MEDICAL MUTUAL®

Drug Policy

Policy:	Olumiant (baricitinib)	Annual Review Date: 09/19/2024 Last Revised Date: 09/19/2024

OVERVIEW

OLUMIANT® (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderate to severe rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. OLUMIANT inhibits JAK, an intracellular enzyme that transmits signals on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. The recommended dose of OLUMIANT is 2 mg once daily. OLUMIANT may be used as monotherapy or in combination with methotrexate or other non-biologic disease modifying antirheumatic drugs (DMARDs). Use of OLUMIANT with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants is not recommended. Approval of the 2 mg dose of OLUMIANT included data from the RA-BEACON study, which involved 527 patients who had an inadequate response to one or more TNF inhibitor therapies. The results of the study showed that patients treated with Olumiant had significantly higher rates of ACR20 response versus placebo-treated patients at Week 12 (49 percent versus of 27 percent, respectively).

POLICY STATEMENT

This policy involves the use of Olumiant. Prior authorization is recommended for pharmacy benefit coverage of Olumiant. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Olumiant as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Olumiant be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Olumiant is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

All reviews for use of Olumiant for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Olumiant is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Rheumatoid Arthritis.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets all of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor; OR
       - **b)** Patient has tried at least one tumor necrosis factor inhibitor but was unable to tolerate a 3-month trial; AND
         Note: Refer to Appendix for examples of tumor necrosis factor inhibitors used for rheumatoid arthritis. Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.
     - **iii.** The medication is prescribed by or in consultation with a rheumatologist.
   - **B)** Patient is Currently Receiving Olumiant. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on the requested drug for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least one of the following (a or b):
       - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
         Note: Examples of standardized and validated objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
       - **b)** Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

2. **Alopecia Areata.** Approve for the duration noted if the patient meets one of the following (A or B):
   Note: Alopecia universalis and alopecia totalis are subtypes of alopecia areata.
   - **A)** Initial Therapy. Approve for 6 months if the patient meets all of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a current episode of alopecia areata lasting for ≥ 6 months; AND
     - **iii.** Patient has ≥ 50% scalp hair loss; AND
     - **iv.** Patient has tried at least one of the following for alopecia areata (a or b):
       - **a)** Conventional systemic therapy; OR

Note: Examples of conventional systemic therapies include corticosteroids, methotrexate, and cyclosporine. An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried Litfulo (ritlecitinib capsules).

b) Topical corticosteroid; AND

v. Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata; AND
Note: Androgenetic alopecia includes male and female pattern hair loss. Other causes of hair loss include trichotillomania, telogen effluviumus, and systemic lupus erythematosus.

vi. The medication is prescribed by or in consultation with a dermatologist.

B) Patient is Currently Receiving Olumiant. Approve for 1 year if the patient meets all of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

iii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Olumiant) in extent and density of scalp hair loss; AND

iv. According to the prescriber, the patient continues to require systemic therapy for treatment of alopecia areata.

Note: International consensus states that systemic treatment is best discontinued once complete regrowth has been achieved and maintained for 6 months or when regrowth is sufficient to be managed topically.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Olumiant has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director. Note: This includes requests for cytokine release syndrome associated with COVID.

2. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Olumiant should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples).[1] Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Olumiant.

3. **Concurrent Use with a Biologic Immunomodulator.** Olumiant is not recommended in combination with biologic immunomodulators.[1]
Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab

subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

4. **Concurrent Use with Topical Janus Kinase Inhibitors (JAKis).** Olumiant should not be administered in combination with a topical JAKi [e.g. Opzelura (ruxolitinib) cream)] used for Atopic Dermatitis. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.
5. **Concurrent use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).[1] Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated in rheumatoid arthritis. Note: This does NOT exclude use of Olumiant with methotrexate; Olumiant has been evaluated with background methotrexate or in combinations with conventional synthetic DMARDs containing methotrexate.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. OLUMIANT ® tablet [prescribing information]. Indianapolis, IN: Eil Lilly and Company; May 2022.
2. Singh, Jasvinder A., et al. "2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis." *Arthritis & Rheumatology*, vol. 68, no. 1, June 2015, pp. 1–26., doi:10.1002/art.39480.
3. McKee, Selina. "US Approves Lilly/Incyte's Olumiant." *PharmaTimes*, PharmaTimes Media Limited, 4 June 2018, www.pharmatimes.com/news/us_approves_lillyincytes_olumiant_1238426.
4. Genovese MC, Kremer J, Zamani O et al. Baricitinib in patients with refractory rheumatoid arthritis. N Engl J Med 2016;374:1243_52.
5. Genovese, Mark C et al. "Response to Baricitinib Based on Prior Biologic Use in Patients with Refractory Rheumatoid Arthritis." *Rheumatology (Oxford, England)* 57.5 (2018): 900–908. *PMC*. Web. 12 June 2018.

Appendix A

Biologic or Targeted Synthetic DMARD	Mechanism of Action	Indications
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF	AS, ASpA ,CD, PPs, PsA, RA
Enbrel® (etanercept for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Humira® (adalimumab for SC injection)	Inhibition of TNF	AS, CD, HS, PPs, RA, UC, UV
Amjevita™ (adalimumab-atto for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Cyltezo® (adalimumab-adbm for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Simponi® (golimumab for SC injection)	Inhibition of TNF	AS, PsA, RA, UC
Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF	AS, PsA, RA, UC
Remicade® (infliximab for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6	CRS, GCA, RA
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6	CRS, GCA, RA
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator	PsA, RA
Orencia® (abatacept for SC injection)	T-cell costimulation modulator	PsA, RA
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody	Various
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1	NOMID, RA
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PPs
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Ilumya™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23	PPs
Tremfya® (guselkumab for SC injection)	Inhibition of IL-23	PPs
Otezla® (apremilast tablets)	Inhibition of PDE4	BD, PPs, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib ER tabs)	Inhibition of the JAK pathways	PsA, RA, UC

Agents and associated indications are for reference only.

"The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding."

AS = Ankylosing Spondylitis, ASpA = Axial Spondyloarthritis, BD = Behcet Disease, CD = Crohn's Disease, CRS = Cytokine Release Syndrome, GCA = Giant Cell Arteritis, GVHD = Graft-Versus-Host Disease, HS = Hidradenitis Suppurativa, NOMID = Neonatal-onset Multisystem Inflammatory Disease, PPs = Plaque Psoriasis, PsA = Psoriatic Arthritis, RA = Rheumatoid Arthritis, SpA = Spondyloarthritis, UC = Ulcerative Colitis, UV = Uveitis