AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Litfulo (ritlecitinib)	Page:	1 of 2
Effective Date:	12/26/2023	Last Review Date:	10/2023

Applies to:	☒Illinois	☐Florida	☐Michigan
	☒New Jersey	☒Maryland	☒Florida Kids
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Litfulo under the patient's prescription drug benefit.

Description:

Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Litfulo

Policy/Guideline:

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   Chart notes or medical record documentation supporting more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
B. Continuation requests:
   Chart notes or medical record documentation supporting positive clinical response (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Criteria for Initial Approval:

Alopecia areata

The requested drug will be covered with prior authorization for the treatment of severe alopecia areata when the following criteria are met:

A. Member is 12 years of age or older
B. This medication must be prescribed by or in consultation with a dermatologist.
C. Member has more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).

D. Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).
E. Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

*If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

F. Member will not use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Criteria for Continuation of Therapy:

Alopecia areata

Authorization may be granted for all members 12 years of age or older (including new members) who are using the requested medication for severe alopecia areata

A. Member has achieved or maintained a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).
B. Member will not use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Approval Duration and Quantity Restrictions:

Approval Duration: 12 months

Quantity Level Limit: 28 capsules per 28 days

References:

1. Litfulo [package insert]. New York, NY: Pfizer Inc.; June 2023.
2. 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. *Lancet*. 2023;401:1518-1529.
3. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on July 3, 2023 from: https://www.cdc.gov/tb/topic/basics/risk.htm.