CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Otezla, Otezla XR (apremilast)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Otezla, initially approved by the FDA in 2014, is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. The specific mechanism(s) by which Otezla exerts its therapeutic action is not well defined. A higher dose of Otezla is available as Otezla XR in a 75 mg tablet.

Otezla (apremilast) will be considered for coverage when the following criteria are met:

Oral Ulcers associated with Behçet's Disease

1. For **initial** authorization:
2. Member is at least 18 years of age; AND
3. Medication must be prescribed by or in consult with a rheumatologist or dermatologist; AND
4. Member has a diagnosis of Behçet's disease; AND
5. Member has recurrent oral ulcers with at least 2 active oral ulcers; AND
6. Member has had a trial and failure of a topical corticosteroid and/or colchicine.
7. **Dosage allowed/Quantity limit:** administer initial titration per package insert. Recommended maintenance dose is 30 mg twice daily or 75 mg once daily. Otezla quantity limit: 60 tablets per 30 days. Otezla XR quantity limit: 30 tablets per 30 days.

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member is 6 years of age and older weighing at least 20 kg; 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 conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.).
5. **Dosage allowed/Quantity limit:** administer initial titration per package insert. Otezla quantity limit: 60 tablets per 30 days. Otezla XR quantity limit: 30 tablets per 30 days.
   a) **Adults**: recommended maintenance dose is 30 mg twice daily or 75 mg once daily.
   b) **Pediatrics**:
      i) 50 kg or more: administer maintenance dose of 30 mg twice daily or 75 mg once daily.

ii) 20 kg to less than 50 kg: administer maintenance dose of 20 mg twice daily.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member is between 6 and 17 years of age and weighs at least 20 kg; AND
2. Member has a documented diagnosis of moderate to severe plaque psoriasis; OR
3. Member is 18 years of age or older; AND
4. Member has a diagnosis of mild to severe plaque psoriasis; AND
5. Medication must be prescribed by or in consultation with a dermatologist; AND
6. Member has a documented diagnosis of plaque psoriasis; AND
7. 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);
   d) At least a 12-week trial of a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin).
8. **Dosage allowed/Quantity limit:** administer initial titration per package insert. Otezla quantity limit: 60 tablets per 30 days. Otezla XR quantity limit: 30 tablets per 30 days
   a) **Adults**: recommended maintenance dose is 30 mg twice daily or 75 mg once daily.
   b) **Pediatrics**:
      i) 50 kg or more: administer maintenance dose of 30 mg twice daily or 75 mg once daily.
      ii) 20 kg to less than 50 kg: administer maintenance dose of 20 mg twice daily

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Otezla (apremilast) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
02/23/2022	Transferred to new template. PSO: Removed "moderate to severe" per label change. Clarified reauthorization criteria for PsA.
05/22/2024	Simplified adult dosing; added references. PsO: added pediatric dosing and quantity limit; specifying those18 years of age and greater must have a diagnosis of mild to severe disease and those between 6 years of age and 17 years of age and greater than 20 kg must have a diagnosis of moderate to severe disease.
09/26/2024	PsO: converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options.
09/15/2025	Added references. Added Otezla XR to policy including separate QL. Removed dosing tables, replaced with refer to PI. Changed "non-biologic DMARD" to "conventional DMARD." PsA: lowered age limit from 18 to 6 years of age and added greater than 20 kg

References:

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