

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 (Preferred Product) QUANTITY LIMIT— 60 per 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Otezla (apremilast) is a **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.

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 predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 30-day trial of sulfasalazine or azathioprine or cyclosporine).
4. **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 (PsO)

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 PsO involves 10% or more of the member's body surface area; AND
4. Member has PsO for 6 months or longer; AND
5. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
6. 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
7. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 30 days.
8. **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 (e.g., documented member's PASI score improvement, etc.).

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 (i.e., Enbrel, Humira, 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 PsO: 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.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria. Clarifications entered for AS and PsA on NSAIDs trial length. Requirements on axial disease type removed from PsA. Physician Global Assessment score removed from diagnosis of PsO. References added. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.

References:

1. Otezla [prescribing information]. Summit, NJ: Celgene Corporation; December, 2015.
2. US Food and Drug Administration Drug Safety Data.
http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf (October 14, 2014).
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
4. 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.
5. Poddubnyy D. Axial spondyloarthritis: is there a treatment of choice? Ther Adv Musculoskelet Dis. 2013;5(1):45 - 54.
6. Gladman DD. Axial disease in psoriatic arthritis. Curr Rheumatol Rep. 2007 Dec;9(6):455-60.
7. Kang EJ, et al. Psoriatic arthritis: latest treatments and their place in therapy. Ther Adv Chronic Dis. 2015;6 (4):194-203.

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