Mass General Brigham
Health Plan

Otezla (apremilast)
Effective 04/01/2024

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
Apremilast inhibits phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) which results in increased intracellular cAMP levels and regulation of numerous inflammatory mediators (e.g. decreased expression of nitric oxide synthase, TNF-α, and interleukin [IL]-23, as well as increased IL-10.

FDA-Approved Indications
1. Plaque psoriasis
2. Active psoriatic arthritis
3. Treatment of oral ulcers associated with Behçet's Disease

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Plaque psoriasis
Authorization may be granted for members new to the plan who have previously received Otezla, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for treatment of plaque psoriasis when all the following criteria are met:
1. 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)

Authorization may be granted for members new to the plan who have previously received Otezla, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for treatment of active PsA when the following criteria are met:

1. 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

Authorization may be granted for members new to the plan who have previously received Otezla, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for treatment of active oral ulcers associated with Bechet's Disease

Continuation of Therapy

Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's condition.

Limitations

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

Otezla	60 tablets per 30 days

References

1. Otezla (apremilast) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2021
2. 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
3. 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.
4. Schafer P. Apremilast mechanism of action and application to psoriasis and psoriatic arthritis. *Biochem Pharmacol*. 2012;83(12):1583-1590.[PubMed 22257911]
5. 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
6. 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
7. 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

8. 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

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