Deuruxolitinib (LEQSELVI) in Alopecia Areata
Criteria for Use
May 2026

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 are selected, the patient will NOT meet criteria for deuruxolitinib.

- ☐ CYP2C9 poor metabolizers (contraindication).^1
- ☐ Concomitant moderate or strong CYP2C9 inhibitors (contraindication); e.g., fluconazole, miconazole, voriconazole, fluvastatin, fluvoxamine, metronidazole, sulfamethoxazole, amiodarone, capecitabine.^1
- ☐ Uncontrolled active infection (however, deuruxolitinib 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 Deuruxolitinib may be initiated after starting antiviral prophylaxis.
- ☐ HBsAg-negative but antibody-to-hepatitis-B-core-antigen (anti-HBc)-positive and not on antiviral prophylaxis.^2 Deuruxolitinib may be initiated after starting antiviral prophylaxis.^2
- ☐ Untreated HIV infection. Treated, well-controlled, asymptomatic HIV-positive patients can be treated with deuruxolitinib.
- ☐ 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 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/mm^3, neutrophils < 1000 cells/mm^3, or hemoglobin < 8 g/dL. (Deuruxolitinib may be started/restarted once the lymphopenia, neutropenia and/or anemia resolve.)
- ☐ Severe renal impairment or end-stage renal disease (eGFR < 30 mL/min)
- ☐ Severe hepatic impairment (Child-Pugh 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 live or live-attenuated vaccines or administration of inactivated, live, or live-attenuated vaccines less than 2 weeks before initiation of deuruxolitinib therapy.^3
- ☐ Breastfeeding. Avoid feeding breastmilk to infants during treatment and for one day after the last dose.
- ☐ NO hair regrowth with previous use of a systemic Janus kinase inhibitor.

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- ☐ Determined patient's CYP2C9 genotype.
- ☐ Prescribed^4 and monitored by a VA/VA Community Care dermatologist or locally designated expert.
- ☐ Diagnosis of **severe alopecia areata** based on ≥ 50% scalp hair loss.^5
- ☐ Offered all age-appropriate vaccinations prior to initiating therapy.^3

☐ Completed tuberculosis (TB) test using tuberculin skin test or interferon-gamma release assay (IGRA).^5

☐ Completed hepatitis B screening (HBsAg, total antibody to hepatitis B core antigen [anti-HBc] and antibody to hepatitis B surface antigen [anti-HBs]).^5

☐ Current or past completion of hepatitis C screening. Deuruxolitinib may be initiated while waiting for test results.^5

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 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: Checked pregnancy status. Counseling provided on potential risks vs benefits of treatment and the use of effective contraception.

☐ For females who are pregnant: Counseling provided on potential risks vs benefits of treatment and patient informed that deuruxolitinib may cause fetal harm.

Abbreviations: GI, gastrointestinal

Other Justification

☐ _____

Footnotes

1 Baricitinib and ritlecitinib are examples of alternative Janus kinase inhibitors that may be considered instead of deuruxolitinib in CYP2C9 poor metabolizers or patients on concomitant moderate or strong CYP2C9 inhibitors.

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

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

4 Prescribed at the FDA-recommended dose for severe alopecia areata.

5 Treatment options for patients who do not have severe alopecia areata: **Mild or localized alopecia areata –** topical and injected intralesional corticosteroids, topical minoxidil 2% or 5%. **Moderate alopecia areata –** potent/very potent topical corticosteroids, intralesional corticosteroids; topical minoxidil 5%, topical immunotherapy (e.g., diphenylcyclopropenone [DPCP], squaric acid dibutylester [SADBE; requires compounding by specialty pharmacy], anthralin cream, psoralen + ultraviolet A [PUVA], and—in carefully selected and monitored cases—oral corticosteroids (short-course or pulsed) or systemic steroid-sparing, conventional synthetic immunomodulators/immunosuppressants (csIMMs; e.g., methotrexate, cyclosporine).

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

Original: May 2026.

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