

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Olumiant (baricitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers. It is also indicated for the treatment of adults with severe alopecia areata. Olumiant has a black box warning for serious infections, mortality, malignancy, major adverse cardiac events, and thrombosis.

Olumiant (baricitinib) will be considered for coverage when the following criteria are met:

1. Member is at least 18 years of age; AND
2. Olumiant is prescribed by or in consult with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;
Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has documentation of an inadequate response to at least two preferred biologic DMARDs including at least one tumor necrosis factor (TNF) antagonist therapies (see Appendix); AND
6. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm³), lymphopenia (ALC <500 cells/mm³), or anemia (hemoglobin < 8 g/dL); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 2 mg once daily. Quantity Limit: 30 tablets per 30 days.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

Alopecia Areata (AA)

12/28/2021	Transferred to new template. Added new reference. Changed initial approval duration to 6 months (was 12 months). Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1.
06/27/2022	Added criteria for new indication of AA.
08/16/2023	AA: Removed attestation of significant psychological distress and trials of topical therapy or an oral corticosteroid.
09/27/2023	AA: added trials of topical therapy or an oral corticosteroid and trial of Litfulo

References:

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3. Smolen JS, Landewé RBM, Bijlsma JWW, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
4. Genovese MC, et al. Baricitinib in Patients with Refractory Rheumatoid Arthritis. *N Engl J Med*. 2016 Mar 31;374(13):1243-52.
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6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752
7. King B, Ohyama M, Kwon O, et al. Two Phase 3 Trials of Baricitinib for Alopecia Areata. *N Engl J Med*. 2022;386(18):1687-1699. doi:10.1056/NEJMoa2110343
8. Wyrwich KW, Kitchen H, Knight S, et al. The Alopecia Areata Investigator Global Assessment scale: a measure for evaluating clinically meaningful success in clinical trials. *Br J Dermatol*. 2020;183(4):702-709. doi:10.1111/bjd.18883
9. Messenger AG, McKillop J, Farrant P, McDonagh AJ, Sladden M. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. *Br J Dermatol*. 2012;166(5):916-926. doi:10.1111/j.1365-2133.2012.10955.x
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11. Rossi A, Muscianese M, Piraccini BM, et al. Italian Guidelines in diagnosis and treatment of alopecia areata. *G Ital Dermatol Venereol*. 2019;154(6):609-623. doi:10.23736/S0392-0488.19.06458-7
12. IPD Analytics. Accessed July 8, 2022.

Effective date: 01/01/2024

Revised date: 09/27/2023

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through adalimumab</i>) • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through Humira</i>) • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Rinvoq

Approved for Non-radiographic Axial	<ul style="list-style-type: none"> • Cimzia • Cosentyx
Approved for Atopic Dermatitis	<ul style="list-style-type: none"> • Rinvoq
Approved for Psoriatic Arthritis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	<ul style="list-style-type: none"> • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira