Olumiant (baricitinib)
Effective 03/01/2023

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 a specialty medication 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

Olumiant is a Janus kinase (JAK) inhibitor indicated for:

- Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.
- Treatment of adult patients with severe alopecia areata.

Olumiant® (baricitinib) is FDA approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The use of Olumiant® (baricitinib) for this indication is permitted only in an inpatient hospital setting.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Olumiant 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:

Severe alopecia areata

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

1. Diagnosis of severe alopecia areata
2. Prescriber is a dermatologist or consult notes from a dermatologist are provided
3. Member is ≥ 18 years of age

4. **ONE** of the following:
    a. **BOTH** of the following:
        i. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication **ALL** to topical corticosteroids*
        ii. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** intralesional corticosteroids*
    b. Provider documentation that member has a large area of hair loss such as ≥ 25% scalp hair loss
5. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Xeljanz® (tofacitinib)
    b. Xeljanz XR® (tofacitinib extended-release)
6. Appropriate dosing
7. Requested quantity is ≤ 1 tablet/day

Moderate to severe rheumatoid arthritis (RA)

1. Member has a diagnosis of moderate to severe rheumatoid arthritis
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARDs (see Appendix A)
3. Paid claims or physician attestation of inadequate response, adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Xeljanz® (tofacitinib)
    b. Xeljanz XR® (tofacitinib extended-release)
4. Appropriate dosing
5. Quantity requested is ≤1 tablet/day

New members currently stable on Olumiant® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy

Reauthorization by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Olumiant 1mg and 2mg	30 tablets per 30 days

Appendix A. Traditional DMARDS

Traditional DMARDS*	
azathioprine	methotrexate*
cyclosporine	sulfasalazine*
hydroxychloroquine*	thalidomide
leflunomide	

If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.

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)

References

1. Olumiant (baricitinib) [prescribing information]. Indianapolis, IN: Lilly USA LLC; December 2021.
2. Taylor PC, Keystone EC, van der Heijde D, et al. Baricitinib versus placebo or adalimumab in rheumatoid arthritis. N Engl J Med. 2017;376(7):652-662
3. Westhovens R, Taylor PC, Alten R, et al. Filgotinib (GLPG0634/GS-6034), an oral JAK1 selective inhibitor, is effective in combination with methotrexate (MTX) in patients with active rheumatoid arthritis and insufficient response to MTX: results from a randomised, dose-finding study (DARWIN 1). Ann Rheum Dis 2017; 76:998
4. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2020.
5. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corporation; March 2020

Review History

05/20/2020 – Created and Reviewed May P&T. Effective 8/1/20.
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
11/17/2021 –Reviewed and Updated for Nov P&T; matched MH UPPL for 1/1/2022 implementation; added appendix with higher dose/more frequent dosing and off label indication. Effective 01/01/2022
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Approval criteria was updated to require a step through at least one anti-TNF agent per updated FDA-labeling. Clarified Overview section to include treatment of COVID-19 in hospitalized adults. Continuation of therapy language was updated. Removed "Atopic Dermatitis" from Appendix C as not relevant. Updated References. Effective 08/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Guideline update following FDA-approval in severe alopecia areata. Criteria will require a step through Xeljanz or Xeljanz XR regardless of their off-label use in this indication. Effective 11/01/2022
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Removed higher doses from appendix as it only pertains to injectable biologics. Removed requirement of a trial with anti-TNF agent for RA. Effective 03/01/23.

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