Leqselvi® (deuruxolitinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Leqselvi is indicated for the treatment of severe alopecia areata in adults

Limitations of Use
Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

POLICY

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

A. For initial requests:
    1. Chart notes, medical records documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
    2. Chart notes or medical record documentation supporting more than 50% scalp hair loss (e.g., Severity of Alopecia Tool (SALT) score of 50 or higher).
B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response, including Severity of Alopecia Tool (SALT) score.

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

Criteria for Initial Approval

Alopecia areata

Authorization of 6 months may be granted for adult patients for the treatment of severe alopecia areata when ALL of the following criteria are met:

1. Patient has a diagnosis of severe alopecia areata (including alopecia totalis and alopecia universalis) defined as having more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
2. Patient has a current episode of alopecia areata lasting more than 6 months without spontaneous regrowth.
3. Duration of current episode of hair loss is less than 10 years.
4. Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).
5. Patient has had an inadequate response to corticosteroids (e.g., intralesional, oral, and/or topical depending on severity and age of the member).
6. Patient has not been previously treated with another JAK inhibitor (e.g., baricitinib, ruxolitinib, tofacitinib) and had an inadequate response (i.e., absence of significant terminal hair growth after at least 12 weeks of treatment).
7. Patient will not use requested medication in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.

Continuation of Therapy

1. Initial Continuation Request
   Authorization of 12 months may be granted for all patients (including new members) who meet Criteria for Initial Approval above and are demonstrating a positive clinical response to therapy as evidenced by an improvement of at least 10% scalp hair coverage.

2. Subsequent Continuation Requests*
   Authorization of 12 months may be granted for all patients (including new members) who meet Criteria for Initial Approval above and achieve or maintain a positive clinical response as evidenced by at least 80% total scalp hair coverage (SALT score of 20 or less).
   **Subsequent continuation requests criteria applies once the member has received at least 12 months of Leqselvi therapy.*

Other

Patient 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.

* 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 patients with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Leqselvi is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

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

Quantity Limits Apply

Leqselvi 8 mg tablets – 60 per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Freitas E, Guttman-Yassky E, Torres T. Baricitinib for the treatment of alopecia areata. *Drugs*. 2023;83(9):761-770. doi:10.1007/s40265-023-01873-w
- Gupta AK, Wang T, Polla Ravi S, Bamimore MA, Piguet V, Tosti A. Systematic review of newer agents for the management of alopecia areata in adults: Janus kinase inhibitors, biologics and phosphodiesterase-4 inhibitors. *J Eur Acad Dermatol Venereol*. 2023;37(4):666-679. doi:10.1111/jdv.18810
- Institute for Clinical and Economic Review (ICER). Accessed July 29, 2024. https://icer.org/
- King B, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. *J Am Acad Dermatol*. 2022a;86(2):359-364. doi:10.1016/j.jaad.2021.08.043
- 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
- Leqselvi. Prescribing information. Sun Pharmaceuticals; July 2024. Accessed July 29, 2024.
- Litfulo. Prescribing information. Pfizer, Inc.; June 2023. Accessed August 5, 2024.

- Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: results of an international expert opinion on treatments for alopecia areata. *J Am Acad Dermatol*. 2020;83(1):123-130. doi:10.1016/j.jaad.2020.03.004
- Mostaghimi A, Gao W, Ray M, et al. Trends in prevalence and incidence of alopecia areata, alopecia totalis, and alopecia universalis among adults and children in a US employer-sponsored insured population. *JAMA Dermatol*. 2023;159(4):411-418. doi:10.1001/jamadermatol.2023.0002
- Rudnicka L, Arenbergerova M, Grimalt R, et al. European expert consensus statement on the systemic treatment of alopecia areata. *J Eur Acad Dermatol Venereol*. 2024;38(4):687-694. doi:10.1111/jdv.19768
- RxPipeline. Accessed July 29, 2024. https://www.caremark.com/wps/portal/client
- Sibbald C. Alopecia areata: An updated review for 2023. *J Cutan Med Surg*. 2023;27(3):241-259. doi:10.1177/12034754231168839
- Sun Pharmaceuticals. Late-breaking phase 3 data at AAD 2023 show oral investigational medicine deuruxolitinib significantly improved scalp hair regrowth in alopecia areata. March 18, 2023. Accessed August 5, 2024. https://sunpharma.com/wp-content/uploads/2023/03/Press-Relaese-Late-Breaking-Phase-3-Data-at-AAD-2023-Show-Oral-Investigational-Medicine-Deuruxolitinib.pdf

POLICY HISTORY

Policy #: 05.05.65
Original Effective Date: December 22, 2024

Reviewed: August 2025

Revised: August 2025

Current Effective Date: October 4, 2025