

### Clinical Pharmacy Program Guidelines for Otezla

Program	Prior Authorization
Medication	Otezla (apremilast)
Pharmacy & Therapeutics Approval Date	3/24/2016
Effective Date	6/1/2016

**1. Background:**

**Indications**

**Psoriatic Arthritis (PsA)**

Indicated for the treatment of adult patients with active psoriatic arthritis.

**Plaque Psoriasis**

Indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

**2. Coverage Criteria:**

<p><b>A. <u>Psoriatic Arthritis</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;"><b>-AND-</b></p> <p>b. Prescribed or recommended by a rheumatologist or dermatologist</p> <p style="text-align: center;"><b>-AND-</b></p> <p>c. Patient is not receiving Enbrel in combination with either of the following:</p> <p style="padding-left: 40px;">(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]</p> <p style="padding-left: 40px;">(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]</p> <p style="text-align: center;"><b>-AND-</b></p> <p>d. One of the following:</p> <p style="padding-left: 40px;">(1) History of failure, contraindication, or intolerance to all of the following:</p>
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- (a) Cimzia (certolizumab)
- (b) Humira (adalimumab)
- (c) Enbrel (etanercept)

**-OR-**

- (2) For continuation of prior Otezla therapy

**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 [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]

**Authorization will be issued for 12 months.**

**B. Plaque Psoriasis**

**1. Initial Authorization**

- a. Diagnosis of moderate to severe chronic plaque psoriasis

**-AND-**

- b. Prescribed or recommended by a dermatologist

**-AND-**

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

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

**-AND-**

d. One of the following:

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

(b) Humira (adalimumab)

(c) Enbrel (etanercept)

**-OR-**

(2) For continuation of prior Otezla therapy

**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 [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]

**Authorization will be issued for 12 months.**

**3. References:**

1. Otezla Prescribing Information. Celgene Corp., September 2014.
2. Kavanaugh A, Mease PJ, Gomez-Reino JJ, et al. Treatment of psoriatic arthritis in a phase 3 randomised, placebo-controlled trial with apremilast, an oral phosphodiesterase 4 inhibitor. *Ann Rheum Dis*. 2014;73(6):1020-6.
3. Reich K, Griffiths C, Leonardi C, et al. Long-term safety and tolerability of apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate to severe psoriasis: Results from a phase III, randomized, controlled trial (ESTEEM 1). *J Am Acad Dermatol*. 2014;70(5) Suppl 1:AB174.
4. Paul C, Crowley J, Cather J, et al. Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with moderate to severe psoriasis: 16-week results of a phase 3, randomized, controlled trial (ESTEEM 2). *J Am Acad Dermatol*. 2014;70(5) Suppl 1:AB164.

Program	Program type – Prior Authorization
<b>Change Control</b>	
Date	Change
June 2014	New drug policy
Feb 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.
March 2016	Added Enbrel to prerequisite therapy requirements Updated policy template