history, and are switching formulation s to a topical formulation, use reauthorization criteria.

	**PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Androderm, generic testosterone gel, Brand Androgel, Brand Testim, Brand Vogelxo, testosterone topical soln, Brand Fortesta, Natesto	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ONE of the following:

1.1 If the request is preferred*, patient has a history of topical or injectable testosterone agent(s) within the past 120 days, confirmed by claims history or chart documentation

OR

1.2 If the request is non-preferred*, BOTH of the following:

1.2.1 ONE of the following:

1.2.1.1 Patient has a history of the requested medication within the past 120 days, confirmed by claims history or chart documentation

OR

1.2.1.2 Patient has had history with injectable/topical product within the past 120 days, confirmed by claims history, and are switching formulations to the requested nonpreferred topical formulation

AND

1.2.2 ONE of the following:

- Previous trial and failure of at least one preferred* topical testosterone agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred* topical testosterone agents

AND

2 - Submission of documentation of total testosterone is less than or equal to 1000 ng/dL within the past 6 months

AND

3 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindications listed in initial authorization criteria (breast cancer in a patient assigned male at birth, pregnancy, prostate cancer)

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

Product Name:Androderm, generic testosterone gel, Brand Androgel, Brand Testim, Brand Vogelxo, testosterone topical soln, Brand Fortesta, Natesto	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Quantity Limit

Approval Criteria

1 - Patient is 16 years of age or older

AND

2 - Patient has utilized at least 14 days of topical testosterone therapy

AND

3 - Submission of documentation of total testosterone level is less than or equal to 400 ng/dL (nanograms/deciliter) while on topical testosterone therapy

Product Name:Androderm, generic testosterone gel, Brand Androgel, Brand Testim, Brand Vogelxo, testosterone topical soln, Brand Fortesta, Natesto	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Quantity Limit

Approval Criteria

1 - Patient has historical approval to exceed the established quantity limits

Product Name:danazol	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must have ONE of the following indications for treatment:

- Angioedema prophylaxis for hereditary angioedema
- Autoimmune hemolytic anemia
- Discoid lupus erythematosus
- Endometriosis
- Fibrocystic breast disease
- Myelosclerosis with myeloid metaplasia

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy

- Active or history of thrombosis or thromboembolic disease

- Androgen-dependent tumor
- Cardiac disease
- Porphyria
- Pregnancy or breast-feeding
- Severe hepatic disease
- Severe renal disease
- Undiagnosed genital bleeding

Product Name:danazol	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Documentation from prescriber indicating continued benefit from the medication without significant adverse events

AND

3 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (active or history of thrombosis or thromboembolic disease, androgen-dependent tumor, cardiac disease, porphyria, pregnancy or breast-feeding, severe hepatic disease, severe renal disease, undiagnosed genital bleeding)

Product Name:Jatenzo	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Patient is 18 years of age or older
- Diagnosis of hypogonadism
- Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Hypogonadal conditions not associated with structural or genetic etiologies
- Pregnancy
- Prostate cancer

AND

3 - ONE of the following:

- Previous trial and failure of at least one preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred* injectable testosterone agents

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

Product Name:Jatenzo	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must meet BOTH of the following:

1.1 History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

AND

1.2 Submission of documentation of total testosterone less than or equal to 1000 ng/dL within the past 6 months

AND

2 - ONE of the following:

- Previous trial and failure of at least one preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over ALL preferred* injectable testosterone agents

AND

3 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, hypogonadal conditions not associated with structural or genetic etiologies, pregnancy, prostate cancer)

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

Product Name:Methitest, methyltestosterone caps	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Must have ONE of the following indications for treatment:

- Cryptorchidism
- Delayed puberty
- Hypogonadism (primary or hypogonadotropic) with submission of documentation of a total testosterone level less than or equal to 350 ng/dL within the past 3 months
- Palliative treatment of metastatic breast cancer

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Pregnancy
- Prostate cancer

AND

3 - ONE of the following:

- Previous trial and failure of a preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use over ALL preferred* injectable agents

AND

4 - ONE of the following:

4.1 If the request is for breast cancer indication, the requested dose does NOT exceed 50 capsules or tablets per day

OR

4.2 For all other indications, the requested dose does NOT exceed 5 capsules or tablets per day

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

Product Name:Methitest, methyltestosterone caps	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty, palliative treatment of metastatic breast cancer, or cryptorchidism AND all of the following:

1.1 History of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

1.2 Documentation from prescriber indicating continued benefit from the medication without significant adverse events

AND

1.3 ONE of the following:

- Previous trial and failure of a preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use over ALL preferred* injectable agents

AND

1.4 Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, pregnancy, prostate cancer)

AND

1.5 ONE of the following:

1.5.1 If the request is for breast cancer indication, the requested dose does NOT exceed 50 capsules or tablets per day

OR

1.5.2 For all other indications, the requested dose does NOT exceed 5 capsules or tablets per day

OR

2 - Diagnosis of hypogonadism AND all of the following:

