CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Otezla (apremilast)
BILLING CODE	Must use valid NDC
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.

ORAL ULCERS ASSOCIATED WITH BEHÇET'S DISEASE

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consult with a rheumatologist or dermatologist; AND
3. Member has a diagnosis of Behçet's disease; AND
4. Member has recurrent oral ulcers with at least 2 active oral ulcers; AND
5. Member has had a trial and failure of a topical corticosteroid and/or colchicine.
6. **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 6 months.

For **reauthorization**:

1. Chart notes must show the member has experienced a decrease in the number of oral ulcers or decrease in pain level associated with oral ulcers.

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

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.).
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 showing 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 or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. 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);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
5. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
6. **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 showing improvement of signs and symptoms of disease (e.g., documented member's BSA 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 diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/10/2017	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.
07/28/2019	New diagnosis of Oral Ulcers Associated With Behçet's Disease added.
11/23/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. PsA: Added requirement of diagnosis of PsA. Removed non-axial disease requirement. Specified trials to be 4 weeks of an NSAID AND 3 months of a DMARD. PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement.
02/03/2021	Behcet's disease: Updated references. Changed initial approval duration from 12 months to 6 months. Specified they must have active ulcers. Changed the step drugs to match EULAR guideline recommendations. Made the renewal criteria specific.
11/17/2021	Annual review, no changes

References:

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12. Hatemi G, Mahr A, Ishigatsubo Y, et al. Trial of Apremilast for Oral Ulcers in Behçet's Syndrome. *N Engl J Med*. 2019;381(20):1918-1928. doi:10.1056/NEJMoa1816594

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