UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2201-12
Program	Prior Authorization/Medical Necessity
Medication	*Orencia® (abatacept) *This program applies to the subcutaneous formulation of abatacept
P&T Approval Date	5/2020, 11/2020, 6/2021, 12/2021, 3/2022, 11/2022, 1/2023, 4/2023, 7/2023, 1/2024, 2/2024, 10/2024
Effective Date	1/1/2025

1. Background:

Orencia® (abatacept) is a selective T-cell costimulation modulator indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis, patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis, and patients 2 years of age and older with active psoriatic arthritis.

Concomitant used of Orencia with other immunosuppressives (e.g., biologic disease-modifying antirheumatic drugs, Janus kinase (JAK) inhibitors) is not recommended.

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. **One** of the following:

a. History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)[b]

-OR-

b. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as

documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)]

-AND-

ii. History of failure, contraindication, or intolerance to **two** of the following preferred products (Document drug, date, and duration of trial):

a. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
b. Cimzia (certolizumab)
c. Enbrel (etanercept)
d. Rinvoq (upadacitinib)
e. Simponi (golimumab)
f. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

(b) **Both** of the following:

i. Patient is currently on Orencia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Orencia*

-AND-

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

-AND-

(4) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Orencia therapy

-AND-

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

Authorization will be issued for 12 months.

B. Juvenile Idiopathic Arthritis (JIA)

1. **Initial Authorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis.

-AND-

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

-AND-

(3) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Orencia therapy

-AND-

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

(golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

C. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. **One** of the following:

a. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

b. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Enbrel (etanercept)]

-AND-

ii. **One** of the following:

a. History of failure, contraindication, or intolerance to **two** of the following preferred products: (document drug, date, and duration of trial)

1. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
2. Cimzia (certolizumab)
3. Cosentyx (secukinumab)
4. Enbrel (etanercept)
5. Rinvoq (upadacitinib)
6. Simponi (golimumab)

7. Skyrizi (risankizumab-rzaa)
8. Stelara (ustekinumab)
9. Tremfya (guselkumab)
10. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

b. **Both** of the following:

1. Patient is less than 18 years of age

-AND-

2. History of failure, contraindication, or intolerance to Stelara (ustekinumab) or Enbrel (etanercept) (document date and duration of trial)

-OR-

(b) **Both** of the following:

i. Patient is currently on Orencia therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Orencia*

-AND-

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

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of

assistance from the Bristol-Myers Squibb sponsored Orencia® Co-Pay Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Orencia** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Orencia therapy

-AND-

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

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

3. Additional Clinical Rules:

- Supply limits may be in place.

The intravenous infusion is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy for Orencia.

4. References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; October 2023.
2. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.
4. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol. 2016 May;68(5):1060-71.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
6. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.

7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
10. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
11. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.

Program	Prior Authorization/Medical Necessity - Orencia (abatacept)
Change Control	
5/2020	New program
11/2020	Added Tremfya as a step therapy medication for psoriatic arthritis. Updated background and references.
6/2021	Removed prescriber requirement from reauthorization criteria. Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting current therapy with Orencia in order to bypass step if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis and psoriatic arthritis with no change to clinical intent. Updated CT/KY footnote.
3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis.
11/2022	Added Enbrel as a preferred step product for RA. Added Enbrel, Rinvoq, and Xeljanz as preferred step products for PsA. Added Enbrel and Rinvoq as an example where appropriate. Added Mississippi to state mandate footnote.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote “For a list of preferred adalimumab products please reference drug coverage tools.”
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
1/2024	Updated PsA criteria based on updated indication for patients 2 years of age or older. Updated Background, References, and state mandate footnote.
2/2024	Removed Olumiant as a preferred product for RA.
10/2024	Updated RA and PsA step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred

	adalimumab products with no change to clinical intent. Added Cosentyx as a step therapy drug for PsA. Removed preferred adalimumab footnote.