UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2317-2
Program	Prior Authorization/Medical Necessity
Medication	Litfulo™ (ritlecitinib)
P&T Approval Date	11/2023, 12/2024
Effective Date	3/1/2025

1. Background:

Litfulo (ritlecitinib) is a kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

Limitations of Use:
Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Litfulo** will be approved based on **all** of the following criteria:

   a. Diagnosis of severe alopecia areata

   -AND-

   b. Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, secondary syphilis, tinea capitis, triangular alopecia, and trichotillomania)

   -AND-

   c. Patient has a current episode of alopecia areata with at least 50% scalp hair loss

   -AND-

   d. Patient is not receiving Litfulo in combination with **either** of the following:

      (1) Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
      (2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

   -AND-

   e. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Litfulo** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to Litfulo therapy

   -AND-

   b. Patient is not receiving Litfulo in combination with **either** of the following:

      (1) Targeted immunomodulator [e.g., Olumiant (baricitinib), Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Rinvoq (upadacitinib)]
      (2) Potent immunosuppressant (e.g., azathioprine or cyclosporine)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Step Therapy may be in place.

4. References:

1. Litfulo [package insert]. New York, NY: Pfizer, Inc.; June 2023.
2. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. *Br J Dermatol*. 2012;166(5):916-926.
3. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022;86(2):359-364.
4. 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(1):123-130.
5. King BA, Senna MM, Ohyama M, et al. Defining Severity in Alopecia Areata: Current Perspectives and a Multidimensional Framework. Dermatol Ther (Heidelb). 2022 Apr;12(4):825-834.

Program	Prior Authorization/Medical Necessity - Litfulo (ritlecitinib)
Change Control	
11/2023	New program.
12/2024	Annual review with no change to coverage criteria.