

PHARMACY POLICY STATEMENT	
Marketplace Marketplace	
DRUG NAME	Olumiant (baricitinib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 30 tablets for 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Olumiant (baricitinib) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

- 1. Member is 18 year of age or older with moderately to severely active RA who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies; AND
- 2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
- 3. Medication must be prescribed by or in consultation with a rheumatologist; AND
- 4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately.
 - *Note*: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA); AND
- 5. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm³), lymphopenia (ALC <500 cells/mm³), or anemia (Hg < 8 g/dL).
- 6. Dosage allowed: 2 mg once daily.

If member meets all the requirements listed above, the medication will be approved for 12 months. For <u>reauthorization</u>:

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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Olumiant (baricitinib) not medically necessary for the treatment of the diseases that are not listed in this document.

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.	
11/17/2021	Annual review, no changes	

References:

- 1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2020.
- 2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
- 3. Smolen JS, Landewé RBM, Bijlsma JWJ, 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.
- 5. Taylor PC, et al. Baricitinib versus Placebo or Adalimumab in Rheumatoid Arthritis. N Engl J Med. 2017 Feb 16;376(7):652-662.

Effective date: 01/01/2022 Revised date: 11/17/2021