

PHARMACY POLICY STATEMENT

Ohio Medicaid

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 tabs 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 moderate to severe 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), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
5. Medication is **not** being used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDS), or with potent immunosuppressants such as azathioprine and cyclosporine.
6. **Dosage allowed:** 2 mg once daily.

Note: Olumiant should be used with caution in members who may be at increased risk of thrombosis.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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 following disease states based on a lack of robust clinical



controlled trials showing superior efficacy compared to currently available treatments:

- Alopecia
- ANCA associated vasculitis
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- Dry eye disease
- For use in combination with other TNF-inhibitors (i.e. Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Infectious uveitis
- Inflammatory bowel diseases (Crohn's disease and ulcerative colitis)
- Lupus perino
- Osteoarthritis
- Prevention of organ transplant rejection
- Plaque psoriasis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi-Harada (VKH) disease

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.

References:

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2018.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Singh JA, Furst DE, Beharat A, et al. 2012 Update the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2012;64(5):625-639.
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: 04/01/2019
Revised date: 02/26/2019