PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Litfulo Prior Authorization Policy
- Litfulo™ (ritlecitinib capsules – Pfizer)

REVIEW DATE: 07/17/2024; selected revision 08/21/2024, 09/11/2024

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.

Guidelines

Although specific drugs are not mentioned, JAK inhibitors (JAKis) as a therapeutic class are addressed in an international expert opinion on treatments for alopecia areata (2020).[2] JAKis are identified among the therapies for treatment of extensive hair loss. First-line treatments for adults include high- or super-high potency topical corticosteroids and/or systemic corticosteroids. Steroid-sparing therapies to mitigate the risk associated with prolonged use of corticosteroids include cyclosporine, methotrexate, azathioprine, and JAKis. Based on expert opinion, JAKis are considered the ideal option amongst systemic, steroid-sparing agents.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Litfulo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

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 ≥ 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

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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 Leqselvi (deuruxolitinib tablets) or Olumiant (baricitinib tablets).

b) High- or super-high potency topical corticosteroid; AND

v. 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Litfulo is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

2. **Concurrent Use with a Topical Janus Kinase Inhibitor (JAKi).**[1] Litfulo should not be administered in combination with a topical 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 Opzelura (ruxolitinib cream).

3. **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), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

4. **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.

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

REFERENCES

1. Litfulo® capsules [prescribing information]. New York, NY: Pfizer; June 2023.

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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.

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APPENDIX

[*] Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; [^] Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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