Protocol for Alopecia Areata Products
Approved January 2025

Litfulo™ (ritlecitinib)
Olumiant® (baricitinib)
Leqselvi™ (deuruxolitinib)

Background:
Alopecia areata is a chronic, relapsing, immune-mediated, inflammatory disorder that affects hair follicles and results in nonscarring hair loss. The severity of the disorder ranges from small patches of alopecia on any hair-bearing area to the complete loss of scalp, eyebrow, eyelash, and body hair.

Criteria for Approval:

1. Patient meets the FDA-approved or compendial-supported age for the product being requested
2. Patient has the diagnosis of severe alopecia areata
3. Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, cicatricial alopecias, tinea capitis, triangular alopecia, trichotillomania, and syphilis)
4. Prior to initiation of therapy, recommended laboratory monitoring is done as indicated by the appropriate prescribing information (e.g., complete blood count with differential white count and platelet count, liver function tests, and pregnancy screening, screening for latent tuberculosis, screening for hepatitis C and screening for hepatitis B, including testing for hepatitis B virus surface antigen and hepatitis B core antibody)
5. Patient has no contraindication to the requested medication
6. Patient is not using or planning to use with other JAK inhibitors, biologic immunomodulators or potent immunosuppressants (e.g., azathioprine, cyclosporine)
7. Initial prescription is written by or in consultation with a dermatologist or other appropriate specialist
8. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Documentation of positive clinical response to therapy
2. Patient is not using or planning to use with other JAK inhibitors, biologic immunomodulators or potent immunosuppressants (e.g., azathioprine or cyclosporine)
3. Patient is routinely monitored for possible complications referenced in the prescribing information

Approval Duration: 12 Months

Quantity Level Limit:
Litfulo: 28 capsules per 28 days
Leqselvi 60 tablets per 30 days
Olumiant: 30 tablets per 30 days

NOTE: Black box warnings exist for serious infections, thrombosis, mortality, malignancy, and major adverse cardiovascular events (MACE).

References:

1. Litfulo™ [packet insert] Pfizer Labs Division of Pfizer Inc. New York, NY 10001. June 2023
2. Olumiant® [packet insert] Lilly USA, LLC Indianapolis, IN 46285. May 2022
3. Shawky AM, Almalki FA, Abdalla AN, Abdelazeem AH, Gouda AM. A Comprehensive Overview of Globally Approved JAK Inhibitors. Pharmaceutics. 2022 May 6;14(5):1001
4. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically
5. Messenger AG. Alopecia Areata: Management. UpToDate November 2, 2023. Accessed online 11.4.24 @ https://www.uptodate.com/contents/alopecia-areata-management?csi=aa393cbe-625a-4f90-a3f7-2c8bad50fef8&source=contentShare
6. Bolduc C. Alopecia Areata Treatment & Management. June 27, 2023. Medscape Dermatology. Accessed online September 18, 2023 at: https://emedicine.medscape.com/article/1069931-treatment