2.1 History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

AND

2.2 Submission of documentation of total testosterone level less than or equal to 1000 ng/dL within the past 6 months

AND

2.3 ONE of the following:

- Previous trial and failure of a preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use over ALL preferred* injectable agents

AND

2.4 Prescriber attests that the patient remains a candidate for treatment, indicating that they

have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, pregnancy, prostate cancer) **AND** **2.5** The requested dose does NOT exceed 5 capsules or tablets per day

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

Product Name:Tlando	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Patient is 18 years of age or older
- Diagnosis of hypogonadism
- Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer
- Hypogonadal conditions not associated with structural or genetic etiologies
- Pregnancy
- Prostate cancer

AND

3 - ONE of the following:

- Previous trial and failure of a preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use over ALL preferred* injectable agents

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

Product Name:Tlando	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Submission of documentation of total testosterone less than or equal to 1000 ng/dL within the past 6 months

AND

3 - ONE of the following:

- Previous trial and failure of a preferred* injectable agent, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use over ALL preferred* injectable agents

AND

4 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer, hypogonadal conditions not associated with structural or genetic etiologies, pregnancy, prostate cancer)

Product Name:Undecatrex	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - ALL of the following:

- Patient is 18 years of age or older
- Diagnosis of hypogonadism
- Submission of documentation of total testosterone level less than or equal to 350 ng/dL (nanograms/deciliter) within the past 3 months

AND

2 - Provider attests that the patient does NOT have any of the following contraindications to therapy:

- Breast cancer in a patient assigned male at birth
- Hypogonadal conditions not associated with structural or genetic etiologies
- Pregnancy
- Prostate cancer

AND

3 - ONE of the following:

- Previous trial and failure of Jatenzo AND Tlando, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over Jatenzo AND Tlando

Product Name:Undecatrex	
Approval Length	1 year(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested medication within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Submission of documentation of total testosterone less than or equal to 1000 ng/dL within the past 6 months

AND

3 - ONE of the following:

- Previous trial and failure of Jatenzo AND Tlando, as confirmed by claims history, chart documentation, or provider attestation including dates of trial
- Medical justification for use of the requested medication over Jatenzo AND Tlando

AND

4 - Prescriber attests that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed in initial authorization criteria (breast cancer in a patient assigned male at birth, hypogonadal conditions not associated with structural or genetic etiologies, pregnancy, prostate cancer)

2 . Revision History

Date	Notes
12/11/2024	Added criteria for new target drug, Undecatrex. Cleaned up GPIs, wh ere applicable. Updated reauth history language for danazol and met hitest and updated contraindication language for xyosted and methite st to align with state policy. Minor cosmetic updates.

Thalomid

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151785
Guideline Name	Thalomid
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	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-216275
Guideline Name	Therapeutic Duplication (Subtype A)
Formulary	• Medicaid - Community & State Indiana

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, 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. Changed to Admin GL type. 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 • 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 • 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-134478
Guideline Name	Tobramycin Inhalation
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	12/1/2023

1 . Criteria

Product Name:Brand Bethkis, Kitabis Pak, Tobi Podhaler, Brand Tobi, generic tobramycin 300 mg/5mL nebu soln, Brand Tobramycin 300 mg/5mL nebu soln	
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:Brand Bethkis, Kitabis Pak, Tobi Podhaler, Brand Tobi, generic tobramycin 300 mg/5mL nebu soln, Brand Tobramycin 300 mg/5mL nebu soln

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.

Topical Anti-Inflammatory Agents, NSAIDs

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161715
Guideline Name	Topical Anti-Inflammatory Agents, NSAIDs
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Diclofenac epolamine patch, generic diclofenac topical solution	
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 Physician documentation indicating oral medications are unsuitable for use

AND **1.1.2** Trial and failure of BOTH of the following: • Diclofenac 1% gel • Pennsaid topical solution **OR** **1.2** Medical justification for use over the preferred* agents

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

2 . Revision History

Date	Notes
12/5/2024	Removed Flector patch and Licart as targets from the guideline. Updated product name list and GPI table accordingly. Updated criteria and notes sections. Minor cosmetic updates.

Topical Immunomodulator Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161797
Guideline Name	Topical Immunomodulator Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

Product Name:Brand Elidel, generic pimecrolimus, generic tacrolimus 0.03%	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 2 years of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 30 days of drug therapy with topical corticosteroids supported by chart documentation, claims history, or prescriber attestation including dates of trial

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids

Product Name:Brand Elidel, generic pimecrolimus, generic tacrolimus 0.03%	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days

Product Name:generic tacrolimus 0.1%	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 16 years of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 30 days of drug therapy with topical corticosteroids supported by chart documentation, claims history, or prescriber attestation including dates of trial

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids

Product Name:generic tacrolimus 0.1%	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days

Product Name:Eucrisa	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 3 months of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 30 days of drug therapy with ONE of the following, supported by chart documentation, claims history, or prescriber attestation including dates of trial:

- Topical corticosteroids
- Topical calcineurin inhibitors (pimecrolimus OR tacrolimus)*

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids, tacrolimus, AND pimecrolimus

Notes	*Those under 2 years of age are exempt from tacrolimus and pimecrolimus step therapy requirement (topical corticosteroids are still required).

