

Specialty Guideline Management

Leqselvi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Leqselvi	deuruxolitinib

Indications

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

FDA-approved Indication¹

Leqselvi is indicated for the treatment of adults with severe alopecia areata.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

Initial requests

Chart notes or medical record documentation supporting at least 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist.

Coverage Criteria

Alopecia areata^{1,2}

Authorization of 12 months may be granted for adult members who have previously received a targeted synthetic drug (e.g., Litfulo, Olumiant) indicated for treatment of severe alopecia areata in the past year.

Authorization of 12 months may be granted for adult members for treatment of severe alopecia areata when both of the following criteria are met:

- Member has at least 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
- Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).

Continuation of Therapy

Alopecia areata^{1,2}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for severe alopecia areata and who achieve or maintain a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Other^{1,3}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

Reference number(s)
6574-A

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). 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.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

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

References

1. Leqselvi [package insert]. Whippany, NJ: Halo Pharmaceutical Inc.; July 2024.
2. King B, Senna MM, Mesinkovska NA, et al. Efficacy and safety of deuruxolitinib, an oral selective Janus kinase inhibitor, in adults with alopecia areata: Results from the Phase 3 randomized, controlled trial (THRIVE-AA1). J Am Acad Dermatol. Published online July 23, 2024. doi:10.1016/j.jaad.2024.06.097.
3. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 4, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.