CareSource Rxinnovations

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:

Rheumatoid Arthritis (RA)

For **initial** authorization:

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.

If all the above requirements are met, the medication will be approved for 6 months.

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.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Alopecia Areata (AA)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Olumiant is prescribed by or in consult with a dermatologist; AND
3. Member has a documented diagnosis of severe alopecia areata as determined by **both** of the following:
   a) Current episode is of 6 months duration or longer with no spontaneous regrowth at any point;
   b) Hair loss encompasses 50% or more of the scalp (i.e., SALT* score of 50 or higher); AND
4. Documented trial and failure of at least one of the following conventional treatments:
   a) Topical immunotherapy (e.g., DPCP or SADBE) for 6 months
   b) Oral corticosteroid for 6 weeks; AND
5. Member has had a trial and failure of Litfulo; AND
6. Member does NOT have any of the following:
   a) Laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm3), lymphopenia (ALC <500 cells/mm3), or anemia (hemoglobin < 8 g/dL);
   b) Primarily "diffuse" pattern of hair loss;
   c) Any other form of alopecia (such as androgenetic); AND
7. Member has had a negative tuberculosis test within the past 12 months.
   Dosage allowed/Quantity limit: 2 mg once daily; increase to 4 mg once daily if the response to treatment is not adequate. Quantity Limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 9 months.

For **reauthorization**:

1. Chart notes must document achievement of a SALT score of 20 or less.

If all the above requirements are met, the medication will be approved for an additional 12 months.

**SALT = Severity of Alopecia Tool*

CareSource considers Olumiant (baricitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/31/2018	New policy for Olumiant created.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added.
11/20/2020	Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Added that member does not have neutropenia, lymphopenia, or anemia. Removed statement that medication is not being used with other biologic DMARDs. Removed repeated TB test in reauth. Replaced list of excluded diagnoses with the generic statement. Updated references.

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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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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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
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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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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	• Actemra *(requires step through adalimumab)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Rinvoq

Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara
Approved for Ulcerative Colitis	• Preferred adalimumab product - adalimumab-adaz, adalimumab-fkjp, Hadlima, or Humira • Stelara • Rinvoq