Product Name:Eucrisa	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 365 days

Product Name:Opzelura	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 12 years of age or older

AND

2 - Patient will NOT be using concurrently with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine

AND

3 - ONE of the following:

3.1 Patient has a diagnosis of atopic dermatitis AND one of the following:

3.1.1 Greater than or equal to 30 days of drug therapy with each of the following, supported by chart documentation, claims history, or prescriber attestation including dates of trial:

- Topical corticosteroids
- Topical calcineurin inhibitors (pimecrolimus OR tacrolimus)

OR

3.1.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids, tacrolimus, AND pimecrolimus

OR

3.2 Patient has a diagnosis of non-segmental vitiligo AND one of the following:

3.2.1 Greater than or equal to 90 days of drug therapy with each of the following, supported by chart documentation, claims history, or prescriber attestation including dates of trial:

- Topical corticosteroids
- Topical tacrolimus

OR

3.2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids AND tacrolimus

AND

4 - Requested quantity does NOT exceed 360 grams per year

Product Name:Opzelura	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days

AND

2 - Requested quantity does NOT exceed 360 grams per year

Product Name:Zoryve 0.15% cream	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 6 years of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 90 days of drug therapy with topical crisaborole, supported by chart documentation, claims history, or prescriber attestation including dates of trial

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical crisaborole

AND

3 - Requested quantity does NOT exceed 180 grams per 30 days

Product Name:Zoryve 0.15% cream	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days

AND

2 - Requested quantity does NOT exceed 180 grams per 30 days

Product Name:Zoryve 0.3% cream	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 6 years of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 90 days of drug therapy with each of the following, supported by chart documentation, claims history, or prescriber attestation including dates of trial:

- Topical corticosteroids
- Topical calcineurin inhibitors (pimecrolimus OR tacrolimus)

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical corticosteroids, tacrolimus, AND pimecrolimus

AND

3 - Requested quantity does NOT exceed 180 grams per 30 days

Product Name:Zoryve 0.3% cream	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days

AND

2 - Requested quantity does NOT exceed 180 grams per 30 days

Product Name:Zoryve foam	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 9 years of age or older

AND

2 - ONE of the following:

2.1 Greater than or equal to 30 days of drug therapy with a product from each of the following categories, supported by chart documentation, claims history, or prescriber attestation including dates of trial:

- Topical antifungal (ciclopirox OR ketoconazole)
- Topical corticosteroid
- Topical calcineurin inhibitors (pimecrolimus OR tacrolimus)

OR

2.2 Prescriber has provided valid medical justification for the use of the requested agent over topical antifungals, topical corticosteroids, tacrolimus, AND pimecrolimus

AND

3 - Requested quantity does NOT exceed 60 grams per 30 days

Product Name:Zoryve foam	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 180 days **AND** **2** - Requested quantity does NOT exceed 60 grams per 30 days

2 . Revision History

Date	Notes
12/9/2024	Updated GL name. Added new criteria for Zoryve 0.15% cream. Updated initial auth t/f language throughout guideline. Updated initial auth duration for Opzelura to 12 months. Added QL criterion to Opzelura and Zoryve products. Update to notes section where applicable and minor cosmetic updates.

Topical Post-Herpetic Neuralgia Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161834
Guideline Name	Topical Post-Herpetic Neuralgia Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

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

Approval Criteria

1 - Patient has tried lidocaine patches

AND

2 - Patient has tried over-the-counter capsaicin cream

Product Name:Ztlido	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient has previous trial of at least 30 days of therapy with preferred lidocaine 5% patches*	
Notes	*PDL link: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

2 . Revision History

Date	Notes
12/10/2024	Added Ztlido

Truqap

Optum Rx®

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. F or BC initial auth section, added "recurrent unresectable (local or regi onal)" as an option for disease type.

Tryvio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154416
Guideline Name	Tryvio
Formulary	• Medicaid - Community & State Indiana

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-124512
Guideline Name	Tukysa
Formulary	• Medicaid - Community & State Indiana

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

Turalio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-164595
Guideline Name	Turalio
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
1/31/2025	Updated GPI.

Tykerb

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165052
Guideline Name	Tykerb
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/12/2025	Updated coverage criteria for breast cancer, central nervous system cancers, chordoma, colon cancer, and rectal cancer.

