UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Orencia

Program	Prior Authorization
Medication	Orencia (abatacept) subcutaneous
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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 adult patients 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. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

b. 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 within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. History of failure, contraindication, or intolerance to **three** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Kevzara (sarilumab)
- Olumiant (baricitinib)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

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

a. Patient is currently on Orencia therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

c. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Orencia therapy

-AND-

b. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

-AND-

c. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. **Both** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following:

- Humira (adalimumab)
- Enbrel (etanercept)
- Cimzia (certolizumab pegol)

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

e. Prescribed by or consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

-OR-

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

a. Patient is currently on Orencia therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

b. Diagnosis of active psoriatic arthritis

-AND-

c. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Orencia therapy

-AND-

b. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

C. Juvenile Idiopathic Arthritis (JIA)

1. **Initial Authorization**

a. Diagnosis of moderately to severely active juvenile idiopathic arthritis

-AND-

b. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. **One** of the following:

(1) History of failure, contraindication, or intolerance to **both** of the following:

(a) Humira (adalimumab)
(b) Enbrel (etanercept)

-OR-

(2) Patient is currently on Orencia therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

d. Prescribed by or consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Orencia therapy

-AND-

b. Patient is not receiving Orencia in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or consultation with a rheumatologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company, June 2020.
2. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019; 71(1): 5-32.

Program	Program type – Prior Authorization
Change Control	
Date	Change
3/2013	New policy
2/2015	Template updated. Orencia IV formulation and criteria removed from criteria as this drug is not available on the outpatient pharmacy benefit. Removed age requirement for all indications. Added embedded step criteria requiring trial of Humira and Cimzia, or continuation of existing Orencia therapy.
3/2016	Initial therapy section: Added Enbrel to list of preferred drugs that require history of failure, contraindication, or intolerance Updated policy template
10/2016	Annual Review – no change
3/2017	Added Otezla to list of medications not to be used with Orencia. Updated background and policy template.
4/2017	Added hydroxychloroquine to example list of non-biologic DMARDs
9/2017	Added psoriatic arthritis and juvenile idiopathic arthritis to coverage criteria. Added Otezla as a trial/fail option for psoriatic arthritis since it is now a preferred product. Updated background and references.

2/2018	Updated step therapy medications in the rheumatoid arthritis section to a trial of two TNF inhibitors and Kevzara due to PDL changes effective 4/1/18. Changed number of trial products from three to two in the psoriatic arthritis section.
8/2018	Annual review. No changes.
3/2019	Removed prescriber check. Removed non-biologic DMARD trial from JIA section. Revised step therapy medications for RA section. Updated references.
11/2019	Revised step therapy medications for PsA. Updated background and references.
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users.
1/2020	Revised RA step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor update to DMARD requirement.
11/2020	Updated background and references.