

Drug Policy

Policy:	Litfulo (ritlecitinib)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023
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OVERVIEW

Litfulo, a kinase inhibitor, is indicated for the treatment of **severe alopecia areata** in patients ≥ 12 years of age.¹ It inhibits the janus kinase 3 (JAK) and tyrosine kinase expressed in hepatocellular carcinoma (TEC) pathways.

POLICY STATEMENT

This policy involves the use of Litfulo. Prior authorization is recommended for pharmacy benefit coverage of Litfulo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Litfulo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Litfulo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Litfulo is recommended in those who meet the following criteria:

1. Alopecia Areata

Approve for the duration noted if the patient meets one of the following (A or B):

Note: Alopecia universalis and alopecia totalis are subtypes of alopecia areata.

A) Initial Therapy. Approve for 6 months if the patient meets all of the following (i, ii, iii, iv, and v):

- i.** Patient is ≥ 12 years of age; AND
- ii.** Patient has a current episode of alopecia areata lasting for ≥ 6 months; AND
- iii.** Patient has $\geq 50\%$ scalp hair loss; AND
- iv.** Patient has tried at least one of the following for alopecia areata (a or b):

- a)** Conventional systemic therapy; OR

Note: Examples of conventional systemic therapies include corticosteroids, methotrexate, and cyclosporine. An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried Olumiant (baricitinib tablet).

- b)** Topical corticosteroid; AND

Drug Policy

- v. Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata; AND
Note: Androgenetic alopecia includes male and female pattern hair loss. Other causes of hair loss include trichotillomania, telogen effluvium, and systemic lupus erythematosus.
 - vi. The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving Litfulo.** Approve for 1 year if the patient meets all of the following (i, ii, iii, and iv):
- i. Patient is ≥ 12 years of age; AND
 - ii. Patient has been established on Litfulo for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
 - iii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss; AND
 - iv. According to the prescriber, the patient continues to require systemic therapy for treatment of alopecia areata.
Note: International consensus states that systemic treatment is best discontinued once complete regrowth has been achieved and maintained for 6 months or when regrowth is sufficient to be managed topically.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 6 months (180 days)
- B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Litfulo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Concurrent Use with an Oral or Topical Janus Kinase Inhibitor (JAKi).¹

Litfulo should not be administered in combination with another JAKi. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.

Note: Examples include Olumiant (baricitinib tablets), Rinvoq (upadacitinib tablets), Xeljanz (tofacitinib tablets), and Opzelura (ruxolitinib cream).

2. Concurrent Use with a Biologic Immunomodulator. Litfulo is not recommended in combination with biologic immunomodulators.¹

Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasentra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

3. Concurrent Use with Other Potent Immunosuppressants (e.g., cyclosporine, azathioprine).¹ Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

Drug Policy

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Litfulo® capsules [prescribing information]. New York, NY: Pfizer; June 2023.
2. 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;83:123-30.