Urea Cycle Disorder Agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-148986
Guideline Name	Urea Cycle Disorder Agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	7/1/2024

1 . Criteria

Product Name:Brand Carbaglu, generic carglumic acid	
Diagnosis	Acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency (submission of chart documentation required)

AND

2 - Dose requested does not exceed 250 mg/kg/day (milligrams per kilogram per day)

AND

3 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be using Carbaglu (carglumic acid) as adjunctive therapy with standard ammonia lowering therapies

AND

4 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

Product Name:Brand Carbaglu, generic carglumic acid	
Diagnosis	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) hyperammonemia
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) hyperammonemia (submission of chart documentation required)

AND

2 - ONE of the following:

2.1 Patient weighs less than or equal to 15 kg (kilograms) and the requested dose does not exceed 150 mg/kg/day (milligrams per kilograms per day)

OR

2.2 Patients weighs greater than 15 kg and the requested dose does not exceed 3.3 grams/m^2/day (grams per square meter per day)

AND

3 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be using Carbaglu (carglumic acid) as adjunctive therapy with standard ammonia lowering therapies

AND

4 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

Product Name:Brand Carbaglu, generic carglumic acid	
Diagnosis	Chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency (submission of chart documentation required)

AND

2 - Dose requested does not exceed 100 mg/kg/day (milligrams per kilogram per day)

AND

3 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

Product Name:Brand Carbaglu, generic carglumic acid	
Diagnosis	Chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - Dose requested does not exceed 100 mg/kg/day (milligrams per kilogram per day)

Product Name:Brand Buphenyl, generic sodium phenylbutyrate	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic urea cycle disorder requiring management in patients with at least ONE of the following enzymatic deficiency(ies) (submission of chart documentation required):

- Argininosuccinic acid synthetase (AS)

- Carbamylphosphate synthetase (CPS)
- Ornithine transcarbamylase (OTC)

AND

2 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be using Buphenyl (sodium phenylbutyrate) as adjunctive therapy with standard ammonia lowering therapies

AND

3 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

AND

4 - Requested dose does not exceed 20 grams per day

AND

5 - ONE of the following:

5.1 The request is for powder for oral solution and does not exceed 2 bottles per 25 days

OR

5.2 The request is for tablets, and BOTH of the following:

- The patient is an adult or pediatric patient weighing greater than or equal to 20 kg (kilograms)
- The requested dose does not exceed 40 tablets per day

Product Name:Brand Buphenyl, generic sodium phenylbutyrate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - Submission of medical records (e.g., chart notes, assessments) confirming patient has been using Buphenyl (sodium phenylbutyrate) as adjunctive therapy and will continue to use standard of care therapies while on Buphenyl therapy

AND

3 - Requested dose does not exceed 20 grams per day

AND

4 - ONE of the following:

4.1 The request is for powder for oral solution and does not exceed 2 bottles per 25 days

OR

4.2 The request is for tablets, and BOTH of the following:

- The patient is an adult or pediatric patient weighing greater than or equal to 20 kg (kilograms)
- The requested dose does not exceed 40 tablets per day

Product Name:Olpruva	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic urea cycle disorder requiring management in patients with at least ONE of the following enzymatic deficiency(ies) (submission of chart documentation required):

- Argininosuccinic acid synthetase (AS)
- Carbamylphosphate synthetase (CPS)
- Ornithine transcarbamylase (OTC)

AND

2 - Patients weighs 20 kg (kilograms) or greater

AND

3 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be using Olpruva (sodium phenylbutyrate) as adjunctive therapy with standard ammonia lowering therapies

AND

4 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

AND

5 - ONE of the following:

5.1 Patient has tried and failed at least 30 days of Buphenyl (sodium phenylbutyrate) AND 30 days Pheburane (sodium phenylbutyrate) therapy, confirmed by claims history or chart documentation

OR

5.2 Prescriber has submitted valid medical justification for the use of Olpruva (sodium phenylbutyrate) over Buphenyl (sodium phenylbutyrate) AND Pheburane (sodium phenylbutyrate)

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

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Patient has previous trial and failure of at least 30 days of Buphenyl (sodium phenylbutyrate) OR 30 days of Pheburane (sodium phenylbutyrate) therapy, confirmed by claims history or chart documentation

OR

2.2 Prescriber has submitted valid medical justification for the use of Olpruva (sodium phenylbutyrate) over Buphenyl (sodium phenylbutyrate) AND Pheburane (sodium phenylbutyrate)

AND

3 - Submission of medical records (e.g., chart notes, assessments) confirming patient has been using Olpruva (sodium phenylbutyrate) as adjunctive therapy and will continue to use standard of care therapies while on Olpruva therapy

Product Name:Pheburane

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Management of chronic urea cycle disorder in patients at least ONE of the following enzymatic deficiency(ies) (submission of chart documentation required):

- Argininosuccinic acid synthetase (AS)
- Carbamylphosphate synthetase (CPS)
- Ornithine transcarbamylase (OTC)

AND

2 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be using Pheburane (sodium phenylbutyrate) as adjunctive therapy with standard ammonia lowering therapies

AND

3 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

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

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - Submission of medical records (e.g., chart notes, assessments) confirming patient has been using Pheburane (sodium phenylbutyrate) as adjunctive therapy and will continue to use standard of care therapies while on Pheburane therapy

Product Name:Ravicti	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic urea cycle disorder requiring management in patients who cannot be managed by dietary protein restriction and/or amino acid supplementation alone with at least ONE of the following enzymatic deficiency(ies) (submission of chart documentation required):

- Argininosuccinic acid synthetase (AS)
- Carbamylphosphate synthetase (CPS)
- Ornithine transcarbamylase (OTC)

AND

2 - Patient is 2 months of age or older

AND

3 - Prescriber attests patient is NOT being treated for N-acetylglutamate synthase (NAGS) deficiency

