CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Otezla (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.

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

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/Quantity limit:** Administer per table below. Quantity limit: 60 tablets per 30 days.

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

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 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/Quantity limit:** Administer per table below. Quantity limit: 60 tablets per 30 days.

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

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 (ie. 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); AND
8. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
9. **Dosage allowed/Quantity limit:**
   a) **Adults:** administer per table below. Quantity limit: 60 tablets per 30 days.

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

   b) **Pediatrics:** administer per table below. Quantity limit: 30 tablets per 30 days.

Body Weight	Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
50 kg or more	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

20 kg to less than 50 kg	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg

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 (e.g., 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.

References:

1. Otezla [prescribing information]. Thousand Oaks, CA: Amgen Inc; 2024.
2. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
3. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
4. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
5. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. *J Am Acad Dermatol*. 2020;S0190-9622(20)32288-X.
6. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
7. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
8. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. *J Am Acad Dermatol*. 2019;81(3):775-804.
9. Menter A, Cordoro KM, Davis DM, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol* 2020;82:161-201.
10. ClinicalTrials.gov. Identifier: NCT02307513. A Phase 3 Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Apremilast (CC-10004) in Subjects With Active Behcet's Disease. Available at: https://clinicaltrials.gov/ct2/show/NCT02307513?term=BCT-002&rank=2.
11. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. *Ann Rheum Dis*. 2018;77(6):808-818. doi:10.1136/annrheumdis-2018-213225
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
13. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):574]. *J Am Acad Dermatol.* 2020;82(1):161-201. doi:10.1016/j.jaad.2019.08.049

Effective date: 10/01/2024
Revised date: 05/22/2024