Otezla (apremilast)
Effective 02/20/19

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
Otzela is an inhibitor of phosphodiesterase 4 (PDE4) and indicated for the treatment of adult patients with active psoriatic arthritis, patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and adult patients with oral ulcers associated with Behcet's Disease.

Coverage Guidelines
Authorization may be granted when the following diagnosis specific criteria are met:

Psoriatic arthritis (PsA)

1. Member has a diagnosis of PsA **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
4. Dosing is appropriate (see appendix A) **AND**
5. Quantity requested does not exceed 60 tablets in 30 days

Moderate-severe plaque psoriasis (PsO):

1. Member has a diagnosis of moderate-severe plaque psoriasis **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional

therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
    i. 1 topical agent + 1 systemic agent
    ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
    iii. 1 systemic agent + 1 phototherapy
    iv. 2 systemic agents
c. Contraindication to ALL conventional therapies
    i. Topical agents
    ii. Phototherapy
    iii. Systemic agents
d. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis

AND

4. Dosing is appropriate (see appendix A) **AND**
5. Quantity requested does not exceed 60 tablets in 30 days

Otezla® Concurrent to Biologic DMARDs*:
Requests for concomitant use of Otezla® (apremilast) with an injectable biologic may be approved if ALL the following are provided:

1. Documentation of severe disease
2. ONE of the following:
    a. Inadequate response or adverse reaction to ONE other injectable biologic which is FDA-approved for the requested indication
    b. Contraindication to ALL other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

Continuation of Therapy
Reauthorization will be granted if documentation is submitted indicating a positive response to therapy.

Limitations

1. Initial approvals for PsA will be granted for 6 months
2. Initial approvals for PsO will be granted for 3 months
3. Reauthorizations will be granted for up to 1 year
4. The following quantity limits apply:

Otezla 30 mg	60 tablets per 30 days
Otezla Therapy Pack 10 & 20 & 30 mg oral	55 tablets per 28 days, maximum of 1 fill

Appendix

Otezla® (apremilast)	**Psoriatic arthritis:** Initial: 10 mg in AM on day 1, 10 mg in AM and 10 mg in PM on day 2, 10 mg in AM and 20 mg in PM on day 3, 20 mg in AM and 20 mg in PM on day 4, 20 mg in AM and 30 mg in PM on day 5, and then 30 mg BID **Plaque psoriasis (moderate-severe) chronic:** Initial: 10 mg in AM on day 1, 10 mg in AM and 10 mg in PM on day 2, 10 mg in AM and 20 mg in PM on day 3, 20 mg in AM and 20 mg in PM on day 4, 20 mg in AM

*The ESTEEM 1 and 2 are phase III, randomized, placebo-controlled studies evaluating Otezla® (apremilast) 30 mg twice daily in patients ≥18 years of age with a ≥12-month history of chronic, moderate-to-severe plaque psoriasis. Patients were excluded from the ESTEEM studies if they had used adalimumab, etanercept, infliximab, or certolizumab pegol within 12 weeks prior to randomization. Patients were not allowed to use concomitant adalimumab, etanercept, infliximab, certolizumab pegol, alefacept, or ustekinumab throughout the studies.

The PALACE 1, 2 and 3 are phase III, randomized, placebo-controlled studies evaluating Otezla® (apremilast) 30 mg twice daily despite prior or current treatment with DMARD therapy. Patients were allowed to receive stable doses of concomitant methotrexate, sulfasalazine, leflunomide, low dose oral corticosteroids and/or NSAIDs during the trial. However, recent literature suggests Otezla® (apremilast) can be safely and effectively combined with phototherapy, systemic, and/or biological agents in patients not responding adequately to these agents alone.

References

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; June 2017.
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]

Review History

02/23/15 – Reviewed P&T Mtg
02/22/16 – Reviewed P&T Mtg
02/27/17 – Reviewed & revised (adopted SGM & Step) P&T Mtg
02/20/19 – Reviewed P&T Mtg

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.