AND

4 - Submission of medical records (e.g., chart notes, assessments) confirming patient will be

using Ravicti (glycerol phenylbutyrate) as adjunctive therapy with standard ammonia lowering therapies

AND

5 - Prescribed by, or in consultation with, a metabolic geneticist or practitioner specialized in treating metabolic disorders

AND

6 - ONE of the following:

6.1 Patient has tried and failed at least 30 days of sodium phenylbutyrate therapy (can cumulate Buphenyl, Pheburane, Olpruva), confirmed by claims history or chart documentation

OR

6.2 Prescriber has submitted valid medical justification for the use of Ravicti (glycerol phenylbutyrate) over all sodium phenylbutyrate products

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

Approval Criteria

1 - History of the requested agent within the past 90 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Patient has previous trial and failure of at least 30 days of sodium phenylbutyrate therapy

(can cumulate Buphenyl, Pheburane, Olpruva), confirmed by claims history or chart documentation **OR** **2.2** Prescriber has submitted valid medical justification for the use of Ravicti (glycerol phenylbutyrate) over all sodium phenylbutyrate products **AND** **3** - Submission of medical records (e.g., chart notes, assessments) confirming patient has been using Ravicti (glycerol phenylbutyrate) as adjunctive therapy and will continue to use standard of care therapies while on Ravicti therapy

2 . Revision History

Date	Notes
6/26/2024	Criteria updated to require submission of notes confirming the use of standard ammonia lowering therapies

Urinary Tract Antispasmodic, Anti-incontinence agents

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-137642
Guideline Name	Urinary Tract Antispasmodic, Anti-incontinence agents
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

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

Approval Criteria

1 - Patient is 3 years of age or older AND less than 13 years of age

OR

2 - Patient is unable to swallow tablets

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

Approval Criteria

1 - Patient is 2 years of age or older AND less than 12 years of age

OR

2 - Patient is unable to swallow tablets

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

Approval Criteria

1 - Patient has tried and failed Myrbetriq

OR

2 - Patient has an intolerance or contraindication to Myrbetriq

2 . Revision History

Date	Notes
12/12/2023	Removed medical rational for use option from Myrbetriq and updated age. Updated Vesicare LS age.

Uterine Disorders

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161798
Guideline Name	Uterine Disorders
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

1 . Criteria

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

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of menorrhagia associated with uterine leiomyomas (fibroids) in a premenopausal female

AND

2.1.2 Previous trial and failure of hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of moderate to severe pain associated with endometriosis in a premenopausal female

AND

2.2.2 One of the following:

2.2.2.1 Previous trial and failure of BOTH of the following:

- Hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]
- NSAID (non-steroidal anti-inflammatory drug) therapy

OR

2.2.2.2 Prescriber has submitted valid medical rationale against the use of both hormonal contraceptives/therapy AND NSAID therapy

AND

3 - Must have a negative pregnancy test in the past 30 days

AND

4 - Must have laboratory tests confirming no hepatic disease in the past 30 days

AND

5 - Requested dose does not exceed 1 tablet (40/1/0.5mg) per day

AND

6 - Patient does NOT have current diagnosis of, risk factors for, or previous history of thromboembolic disorders or vascular events

AND

7 - Patient does NOT have a current diagnosis or history of breast cancer or other hormone-sensitive malignancies

AND

8 - Patient does NOT have increased risk factors for hormone-sensitive malignancies

AND

9 - Patient does NOT have a diagnosis of osteoporosis

AND

10 - Patient does NOT have undiagnosed abnormal uterine bleeding

Product Name:Myfembree	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient will not be exceeding 24 total months of therapy per lifetime with relugolix/estradiol/norethindrone acetate (Myfembree)

AND

3 - Prescriber states that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed below:

- Current diagnosis of, risk factors for, or previous history of thromboembolic disorders or vascular events
- Current diagnosis or history of breast cancer or other hormone-sensitive malignancies
- Increased risk factors for hormone-sensitive malignancies
- Diagnosis of osteoporosis
- Undiagnosed abnormal uterine bleeding

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

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of menorrhagia associated with uterine leiomyomas (fibroids) in a premenopausal female

AND

3 - Previous trial and failure of hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]

AND

4 - Must have a negative pregnancy test in the past 30 days

AND

5 - Must have laboratory tests confirming no hepatic disease in the past 30 days

AND

6 - Requested dose does not exceed 2 capsules [1 x 300/1/0.5 mg (milligrams); 1 x 300 mg] per day

AND

7 - Patient will NOT have concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)

AND

8 - Patient does NOT have current diagnosis of, risk factors for, or previous history of thromboembolic disorders or vascular events

AND

9 - Patient does NOT have a current diagnosis or history of breast cancer or other hormone-sensitive malignancies

AND

10 - Patient does NOT have increased risk factors for hormone-sensitive malignancies

AND

11 - Patient does NOT have a diagnosis of osteoporosis

AND

12 - Patient does NOT have undiagnosed abnormal uterine bleeding

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

Approval Criteria

1 - Patient has a history of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient will not be exceeding 24 total months of therapy per lifetime with elagolix/estradiol/norethindrone acetate (Oriahnn)

