Otezla (apremilast)
Effective 08/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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 (apremilast) is an inhibitor of phosphodiesterase 4 (PDE4) and indicated for the treatment of adult patients with active psoriatic arthritis, patients with 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 reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Otezla excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Psoriatic Arthritis (PsA)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
    b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing
4. Quantity requested is ≤2 tablets/day

Plaque Psoriasis (PsO):
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Plaque Psoriasis (mild, moderate or severe)
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Contraindication to **ALL** conventional therapies:
        i. topical agents
        ii. phototherapy
        iii. systemic agents
3. Appropriate dosing
4. Quantity requested is ≤ 2 tablets/day

Oral ulcers associated with Behçet's Disease
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Quantity requested is ≤2 tablets/day

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations
1. Initial approvals will be granted for:
    a. Plaque psoriasis: 3 months
    b. All other diagnosis: 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

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

Appendix

Appendix A: Dosing

Otezla® (apremilast)	**Psoriatic arthritis, Plaque psoriasis, and Oral ulcers associated with Behçet's Disease** 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

Appendix B. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix C: More frequent/Higher doses

Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is 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

Appendix D: Off-Label Indications

Lichen Planus

Requests for Otezla® (apremilast) in lichen planus may be approved if the prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** high-potency or super high potency topical corticosteroid or contraindication to **ALL** high-potency or super high potency topical corticosteroids
3. Paid claims or physician documented inadequate response or adverse reaction to **ONE** intralesional corticosteroid or contraindication to **ALL** intralesional corticosteroids
4. Paid claims or physician documented inadequate response or adverse reaction to **TWO** or a contraindication to **ALL** of the following:
    a. Phototherapy
    b. Acitretin

c. Cyclosporine
d. Dapsone
e. Hydroxychloroquine
f. Hydroxyzine
g. Methotrexate
h. Metronidazole
i. Mycophenolate mofetil
j. Sulfasalazine
k. Systemic glucocorticoids

References

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; December 2021.
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
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Guideline updated to reflect newly FDA-approved indication: plaque psoriasis across all severities. Continuation of therapy language was updated. Appendices for More frequent/Higher doses and Off-Label Indications were added. Updated References. Effective 08/01/2022.

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