

## PHARMACY POLICY STATEMENT

### Marketplace

|                     |                                  |
|---------------------|----------------------------------|
| <b>DRUG NAME</b>    | <b>Leqselvi (deuruxolitinib)</b> |
| <b>BENEFIT TYPE</b> | Pharmacy                         |
| <b>STATUS</b>       | 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 a trial and failure of Olumiant; AND
6. Member has an absolute lymphocyte count  $\geq 500$  cells/mm<sup>3</sup>, absolute neutrophil count  $\geq 1,000$  cells/mm<sup>3</sup> and a hemoglobin  $\geq 8$  g/dl documented in chart notes; AND
7. Chart notes include documentation that member is **NOT** a CYP2C9 poor metabolizer; AND
8. Member has had or will have completed a tuberculosis test within the past 12 months; AND
9. 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.
10. **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. |
| 09/19/2025 | Added trial of Olumiant          |

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

Effective date: 01/01/2026

Revised date: 09/19/2025