AND

3 - Prescriber states that the patient remains a candidate for treatment, indicating that they have NOT developed any of the contraindication(s) listed below:

- Concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)
- Current diagnosis of, risk factors for, or previous history of thromboembolic disorders or vascular events
- Current diagnosis or history of breast cancer or other hormone-sensitive malignancies
- Increased risk factors for hormone-sensitive malignancies
- Diagnosis of osteoporosis
- Undiagnosed abnormal uterine bleeding

Product Name:Orilissa 150 mg	
Diagnosis	Endometriosis
Approval Length	Endometriosis alone: 12 month ; Endometriosis-related dyspareunia: 6 month approval maximum *
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - ONE of the following:

2.1 BOTH of the following:

2.1.1 Diagnosis of moderate to severe pain associated with endometriosis

AND

2.1.2 Requested dose does not exceed 150 mg (milligrams) daily

OR

2.2 BOTH of the following:

2.2.1 Diagnosis of moderate to severe pain associated with endometriosis with co-existing endometriosis-related dyspareunia

AND

2.2.2 Requested dose does not exceed 400 mg daily for a maximum of 6 months

AND

3 - ONE of the following:

3.1 Previous trial and failure of BOTH of the following:

- Hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]
- NSAID (non-steroidal anti-inflammatory drug) therapy

OR

3.2 Prescriber has submitted valid medical justification for the use of Orilissa (elagolix) over both hormonal contraceptives/therapy AND NSAID therapy

AND

4 - Patient has a negative pregnancy test in the past 30 days

AND

5 - ONE of the following:

5.1 Laboratory tests confirming no hepatic disease worse than Child-Pugh A in the past 30 days

OR

5.2 Patient has Child-Pugh B hepatic disease, and adjusted dosing will be limited to 150 mg daily for a maximum of 6 months**

AND

6 - Patient will NOT have concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)

AND

7 - Patient does NOT have a diagnosis of osteoporosis

Notes	* Patients with Child-Pugh class B hepatic impairment will be limited t o the 150mg daily dose for a maximum of 6 months irrespective of indi cation.

Product Name:Orilissa 150 mg	
Diagnosis	Endometriosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of the requested medication for at least 90 days within the past 120 days, confirmed by claims history or chart documentation

AND

2 - Patient will not be exceeding 24 total months of therapy per lifetime with elagolix (Orilissa)

AND

3 - Prescriber states that the patient remains a candidate for treatment, indicating that they do NOT have concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)

AND

4 - Patient does NOT have a diagnosis of osteoporosis

Product Name:Orilissa 200 mg	
Diagnosis	Endometriosis with Co-existing Endometriosis-Related Dyspareunia
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - BOTH of the following:

2.1 Diagnosis of moderate to severe pain associated with endometriosis with co-existing endometriosis-related dyspareunia

AND

2.2 Requested dose does not exceed 400 mg (milligrams) daily for a maximum of 6 months

AND

3 - ONE of the following:

3.1 Previous trial and failure of BOTH of the following:

- Hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]
- NSAID (non-steroidal anti-inflammatory drug) therapy

OR

3.2 Prescriber has submitted valid medical justification for the use of Orilissa (elagolix) over both hormonal contraceptives/therapy AND NSAID therapy

AND

4 - Patient has a negative pregnancy test in the past 30 days

AND

5 - Laboratory tests confirming no hepatic disease worse than Child-Pugh A in the past 30 days

AND

6 - Patient will NOT have concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations (e.g., cyclosporine, gemfibrozil)

AND

7 - Patient does NOT have a diagnosis of osteoporosis

2 . Revision History

Date	Notes
12/10/2024	Updated Myfembree criteria

Vafseo

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161835
Guideline Name	Vafseo
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
12/10/2024	New program

Vaginal Antimicrobials

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-154729
Guideline Name	Vaginal Antimicrobials
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name:Xaciato gel	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Previous trial and failure of a preferred topical antibacterial agent*	
Notes	*PDL: https://www.uhcprovider.com/en/health-plans-by-state/indiana-health-plans/in-comm-plan-home/in-cp-pharmacy.html

Product Name:Tinidazole tablets

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tried and failed metronidazole

OR

2 - Prescriber has provided medical justification as to why metronidazole is not appropriate for use (e.g., infection being treated is not susceptible to preferred agent)

2 . Revision History

Date	Notes
9/11/2024	New

Valchlor

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-97113
Guideline Name	Valchlor
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

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

Vanflyta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-161254
Guideline Name	Vanflyta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2025

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
11/25/2024	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-82030
Guideline Name	Vecamyl
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Venclexta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-150892
Guideline Name	Venclexta
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/2/2024

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
8/2/2024	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 (fezolinetant)

Prior Authorization Guideline

Guideline ID	GL-137497
Guideline Name	Veozah (fezolinetant)
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2024

1 . Criteria

Product Name:Veozah	
Approval Length	6 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 - Patient is 18 years of age or older

