CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Leqselvi (deuruxolitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Leqselvi, approved by the FDA in 2024, is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata.
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.
Leqselvi was approved based on two randomized phase 3 trials showing a significant difference in response rate based on a Severity of Alopecia Tool (SALT) score of 20 or less.

Leqselvi (deuruxolitinib) will be considered for coverage when the following criteria are met:

Alopecia Areata (AA)

For **initial** authorization:
1. Member is at least 18 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. Member has documented trial and failure of **ONE** of the following:
   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 cells/mm^3, absolute neutrophil count ≥ 1,000 cells/mm^3 and a hemoglobin ≥ 8 g/dl documented in chart notes; AND
6. Chart notes include documentation that member is **NOT** a CYP2C9 poor metabolizer; AND
7. Member has had or will have completed a tuberculosis test within the past 12 months; AND
8. Provider attests member does **NOT** have ANY of the following:
   a) Active hepatitis B or C;
   b) Concomitant use with moderate or strong CYP2C9 inhibitors;
   c) Concomitant use with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
9. **Dosage allowed/Quantity limit:** administer 8 mg orally twice daily. Quantity limit: 60 tablets per 30 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 Leqselvi (deuruxolitinib) 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
07/26/2024	New policy for Leqselvi created.

References:

1. Leqselvi [package insert]. Sun Pharmaceutical Industries, Inc.; 2024.
2. 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
3. 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
4. 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
5. 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
6. King B, Senna MM, Mesinkovska NA, et al. Efficacy and safety of deuruxolitinib, an oral selective Janus kinase inhibitor, in adults with alopecia areata: Results from the Phase 3 randomized, controlled trial (THRIVE-AA1*). J Am Acad Dermatol*. Published online July 23, 2024. doi:10.1016/j.jaad.2024.06.097

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