

Baricitinib (OLUMIANT) in Alopecia Areata

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.

Refer to Product Information for detailed prescribing information.

Exclusion Criteria

If ANY of the following are 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. Baricitinib may be initiated after starting antiviral prophylaxis.^1
- Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with baricitinib.
- Congenital or acquired immunodeficiency
- Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer unless it is documented that the treating dermatologist 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/mm³, absolute neutrophils < 1000 cells/mm³, or hemoglobin < 8 g/dL. (Baricitinib may be started / restarted once the lymphopenia, neutropenia and/or anemia resolve.)
- Severe renal impairment (eGFR < 30 mL/min/1.73 m²).
- Severe hepatic impairment (Child-Pugh class C).
- Concomitant therapy with immunosuppressive biologics or potent immunosuppressants (e.g., other Janus kinase inhibitors, biologic immunomodulators, 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.^2
- NO hair regrowth with previous use of a systemic Janus kinase inhibitor

Inclusion Criteria

ALL of the following must be selected in order to meet criteria:

- Prescribed³ and monitored by a VA/VA Community Care dermatologist or locally designated expert.
- Diagnosis of severe alopecia areata based on $\geq 50\%$ scalp hair loss.
- Offered all age-appropriate vaccinations prior to initiating therapy.²
- Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA).⁴
- Completed hepatitis B screening (HBsAg, total antibody to hepatitis B core antigen [anti-HBc] and antibody to hepatitis B surface antigen [anti-HBs]).⁴
- Current or past completion of hepatitis C screening. Baricitinib may be initiated while waiting for test results.⁴

Alopecia areata is NOT a cosmetic condition. The Directive 1108.08 policy on Cosmetic and Enhancement Drugs does NOT apply.

Additional Inclusion Criteria

Select if appropriate.

- If HBsAg-negative but anti-HBc-positive and consult is deemed indicated: A GI / liver or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.
- For females who can become pregnant: Checked pregnancy status. 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 equivalent) vaccine should be completed or at least initiated by the end of the first year of treatment with baricitinib, preferably when baricitinib dosage is low, disease is stable, or at other times when a robust immune response to vaccination can be expected.
- 3 Prescribed at the FDA-recommended dose for severe alopecia areata, adjusting for strong organic anion transporter 3 inhibitor (e.g., probenecid) drug interactions, moderate renal impairment (eGFR 30 to < 60 mL/min/1.73 m²), and hematocytopenias.
- 4 Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.

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Contact: Francine Goodman, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)