AND

3 - ONE of the following:

3.1 Patient has tried and failed at least 90 days of therapy with ONE hormonal agent (e.g., oral, injectable, topical, transdermal, or vaginal), confirmed by claims history or chart documentation

OR

3.2 BOTH of the following:

3.2.1 Patient has contraindication to hormonal therapy (submission of supporting chart documentation required)

AND

3.2.2 Patient has tried and failed at least 90 days of therapy with ONE non-hormonal agent (e.g., gabapentin, paroxetine, venlafaxine, oxybutynin), confirmed by claims history or chart documentation

OR

3.3 Prescriber has submitted valid medical justification for the use of Veozah (fezolinetant) over hormonal therapy AND other non-hormonal therapy

AND

4 - Prescriber attests to ALL of the following:

- Patient does not have cirrhosis
- Patient does not have severe renal impairment or end-stage renal disease (ESRD)
- Patient is not currently utilizing a CYP1A2 inhibitor and will not be initiated on CYP1A2 inhibitor therapy while on concomitant Veozah (fezolinetant) therapy

Product Name:Veozah	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of the requested agent for at least 90 days of the past 120 days, confirmed by claims history or chart documentation

AND

2 - ONE of the following:

2.1 Patient has previously tried and failed at least 90 days of therapy with ONE hormonal agent (e.g., oral, injectable, topical, transdermal, or vaginal), confirmed by claims history or chart documentation

OR

2.2 Patient has contraindication to hormonal therapy and has previously tried and failed at least 90 days of therapy with ONE non-hormonal agent (e.g., gabapentin, paroxetine, venlafaxine, oxybutynin), confirmed by claims history or chart documentation

OR

2.3 Prescriber has submitted valid medical justification for the use of Veozah (fezolinetant) over hormonal therapy AND other non-hormonal therapy

AND

3 - Prescriber attests to ALL of the following:

- Patient does not have cirrhosis
- Patient does not have severe renal impairment or end-stage renal disease (ESRD)

- Patient is currently not on a CYP1A2 inhibitor and will not be initiated on a CYP1A2 inhibitor while on concomitant Veozah (fezolinetant) therapy

2 . Revision History

Date	Notes
12/8/2023	New guideline

Verzenio

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151751
Guideline Name	Verzenio
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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
8/14/2024	Updated background and added clinical criteria for endometrial carci noma per NCCN

Vijoice

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-152574
Guideline Name	Vijoice
Formulary	• Medicaid - Community & State Indiana

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

Vizimpro

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-118477
Guideline Name	Vizimpro
Formulary	• Medicaid - Community & State Indiana

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

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

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-165105
Guideline Name	Votrient
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/1/2025

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
2/13/2025	Updated criteria for Sarcoma (matched core)

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.

Voydeya

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151749
Guideline Name	Voydeya
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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

8/14/2024	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

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

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121540
Guideline Name	Vyndaqel and Vyndamax
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	3/19/2023

1 . Criteria

Product Name:Vyndaqel, Vyndamax	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

AND

2 - Diagnosis of cardiomyopathy secondary to transthyretin-mediated amyloidosis (ATTR-CM)

AND

3 - Diagnosis confirmed either histologically OR by genetic testing

AND

4 - Prescribed by, or in consultation with, a cardiologist

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

Approval Criteria

1 - History of the requested medication in the past 90 days

2 . Revision History

Date	Notes
2/21/2023	Added prescriber check in initial authorization and updated approval l ength. Added reauthorization criteria.

Wainua

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-146138
Guideline Name	Wainua
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
4/24/2024	New program.

Wegovy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-146956
Guideline Name	Wegovy
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

1 . Criteria

Product Name:Wegovy	
Approval Length	1 year(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 45 years of age or older

AND

2 - Diagnosis of cardiovascular disease (CVD) in an obese or overweight patient who needs risk reduction of major adverse cardiovascular events (MACE) and all of the following:

2.1 Submission of clinical documentation (e.g., chart notes) of patient having a BMI (body mass index) of greater than or equal to 27 kg/m2 (kilograms per square meter) within the past 3 months

AND

2.2 Submission of clinical documentation (e.g., chart notes) of patient having one of the following within the past year:

2.2.1 Prior myocardial infarction (MI)

OR

2.2.2 Prior stroke (ischemic or hemorrhagic)

OR

2.2.3 Symptomatic peripheral arterial disease (PAD) as evidenced by one of the following:

- Amputation due to atherosclerotic disease
- History of peripheral arterial revascularization procedure
- Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest)

AND

2.3 One of the following:

2.3.1 Submission of clinical documentation (e.g., chart notes) or confirmation by claims history that patient is optimized on guideline directed-therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents

OR

2.3.2 Prescriber has provided medical justification as to why patient cannot use beta-

blockers, RAS inhibitors, AND lipid-lowering therapies (please document dates of trial, if applicable)

AND

2.4 Prescriber attests to all of the following:

- Patient does not have Type 1 or Type 2 diabetes
- Patient will use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity
- Patient will not use with other semaglutide products or with any other GLP-1 Receptor Agonists or combination products

