

PHARMACY POLICY STATEMENT Kentucky 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 NOT MEDICALLY NECESSARY	Click Here

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. Treatment failure requires at least 30 days of therapy (for each drug) without an adequate response; 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 30 days 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 a 30-day trial of methotrexate and 30-day trial of 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. Treatment failure requires at least 30 days of therapy (for each drug) without an adequate response; 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 ≥ 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 30 days of photochemotherapy (i.e. psoralen plus ultraviolet A therapy);
 - b) At least 30 days 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 30-day 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, acetrelin) for at least 30 days.
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
05/15/2017	New policy for Otezla created. Policies SRx-0042 and SRx-0043 archived. For diagnosis of PP: immunosuppressive criterion was separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel were listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement was added. For diagnosis of PsA: TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.

References:

1. US Food and Drug Administration Drug Safety Data. 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. National Institutes of Health, Clinicaltrials.gov. [cited 9/16/2014]; Available from: <http://www.clinicaltrials.gov>.
5. Otezla [prescribing information]. Summit, NJ: Celgene Corporation; December, 2015.
6. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2014.

Effective date: 05/15/2017

Revised date: 05/15/2017