Baricitinib (OLUMIANT) in Rheumatoid Arthritis
Criteria for Use
August 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following is selected, the patient will not meet criteria for baricitinib.

- ☐ Uncontrolled active infection (however, baricitinib may be started / restarted once treatment for the infection is initiated).
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.^1 Baricitinib may be initiated after starting antiviral prophylaxis.
- ☐ HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.^1 Baricitinib may be initiated after starting antiviral prophylaxis.
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with baricitinib.
- ☐ Congenital or acquired immunodeficiency.
- ☐ Malignancy in the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer unless it is documented that the treating rheumatologist and oncologist agree that risk-benefits favor using the drug.
- ☐ At increased risk of thrombosis or major adverse cardiovascular events where potential harms are expected to outweigh the anticipated benefits.
- ☐ Lymphocytes < 500 cells/mm^3 confirmed by repeat testing, absolute neutrophils < 1000 cells/mm^3, or hemoglobin < 8 g/dL. (Baricitinib may be started / restarted once the lymphopenia, neutropenia and/or anemia resolve.)
- ☐ Severe renal impairment (GFR < 30 mL/min/1.73 m^2).
- ☐ Severe hepatic impairment (Child-Pugh class C).
- ☐ Concomitant therapy with immunosuppressive biologics or potent immunosuppressants (e.g., azathioprine, cyclosporine, tacrolimus) except overlaps during treatment transition.
- ☐ Concomitant therapy with strong CYP3A4 inducers (e.g., rifampin).
- ☐ Pregnancy
- ☐ Breastfeeding
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of baricitinib therapy.

Inclusion Criteria

ALL of the following must be selected to meet criteria.

- ☐ Prescribed and monitored by a VA/VA Community Care rheumatologist or locally designated expert.
- ☐ Moderate to severe active **rheumatoid arthritis.**
- ☐ Prescribed at the FDA-recommended dose for rheumatoid arthritis, adjusting for strong organic anion transporter 3 inhibitor (e.g., probenecid) drug interactions, moderate renal impairment (GFR 30 to 60 mL/min/1.73 m^2), and hematocytopenias.
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].
- ☐ Completed hepatitis B screening (HBsAg, total antibody to hepatitis B core antigen [anti-HBc] and antibody to hepatitis B surface antigen [anti-HBs]).
- ☐ Current or past completion of hepatitis C screening. Baricitinib may be initiated while waiting for test results.
- ☐ **Tumor necrosis factor inhibitor (TNFI)** therapy is medically inadvisable, not tolerated, or not adequate (i.e., NO response to ONE TNFI after 3 months, partial response to 3-month trials of TWO TNFIs = total 6 months, or loss of initial response).

Additional Inclusion Criteria

Select if applicable.

- ☐ If HBsAg-negative but anti-HBc-positive and consult is deemed indicated: A GI/liver or infectious diseases expert has been (e-) consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.
- ☐ For females who are breastfeeding/providing breastmilk to an infant: Counseling provided on potential risks vs benefits of treatment.

Abbreviations: GI, gastrointestinal

Footnotes

[1] Antiviral prophylaxis for HBV: Agents with high genetic barrier to resistance such as entecavir or tenofovir should be used.

[2] When possible, vaccinations should be updated before the patient initiates baricitinib. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with baricitinib, preferably when dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.

[3] Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.

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