AND

3 - Dose requested does not exceed 2.4 mg/week (milligrams per week)

Product Name:Wegovy	
Approval Length	1 year(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - History of requested agent for at least 90 days within the past 120 days, as confirmed by claims history, chart documentation, or provider attestation including dates of trial

AND

2 - Diagnosis of cardiovascular disease (CVD) in an obese or overweight patient who needs risk reduction of major adverse cardiovascular events (MACE) and both of the following:

2.1 Prescriber attests to all of the following:

- Patient does not have Type 1 or Type 2 diabetes
- Patient will continue to use Wegovy (semaglutide) in combination with reduced calorie diet and increased physical activity

- Patient will not use with other semaglutide products or with any other GLP-1 RA or combination agents

AND

2.2 One of the following:

2.2.1 Submission of clinical documentation (e.g., chart notes) or confirmation by claims history that patient continues to utilize optimized on guideline directed-therapy, including beta-blockers and/or renin-angiotensin system (RAS) inhibitors AND lipid-lowering agents

OR

2.2.2 Prescriber has provided medical justification as to why patient cannot use beta-blockers, RAS inhibitors, AND lipid-lowering therapies (please document dates of trial, if applicable)

AND

3 - Dose requested does not exceed 2.4 mg/week (milligrams per week)

2 . Revision History

Date	Notes
5/1/2024	New guideline

Xalkori

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147469
Guideline Name	Xalkori
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/17/2024	Added criteria for melanoma. Added the sprinkle caps.

Xdemvy

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147056
Guideline Name	Xdemvy
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/2/2024	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.

Xenleta

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-121344
Guideline Name	Xenleta
Formulary	• Medicaid - Community & State Indiana

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-151734
Guideline Name	Xermelo
Formulary	• Medicaid - Community & State Indiana

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-150103
Guideline Name	Xifaxan
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	8/1/2024

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
7/22/2024	Updated language from "Diagnosis of hepatic encephalopathy" to "U sed for prophylaxis of hepatic encephalopathy (HE) recurrence" to ali gn with PI; Minor cosmetic updates.

Xolremdi

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-156893
Guideline Name	Xolremdi
Formulary	• Medicaid - Community & State Indiana

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

Xospata

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147515
Guideline Name	Xospata
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/20/2024	Updated treatment criteria for AML to include additional NCCN recommendations.

Xpovio

Optum Rx®

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-152524
Guideline Name	Xtandi
Formulary	• Medicaid - Community & State Indiana

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	Copy core

Xuriden

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-82040
Guideline Name	Xuriden
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2021

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
3/5/2021	Bulk Load

Yonsa

Prior Authorization Guideline

Guideline ID	GL-146977
Guideline Name	Yonsa
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/1/2024	Replaced GPI "21406010200310" with new GPI "21406010250310". No changes to criteria.

Yorvipath

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.

Zelboraf

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-147404
Guideline Name	Zelboraf
Formulary	• Medicaid - Community & State Indiana

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.

Zilbrysq

Prior Authorization Guideline

Guideline ID	GL-208209
Guideline Name	Zilbrysq
Formulary	• Medicaid - Community & State Arizona • 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.

Zolinza

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-96942
Guideline Name	Zolinza
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	1/1/2022

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

Zurzuvae

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-143437
Guideline Name	Zurzuvae
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	4/1/2024

1 . Criteria

Product Name:Zurzuvae	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postpartum depression (PPD)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient is within 12 months (365 days) of being postpartum (Documentation of date of delivery required)

AND

4 - Patient is not exceeding one treatment course (14 days of therapy) per 365 days

AND

5 - Requested dose dose not exceed one of the following:

5.1 If the request is for 20 mg OR 25 mg capsules: 28 capsules for 14-day period (2 capsules per day)

OR

5.2 If the request is for 30 mg capsules, BOTH of the following:

5.2.1 Dose does not exceed 14 capsules for 14-day period (1 capsule per day)

AND

5.2.2 Submission of medical records (e.g., chart notes, laboratory tests/values, assessments) confirming one of the following:

- Severe hepatic impairment (Child-Pugh C)
- Moderate to severe renal impairment (eGFR less than 60 mL/min/1.73m2)

2 . Revision History

Date	Notes

2/22/2024	New

Zydelig

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-127469
Guideline Name	Zydelig
Formulary	• Medicaid - Community & State Indiana

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
7/3/2023	Clarified criteria for CLL/SLL per NCCN guidelines. Updated Markets in Scope

Zykadia

Prior Authorization Guideline

Guideline ID	GL-147517
Guideline Name	Zykadia
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	6/1/2024

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
5/20/2024	Added coverage criteria for inoperable inflammatory myofibroblastic t umor and anaplastic large cell lymphoma per NCCN. Corrected Erdh eim-Chester Disease spelling.

Zytiga

Optum Rx®

Prior Authorization Guideline

Guideline ID	GL-151386
Guideline Name	Zytiga
Formulary	• Medicaid - Community & State Indiana

Guideline Note:

Effective Date:	9/1/2024

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

8/13/2024	Added criteria for salivary gland tumor per NCCN