PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Litfulo (ritlecitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Litfulo is a kinase inhibitor approved in 2023. It is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
Alopecia areata is a T-cell mediated autoimmune, nonscarring form of hair loss with an underlying immunoinflammatory pathogenesis. It affects both children and adults, with a prevalence of about 2% globally. Alopecia areata can have a considerable impact on quality of life including anxiety or depression.
Litfulo was approved based on a randomized phase 2b-3 trial showing a significant difference in response rate based on a Severity of Alopecia Tool (SALT) score of 20 or less. The difference in response rate was 21.9% (14.7–30.2; p<0·0001) for the 50 mg dose.

Litfulo (ritlecitinib) will be considered for coverage when the following criteria are met:

Alopecia Areata (AA)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of severe alopecia areata confirmed by **both** of the following:
   a) Current episode is of 6 months duration or longer with no spontaneous regrowth at any point;
   b) Hair loss encompasses 50% or more of the scalp confirmed by a Severity of Alopecia Tool (SALT) score of 50 or higher; AND
4. Documented trial and failure of at least **one** of the following conventional treatments:
   a) Topical immunotherapy (e.g., DPCP or SADBE) for 6 months;
   b) Oral corticosteroid for 6 weeks; AND
5. Member has an absolute lymphocyte count > 500/mm^3 and a platelet count > 100,000/mm^3 documented in chart notes; AND
6. Member has had or will have completed a tuberculosis test within the past 12 months; AND
7. Medication is not being used with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
8. **Dosage allowed/Quantity limit**: 50 mg orally once daily. Quantity Limit: 28 capsules per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document achievement of a SALT score of 20 or less.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Litfulo (ritlecitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/31/2023	New policy for Litfulo created.
09/27/2023	Added trial of topical therapy or an oral corticosteroid.

References:

1. Litfulo [package insert]. New York, NY; Pfizer Labs. 2023.
2. Messenger AG, McKillop J, Farrant P, McDonagh AJ, Sladden M. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. *Br J Dermatol.* 2012;166(5):916-926. doi:10.1111/j.1365-2133.2012.10955.x
3. King B, Zhang X, Harcha WG, et al. Efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata: a randomised, double-blind, multicentre, phase 2b-3 trial [published correction appears in Lancet. 2023 Jun 10;401(10392):1928]. *Lancet*. 2023;401(10387):1518-1529. doi:10.1016/S0140-6736(23)00222-2
4. Harries MJ, Sun J, Paus R, King LE Jr. Management of alopecia areata. *BMJ*. 2010;341:c3671. Published 2010 Jul 23. doi:10.1136/bmj.c3671
5. Cranwell WC, Lai VW, Photiou L, et al. Treatment of alopecia areata: An Australian expert consensus statement. *Australas J Dermatol.* 2019;60(2):163-170. doi:10.1111/ajd.12941
6. Almutairi N, Nour TM, Hussain NH. Janus Kinase Inhibitors for the Treatment of Severe Alopecia Areata: An Open-Label Comparative Study. *Dermatology*. 2019;235(2):130-136. doi:10.1159/000494613

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