ritlecitinib tosylate (Litfulo®)

Pharmacy Benefit Drug Policy

Drug Details

USP Category: DERMATOLOGICAL AGENTS
Mechanism of Action: An oral kinase inhibitor

Label Name	Quantity Limit
Litfulo 50 MG CAP	1 cap/day

Condition(s) listed in policy *(see coverage criteria for details)*

- Severe Alopecia Areata (AA)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

The following condition(s) require Prior Authorization/Preservice:

Severe Alopecia Areata (AA)

Initial authorization

1. Being prescribed by, or in consultation with a dermatologist, AND
2. Patient age is consistent with the FDA-approved minimum, AND
3. Diagnosis of severe alopecia areata with at least one of the following:
    1. Severity of Alopecia Tool (SALT) score of at least 50, OR
    2. Hair loss encompasses at least 50% of the scalp, OR
    3. Alopecia Areata Investigator Global Assessment (AA-IGA) score of at least 3, AND
4. Not used in combination with other JAK inhibitors (e.g., Xeljanz, Rinvoq) or immunosuppressants (e.g., methotrexate, azathioprine), AND
5. Dose does not exceed the FDA-approved maximum.

Reauthorization

1. The patient has achieved hair regrowth and continues to benefit while taking Litfulo, AND
2. Not used in combination with other JAK inhibitors (e.g., Xeljanz, Rinvoq) or immunosuppressants (e.g., methotrexate, azathioprine)

Coverage Period:
Initial: 6 months
Reauthorization: one year

Additional Information

- Litfulo's label includes a boxed warning regarding the risk for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis, which is included in the labels for other JAK inhibitors.
- Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
- Clinical Trials Data: The approval of Litfulo was based on results from the Phase 2b/3 ALLEGRO trial, which evaluated Litfulo versus placebo in 718 patients 12 years of age and older with severe AA, defined as ≥50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT). Trial participants were randomized to receive once-daily Litfulo at doses of 30 mg or 50 mg (with or without 1 month of initial treatment with once-daily Litfulo 200 mg), Litfulo 10 mg, or placebo. The FDA-approved dose for Litfulo is 50 mg once daily. Results from the ALLEGRO trial showed that, after 6 months of treatment, 23% of patients treated with Litfulo 50 mg had 80% or more scalp hair coverage, compared to 1.6% of patients in the placebo group, with efficacy and safety results consistent between adolescent and adult patients. The most common adverse events reported in the study, in at least 4% of patients treated with Litfulo, were headache (10.8%), diarrhea (10%), acne (6.2%), rash (5.4%), and urticaria (4.6%).

References

1. Litfulo. Prescribing information. Pfizer labs. New York, NY. 6/2023

Review History

Date of Last Annual Review:
Date of last revision:
Changes from previous policy version:

- New policy

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee