Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Litfulo® (ritlecitinib)**

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Litfulo (ritlecitinib) is a kinase inhibitor indicated for the treatment of:

Disease State	
Alopecia Areata	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Litfulo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of severe alopecia areata

AND

2. Documented Severity of Alopecia Tool (SALT) score of 50 or higher

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of severe alopecia areata

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the Member experienced a beneficial clinical response defined as an improvement from baseline in extent and density of scalp hair loss

AND

6. Documentation from the prescribing physician that the patient continues to require systemic therapy for the treatment of alopecia areata

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals.
3. A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
4. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. King B, et al. Efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata: a randomized, double-blind, multicentre, phase 2b-3 trial. The Lancent. 2023 May;401(10387):1518-29.
2. Litfulo (ritlecitinib) [prescribing information]. New York, NY; Pfizer Labs; June 2023.
3. Meah N, et al. The alopecia areata consensus of experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. Journal of the American Academy of Dermatologist. 2020 July;83(1):123-30.
4. Meah N, et al. The alopecia areata consensus of experts (ACE) study part II: Results of an international expert opinion on diagnosis and laboratory evaluation for alopecia areata. Journal of the American Academy of Dermatologist. 2021 June;84(6):1594-1601.
5. Messenger AG, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. British Journal of Dermatology. 2012 April 23;166(5):916-26.

Approval And Revision History

December 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- March 12, 2024: Removed prerequisite trials from coverage criteria for alopecia areata. Removed the Limitation Documentation of a patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products (effective 4/1/2024).
- January 14, 2025: No changes (eff 1/14/25).
- October 14, 2025: Initial approvals limited to 6 months with annual reauthorization coverage criteria added. Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy (eff 1/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.