

# PHARMACY POLICY STATEMENT

## Indiana Medicaid

<b>DRUG NAME</b>	<b>Litfulo (ritlecitinib)</b>
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

Effective date: 01/01/2024

Creation date: 09/27/2023