UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Otezla

Program	Prior Authorization
Medication	Otezla (apremilast)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2014
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is also indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and adult patients with oral ulcers associated with Behcet's Disease.

2. Coverage Criteria:

A. <u>Psoriatic Arthritis</u>

1. <u>Initial Authorization</u>

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at the maximally indicated dose 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 Otezla in combination with either of the following:

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

-AND-

d. Prescribed by or in 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 Otezla therapy

-AND-

b. Patient is not receiving Otezla in combination with either of the following:

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

-AND-

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

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

B. Plaque Psoriasis

1. Initial Authorization

a. Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

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

-AND-

c. **Both** of the following:

(1) History of failure to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

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

-AND-

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

-AND-

d. Patient is not receiving Otezla in combination with either of the following:

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

-AND-

e. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. Documentation of positive clinical response to Otezla therapy

-AND-

b. Patient is not receiving Otezla in combination with either of the following:

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

-AND-

c. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

C. Behcet's Disease

1. Initial Authorization

a. Diagnosis of Behcet's Disease

-AND-

b. Patient has active oral ulcers

-AND-

c. History of failure, contraindication, or intolerance to one non-biologic (e.g., corticosteroids, colchicine) within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

d. Patient is not receiving Otezla in combination with either of the following:

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

-AND-

e. Prescribed by or in 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 Otezla therapy

-AND-

b. Patient is not receiving Otezla in combination with either of the following:

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

-AND-

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

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

3. References:

1. Otezla [package insert]. Summit, NJ: Celgene Corp., July 2019.
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3. 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.
4. 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.
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7. 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.
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 management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.

9. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
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	Program type – Prior Authorization
Change Control	
Date	Change
6/2014	New drug policy
2/2015	Added new criteria for plaque psoriasis, initial and reauthorization. Revised existing psoriatic arthritis criteria to now require trial of Humira and Cimzia. The requirement was previously Humira and Enbrel.
3/2016	Added Enbrel to prerequisite therapy requirements Updated policy template
10/2016	Annual Review – no change
2/2017	Annual Review- no change.
9/2017	Removed trial of TNFs from policy since Otezla is now a preferred product. Updated background and references.
8/2018	Annual Review – Updated References
3/2019	Removed prescriber check. Updated references.
11/2019	Added prerequisite medications for psoriasis and psoriatic arthritis. Added review criteria for Behcet's Disease. Updated background and references.
12/2019	Added prerequisite therapy documentation of drug, date, and duration of trials.

5/2020	Added prescriber requirement. Minor revisions to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.