

deuruxolitinib (Leqselvi™)**Policy # 00947**

Original Effective Date: 12/01/2025

Current Effective Date: 12/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider deuruxolitinib (Leqselvi™)[‡] for the treatment of severe alopecia areata to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of deuruxolitinib (Leqselvi) will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of severe alopecia areata; AND
- Patient is 18 years of age or older; AND
- The requested drug is NOT used in combination with potent immunosuppressants such as azathioprine and cyclosporine; AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Patient's current alopecia areata episode has lasted at least 6 months; AND
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient's current alopecia areata episode encompasses at least 50% of the scalp; AND
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*
- There has NOT been spontaneous improvement in the patient's alopecia areata over the past 6 months; AND
*(Note: This specific patient selection criterion is an additional Company requirement, for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The patient is NOT a cytochrome P450 2C9 (CYP2C9) poor metabolizer; AND
- The patient has tried and failed (i.e., intolerance or inadequate response) ritlecitinib (Litfulo™)[‡] and baricitinib (Olmiant®)[‡] unless there is clinical evidence or patient history that suggests the use of ritlecitinib (Litfulo) and baricitinib (Olmiant) will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient selection criterion is an additional Company requirement, for coverage eligibility and will be denied as not medically necessary** if not met.)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of ritlecitinib (Litfulo) when any of the following criteria are not met to be **not medically necessary****

- Patient's current alopecia areata episode has lasted at least 6 months
- Patient's current alopecia areata episode encompasses at least 50% of the scalp
- There has NOT been spontaneous improvement in the patient's alopecia areata over the past 6 months
- The patient has tried and failed ritlecitinib (Litfulo) and baricitinib (Olumiant)

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of deuruxolitinib (Leqselvi) when the patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational**.*

Background/Overview

Leqselvi is an oral Janus kinase (JAK) inhibitor indicated for the treatment of severe alopecia areata in adult patients. The recommended dosage is 8 mg taken twice daily (BID), with or without food. Leqselvi is contraindicated in individuals who are poor metabolizers of cytochrome P450 2C9 (CYP2C9) and in those concurrently receiving moderate or strong CYP2C9 inhibitors due to potential safety concerns and altered drug metabolism.

Alopecia Areata

Alopecia areata is an autoimmune disease that results in significant hair loss. Hair loss can affect several areas of the body, including the scalp and face, and can range from hair loss in small patches to complete hair loss on the scalp or body. Traditional therapies often used in the treatment of more severe cases of alopecia areata include systemic corticosteroids, immunosuppressants, and contact immunotherapy, though these are all associated with high relapse rates and adverse reactions. Other drugs with FDA approval for alopecia areata include ritlecitinib (Litfulo) and baricitinib (Olumiant).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Leqselvi is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata. It was approved in July 2024.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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Leqselvi was evaluated in two randomized, double-blind, placebo-controlled, multinational Phase III pivotal trials, THRIVE-AA1 and THRIVE-AA2, in adults with alopecia areata and $\geq 50\%$ scalp hair loss. Patients were randomized to receive Leqselvi 8 mg twice daily (BID), Leqselvi 12 mg BID, or placebo BID for 24 weeks. The primary endpoint in both studies was the proportion of patients achieving a Severity of Alopecia Tool (SALT) score of 20 or less, indicating 20% or less scalp hair loss.

In THRIVE-AA1, 29.6% of patients treated with Leqselvi 8 mg BID achieved a SALT score of ≤ 20 at Week 24, compared to 0.8% in the placebo group ($P < 0.0001$). In THRIVE-AA2, 33.0% of patients receiving Leqselvi 8 mg BID met the same endpoint versus 0.8% with placebo ($P < 0.0001$). Additionally, significantly more patients achieved a SALT score of 10 or less ($\geq 90\%$ scalp hair coverage) at Week 24 with Leqselvi 8 mg BID (20.8% in THRIVE-AA1 and 24.9% in THRIVE-AA2) compared to placebo ($< 0\%$).

References

1. Leqselvi [package insert]. Sun Pharmaceuticals Industries, Inc. Whippany, New Jersey. Updated July 2024.

Policy History

Original Effective Date: 12/01/2025

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11/06/2025 Medical Policy Committee review

11/12/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 11/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.