Ritlecitinib (LITFULO) in Alopecia Areata
Criteria for Use
December 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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. Also refer to the Ritlecitinib in Alopecia Areata monograph available at the PBM SharePoint.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for ritlecitinib.

- ☐ Active, serious, systemic or localized infection, including undrained abscess (however, ritlecitinib may be started / restarted once the infection is controlled).
- ☐ Untreated latent or active tuberculosis infection.
- ☐ Hepatitis B surface antigen (HBsAg)-positive and not on antiviral prophylaxis.[1] Ritlecitinib may be initiated after starting antiviral prophylaxis.[1]
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with ritlecitinib.
- ☐ Malignancy within the previous 5 years other than successfully treated nonmelanoma skin cancer or successfully treated cervical cancer unless 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.
- ☐ Platelets < 100,000/mcL or lymphocytes < 500 cells/mcL. (Ritlecitinib may be started / restarted once these values are exceeded.)
- ☐ Severe hepatic impairment (Child-Pugh class C).
- ☐ Concomitant therapy with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants except overlaps during treatment transition.
- ☐ Concomitant therapy with strong CYP3A inducers (e.g., rifampin).
- ☐ Pregnancy
- ☐ Lactating
- ☐ Concomitant live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of ritlecitinib.[2]

Inclusion Criteria

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

- ☐ Prescribed and monitored by a VA / VA Community Care dermatologist or locally designated expert.[3]

- ☐ Diagnosis of severe alopecia areata based on ≥ 50% scalp hair loss
- ☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA).
- ☐ Completed hepatitis B screening (at minimum, 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. Ritlecitinib may be initiated while waiting for test results.

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, 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 patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.
- ☐ For patients who are lactating: Advised to avoid giving breastmilk to infant during therapy and for at least 14 hours after the last dose.

Other Justification

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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 ritlecitinib. Unless contraindicated, recombinant zoster (SHINGRIX) vaccine should be completed or at least initiated by the end of the first year of treatment with ritlecitinib, preferably when 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.

Supplemental Information

This supplemental information is provided to assist in adjudication of requests for ritlecitinib in alopecia areata.

Section	Criterion	Issues for Consideration
Inclusion Criteria	Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay [IGRA].	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
	Completed hepatitis B screening (at minimum, HBsAg, total anti-HBc and antibody to hepatitis B surface antigen [anti-HBs]).	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered. Anti-HBs may help to identify patients who require initial or booster vaccination (anti-HBs titers >= 10 IU/L are generally considered protective) or HBsAg-negative patients without past vaccination who have occult HBV from past infection (anti-HBs positive and lost anti-HBc).
	Current or past completion of hepatitis C screening. (ritlecitinib may be initiated while waiting for test results.).	Routine retesting is not required for prescription renewals. Retesting in high-risk patients should be considered.
Additional Inclusion Criteria	If HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive, a gastroenterologist / hepatologist or infectious diseases expert has been consulted for advice on whether to start antiviral prophylaxis or to preemptively monitor for HBV reactivation.	In patients who are HBsAg-negative but **anti-HBc-positive**, the presence of antibody to hepatitis B surface antigen (anti-HBs) does not guarantee protection against HBV reactivation, and the available evidence is insufficient to support the use of anti-HBs titers in deciding whether to give antiviral prophylaxis. Management depends on the patient's risk of HBV reactivation. [Reddy K, et al. American Gastroenterological Association Institute Guideline on the Prevention and Treatment of Hepatitis B Virus Reactivation During Immunosuppressive Drug Therapy. Gastroenterology. 2015;148(1):215–219. doi: https://doi.org/10.1053/j.gastro.2014.10.039 Ekpanyapong S, Reddy KR. Hepatitis B Virus Reactivation: What Is the Issue, and How Should It Be Managed? Clin Liver Dis. 2020 Aug;24(3):317-333. doi: 10.1016/j.cld.2020.04.002.]

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