ritlecitinib (Litfulo™)

Policy # 00862
Original Effective Date: 01/08/2024
Current Effective Date: 09/01/2025

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 ritlecitinib (Litfulo™)‡ for the treatment of severe alopecia areata to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of ritlecitinib (Litfulo) will be considered when **all** of the following criteria are met:

- Patient has a diagnosis of severe alopecia areata; AND
- Patient is 12 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.
  *(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.)*

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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

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 ritlecitinib (Litfulo) when the patient selection criteria are not met (with the exception of those denoted as **medically necessary**)** to be **investigational.***

Background/Overview

Litfulo is a janus kinase (JAK) inhibitor that is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older. The recommended dose of Litfulo is 50 mg orally once daily.

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. The only other drug with FDA approval for severe alopecia areata is baricitinib (Olumiant®)‡.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Litfulo was approved in June of 2023 for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

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.

The efficacy and safety of Litfulo were evaluated in one randomized, double-blind, placebo-controlled trial in subjects 12 years of age and older with alopecia areata with ≥ 50% scalp hair loss, including alopecia totalis (AT) and alopecia universalis (AU).

This trial evaluated a total of 718 subjects who were randomized to one of the following treatment regimens for 48 weeks: 1) 200 mg once daily for 4 weeks followed by 50 mg once daily for 44 weeks; 2) 200 mg once daily for 4 weeks followed by 30 mg once daily for 44 weeks; 3) 50 mg once daily for 48 weeks; 4) 30 mg once daily for 48 weeks; 5) 10 mg once daily for 48 weeks; 6) placebo for 24 weeks followed by 200 mg once daily for 4 weeks and 50 mg once daily for 20 weeks; or 7) placebo for 24 weeks followed by 50 mg once daily for 24 weeks.

Across all treatment groups 62% of subjects were female, 68% were White, 26% were Asian, and 4% were Black or African American. The majority of subjects (85%) were adults (≥ 18 years of age) with a mean age of 33.7 years. A total of 105 (15%) subjects 12 to < 18 years of age and 20 (3%) subjects 65 years of age and older were enrolled. The mean baseline Severity of Alopecia Tool (SALT) score ranged from 88.3 to 93.0 across treatment groups; among subjects without AT/AU at baseline, the mean SALT score ranged from 78.3 to 87.0. The majority of subjects had abnormal eyebrows (83%) and eyelashes (75%) at baseline across treatment groups. The median duration since alopecia areata diagnosis was 6.9 years and the median duration of the current alopecia areata episode was 2.5 years. Randomization was stratified by AT/AU status with 46% of subjects classified as AT/AU based upon a baseline SALT score of 100.

Assessment of scalp hair loss was based on the SALT score. At Week 24, a greater proportion of subjects had a SALT ≤ 20 response (20% or less of scalp hair loss) and SALT ≤ 10 response (10% or less of scalp hair loss) with Litfulo compared to placebo. At Week 24, 23% of patients in the Litfulo 50 mg QD group vs. 2% of patients in the placebo group had a response based on a SALT score of 20 or less (20% or less of scalp hair loss). A SALT score of 10 or less at Week 24 was achieved in 14% of patients given Litfulo vs. 2% of patients given placebo.

References

1. Litfulo [package insert]. Pfizer. New York, New York. Updated June 2023.
2. Litfulo Drug Evaluation. Express Scripts. Updated August 2023.

Policy History

Original Effective Date: 01/08/2024
Current Effective Date: 09/01/2025

12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. New policy.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/05/2025 Medical Policy Committee review
06/11/2025 Medical Policy Implementation Committee approval. Added requirement that patient must have a negative TB test prior to therapy. Added requirement that Litfulo not be used in combination with potent immunosuppressants.
Next Scheduled Review Date: 06/2026

*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.

**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.

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.