

| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
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| Original Development Date: Original Effective Date: Revision Date: | April 12, 2024 |

LitfuloTM (ritlecitinib)

LENGTH OF AUTHORIZATION: Initial therapy - 6 months

 $Continuation \ of \ the rapy-1 \ year$

REVIEW CRITERIA:

- Patient must be ≥ 12 years of age.
- Patient must have a documented diagnosis of severe alopecia areata with ≥ 50% scalp hair loss. Supporting documentation (e.g., progress notes, Severity of Alopecia Tool [SALT] results, etc.) must be provided.
- Patient has had an inadequate response, intolerance, or contraindication to the following (clinical documentation must be submitted demonstrating response to previous therapies):
 - A 3-month minimum trial of ≥ 1 preferred systemic agent (e.g., cyclosporine, corticosteroids, methotrexate); OR
 - Topical corticosteroids.
- Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or causes of hair loss other than alopecia areata.
- Prescribed by or in consultation with a dermatologist.
- Patient had a negative TB test prior to initiating therapy, and results have been provided.
- LitfuloTM will not be used concomitantly with any JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; AND
- Documentation of positive clinical response to treatment (e.g., decreased hair loss, increased scalp hair coverage, or improved SALT score); AND
- Patient has not experienced any treatment-restricting adverse effects; AND
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 50 mg capsules

