Otezla (apremilast)
Effective 12/1/2019

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis
3. Treatment of oral ulcers associated with Behcet's Disease

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

Coverage Guidelines

Moderate to severe plaque psoriasis

Authorization may be granted for members who have previously received Otezla or any biologic disease-modifying antirheumatic drug (DMARD) indicated for the treatment of moderate to severe plaque psoriasis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:

1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

2. Member meets any of the following criteria:
    a. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
        i. 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, acitretin)
        ii. 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
        iii. 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
        iv. 2 systemic agents
3. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). (see Appendix A).
4. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)

1. Authorization may be granted for members who have previously received Otezla or any biologic disease-modifying antirheumatic drug (DMARD) indicated for the treatment of moderate to severe plaque psoriasis, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
   OR
2. Authorization may be granted for treatment of active PsA when all the following criteria are met:
    a. One of the following:
        i. Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
        ii. Member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
        iii. All TNF inhibitors indicated for PsA are not appropriate for the member
    OR
    b. One of the following:
        i. Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
        ii. Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or has a contraindication to sulfasalazine.

Oral ulcers associated with Behcet's Disease

1. Authorization may be granted for members who have previously received Otezla for the treatment oral ulcers associated with Bechet's Disease, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
   OR
2. Authorization may be granted for treatment of oral ulcers associated with Bechet's Disease when the member has experienced an inadequate response or intolerance to topical or oral steroids **and** colchicine.
   OR
3. The member has a contraindication to topical and oral steroids and colchicine

Continuation of Therapy

Members must meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Otezla as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Appendices

A. Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin.

1. Alcoholism, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

B. Examples of TNF Inhibitors Indicated for PsA

1. Cimzia
2. Enbrel
3. Humira
4. Remicade
5. Simponi

Limitations

1. Initial and reauthorizations are issued for 24 months
2. The following quantity limits apply:

For all diagnoses	#60 tablets per 30 days

References

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; APRPI.007 07/19
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
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. Hatemi G, Melikoglu M, Tunc R, et al. Apremilast for Behçet's syndrome--a phase 2, placebo-controlled study. N Engl J Med 2015; 372:1510
6. Maan R, de Knegt RJ, Veldt BJ. Management of thrombocytopenia in chronic liver disease: focus on pharmacotherapeutic strategies. Drugs. 2015; 75:1981-92.

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)

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