Mass General Brigham
Health Plan

Otezla (apremilast)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Otezla (apremilast) is an inhibitor of phosphodiesterase 4 (PDE4) indicated for the treatment of:

- Active psoriatic arthritis
- Plaque psoriasis in patients not candidates for phototherapy or systemic therapy
- Oral ulcers associated with Behcet's Disease

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when all the following diagnosis-specific criteria have been met:

<u>Plaque psoriasis</u>

1. Diagnosis of plaque psoriasis
2. Member meets ONE of the following criteria:
    i. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        1. Corticosteroids (e.g., betamethasone, clobetasol)
        2. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        3. Tazarotene
        4. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        5. Anthralin
        6. Coal tar
    ii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)

1. Diagnosis of active psoriatic arthritis
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Oral ulcers associated with Behçet's Disease

1. Diagnosis of active oral ulcers associated with Bechet's Disease

Continuation of Therapy

Requests for reauthorization for all diagnoses will be approved when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial authorizations and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Drug Name	Quantity Limit
Otezla	60 tablets per 30 days

References

1. Coates LC, Kavanaugh A, Mease PJ, et al. Group for research and assessment of psoriasis and psoriatic arthritis 2015 treatment recommendation for psoriatic arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
2. Hatemi G, Mahr A, Ishigatsubo Y, et al. Trial of Apremilast for Oral Ulcers in Behçet's Syndrome. N Engl J Med 2019; 381:1918
3. Leccese P, Ozguler Y, Christensen R, et al. Management of skin, mucosa and joint involvement of Behçet's syndrome: A systematic review for update of the EULAR recommendations for the management of Behçet's syndrome. Semin Arthritis Rheum 2019; 48:752
4. Loos AM, Liu S, Segel C, et al. Comparative effectiveness of targeted immunomodulators for the treatment of moderate-to-severe plaque psoriasis: A systematic review and network meta-analysis. J Am Acad Dermatol 2018; 79:135
5. Nash P, Ohson K, Walsh J, et al. Early and sustained efficacy with apremilast monotherapy in biological-naïve patients with psoriatic arthritis: a phase IIIB, randomised controlled trial (ACTIVE). Ann Rheum Dis 2018; 77:690
6. Otezla (apremilast) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2024.
7. Papp KA, Kaufmann R, Thaçi D, et al. Efficacy and safety of apremilast in subjects with moderate to severe plaque psoriasis: results from a phase II, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-comparison study. J Eur Acad Dermatol Venereol 2013; 27: e376
8. Schafer P. Apremilast mechanism of action and application to psoriasis and psoriatic arthritis. *Biochem Pharmacol*. 2012;83(12):1583-1590.[PubMed 22257911]

Review History

Reviewed: 02/23/15; 02/22/16 P&T Mtg

Revised: 02/27/17 (adopted SGM & Step); 2/26/18 P&T Mtg; 02/20/19; 9/18/19 (Added oral ulcers associated with Behcet's Disease as an indication)
09/16/20 – Reviewed at P&T
05/19/2021 – Reviewed and Updated for May P&T; started and stabilized statement updated for all indications to say "Authorization may be granted for members new to The plan"; moderate to severe plaque psoriasis conventional therapy requirements was changed from AND to OR. Effective 08/01/2021.
01/19/2022 – Reviewed and Updated for Jan P&T; Plaque psoriasis indication was expanded from moderate to severe to all severities of plaque psoriasis. Updated BSA% from at least 5% to at least 3% to align with definition mild disease as FDA has expanded indication. References updated. Effective 03/01/2022.
09/21/2022 – Reviewed and Updated for Sept P&T; Removed TNF requirement for psoriatic arthritis. Effective 11/01/2022.
7/12/2023 – Reviewed and Updated for July P&T; Removed Appendix B (examples of TNF inhibitors indicated for PsA)
11/15/2023 – Reviewed and Updated for Nov P&T; Removed TB requirement. Removed Appendix. For Behcet's disease – removed requirement of oral colchicine or steroids. For Psoriatic arthritis – added examples of disease and removed conventional therapy.
3/13/2024 – Reviewed and Updated for March P&T; removed BSA requirement for plaque psoriasis. Effective: 4/1/2024
10/09/2024 – Reviewed and updated for October P&T. Updated reauthorization criteria to align with other immunomodulators. Effective 1/1/2025.