

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

DRUG NAME	Otezla (apremilast)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel & Humira QUANTITY LIMIT – 60 per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Otezla (apremilast) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### ACTIVE PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by a rheumatologist or dermatologist; AND
3. Member has tried and failed treatment with **both** Enbrel and Humira; AND
4. Member meets at least **one** of the following scenarios:
  - a) Member has predominantly axial disease (i.e. sacroiliitis or spondylitis) as indicated by radiographic evidence;
  - b) Member has shown symptoms of predominantly axial disease (i.e. sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) and has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;
  - c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID.
5. **Dosage allowed:** Initial: 10 mg in the morning. Titrate upward by additional 10 mg per day on days 2 to 5 as follows: Day 2: 10 mg twice daily; Day 3: 10 mg in the morning and 20 mg in the evening; Day 4: 20 mg twice daily; Day 5: 20 mg in the morning and 30 mg in the evening. Maintenance dose: 30 mg twice daily starting on day 6.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## PLAQUE PSORIASIS (PP)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by a rheumatologist or dermatologist; AND
3. Member has PP involves 10% or more of the member's body surface area; AND
4. Member has PP for 6 months or longer; AND
5. Member has tried and failed treatment with **both** Enbrel and Humira; AND
6. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
7. Member's Physician Global Assessment (sPGA) of  $\geq 3$  (moderate or severe disease); AND
8. Member has tried and failed to respond to treatment with at least **one** of the following:
  - a) At least 12 weeks of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
  - b) At least 12 weeks of phototherapy (i.e. UVB light therapy, Excimer laser treatments; tanning beds emit mostly UVA light and therefore would not meet this criteria).
  - c) At least a 4 week trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
9. Member has tried and failed to respond to treatment of an immunosuppressant (i.e. cyclosporine, methotrexate, acetretin) for at least a 12 week trial.
10. **Dosage allowed:** Initial: 10 mg in the morning. Titrate upward by additional 10 mg per day on days 2 to 5 as follows: Day 2: 10 mg twice daily; Day 3: 10 mg in the morning and 20 mg in the evening; Day 4: 20 mg twice daily; Day 5: 20 mg in the morning and 30 mg in the evening. Maintenance dose: 30 mg twice daily starting on day 6.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Otezla (apremilast) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Active infections
- Ankylosing Spondylitis
- Asthma
- Cellulitis
- Crohn's disease
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (Enbrel, Humia, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Relapsing polychondritis

- Rheumatoid Arthritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu’s arteritis
- Ulcerative colitis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/12/2017	New policy for Otezla created. For diagnosis of PP: immunosuppressive criteria separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel are listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement added. For diagnosis of PsA: TNF inhibitors Humira and Enbrel are listed as required trials. List of diagnoses considered not medically necessary added.

References:

1. US Food and Drug Administration Drug Safety Data. [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/125261s114lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf) (October 14, 2014)
2. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
3. Menter A, Korman NJ, Elmets CA, et al. 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 Feb 7. [Epub ahead of print]
4. MCG 20th edition, 2016.
5. National Institutes of Health, Clinicaltrials.gov. [cited 9/16/2014]; Available from: <http://www.clinicaltrials.gov>
6. Otezla [prescribing information]. Summit, NJ; Celgene Corporation: December, 2015.
7. Wolters Kluwer. Facts & Comparisons. [www.factsandcomparisons.com](http://www.factsandcomparisons.com), 2014.

Effective date: 10/01/2017

Revised date: 05/12/2017