# Olumiant (baricitinib)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Olumiant drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Humira, Enbrel, Cosentyx, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Olumiant is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.
2. Olumiant is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
3. Olumiant is indicated for the treatment of adult patients with severe alopecia areata.

   Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting.


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## POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

**A. Rheumatoid Arthritis**

1. For initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

**B. Alopecia Areata**

1. For initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   ii. Chart notes or medical record documentation of the Severity of Alopecia Tool (SALT) score.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response including Severity of Alopecia Tool (SALT) score.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

**A. Rheumatoid Arthritis**

Criteria for initial approval for rheumatoid arthritis will only apply when at least ONE of the following criteria are met:

1. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Enbrel, Humira, Rinvoq and Xeljanz/Xeljanz XR)
2. Member has a clinical reason to avoid Enbrel and Humira (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with the preferred products, Rinvoq AND Xeljanz/Xeljanz XR
3. Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Criteria for Initial Approval

**A. Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
   a. Member meets either of the following criteria:
      i. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)

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ii. Member has been tested for ALL of the following biomarkers:
    1. RF
    2. Anti-CCP
    3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

b. Members has experienced an inadequate response to at least one tumor necrosis factor (TNF) inhibitor.

**B. Alopecia Areata**

1. Authorization of 4 months may be granted for treatment of alopecia areata when the following criteria are met:
    a. Member has severe alopecia as defined by having at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
    b. Member does not have diagnosis of "diffuse" pattern alopecia areata, androgenetic alopecia, or other forms of alopecia
    c. Member has had an inadequate response to a topical corticosteroid
    d. Member has not been previously treated with a JAK inhibitor (e.g., tofacitinib, ruxolitinib) and had an inadequate response (i.e., absence of significant terminal hair growth after at least 12 weeks of treatment)

Continuation of Therapy

**A. Moderately to severely active rheumatoid arthritis (RA)**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability

**B. Alopecia Areata**

Initial continuation request: Authorization of 6 months may be granted for all members (including new members) who are using the requested medication for severe alopecia areata and are demonstrating a positive clinical response to therapy as evidenced by an improvement of at least 10% in the SALT score.

Subsequent continuation requests*: Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for severe alopecia areata and have achieved or maintained a positive clinical response to therapy as evidenced by a SALT score of 20 or less.

*Subsequent continuation requests criteria applies when member has received at least 9 months of Olumiant therapy.

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic DMARD, targeted synthetic DMARD, or potent immunosuppressants such as azathioprine or cyclosporine.

Olumiant is considered **not medically necessary** for members who do not meet the criteria set forth above.

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Note: Prior Authorization not required for when used in accordance with the FDA's EUA in hospitalized patients.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply
Olumiant - 30 tablets per 30 days

Appendix
**Appendix A: Clinical reasons to avoid TNF-inhibitors**

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

## REFERENCES


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- FDA News release. Food and Drug Administration Web site. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19. Accessed November 20, 2020.
- Smolen JS, Landewé R, Bijlsma J, 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*:685-699.
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*Some content reprinted from CVSHealth

## POLICY HISTORY

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