Original Effective Date: 12/17/2025
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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C29923-A

Leqselvi (deuruxolitinib) MNR

PRODUCTS AFFECTED

Leqselvi (deuruxolitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe Alopecia Areata

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. SEVERE ALOPECIA AREATA:
REVIEWER NOTE: PLEASE FIRST REFER TO STATE AND LINE OF BUSINESS EXPLANATION OF BENEFITS TO DETERMINE IF HAIR LOSS/COSMETIC INDICATIONS ARE A COVERED BENEFIT

1. Documentation of diagnosis of severe alopecia areata
   AND
2. Documentation current episode is of 6 months in duration or longer with no spontaneous regrowth at ANY point within the 6 months.
   AND
3. Documentation that member hair loss encompasses 50% or more of the scalp [i.e., SALT (Severity of Alopecia Tool) score of 50 or higher]
   AND
4. Documentation of an inadequate response (for 6 months), serious side effects, or contraindication to topical immunotherapy OR oral corticosteroids for 6 weeks
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Leqselvi (deuruxolitinib) include: use in members who are CYP2C9 poor metabolizers, use with moderate or strong CYP2C9 inhibitors, and avoid use of live vaccines during or immediately prior to treatment with deuruxolitinib.]
   NOTE: An FDA-cleared or -approved test for the detection of CYP2C9 variants to direct the use of deuruxolitinib is not currently available.
   AND
6. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
   AND
7. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, upadacitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation

CONTINUATION OF THERAPY:

A. SEVERE ALOPECIA AREATA:

REVIEWER NOTE: PLEASE FIRST REFER TO STATE AND LINE OF BUSINESS EXPLANATION OF BENEFITS TO DETERMINE IF HAIR LOSS/COSMETIC INDICATIONS ARE A COVERED BENEFIT

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label
   AND
4. Documentation of achievement of a SALT score of 20 or less [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
8 mg twice daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Alopecia Agents - Janus Kinus (JAK) Inhibitors

FDA-APPROVED USES:
Indicated for the treatment of adults with severe alopecia areata
Limitations of Use: Leqselvi is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Alopecia areata (AA) is a chronic, relapsing disorder characterized by nonscarring hair loss. This autoimmune skin disorder usually effects the scalp and face but can affect hair on other parts of the body. Patients with limited AA (usually considered hair loss affecting <20% of the scalp surface area) tend to have unpredictable spontaneous remissions and relapses. Patients with moderate to severe AA tend to have a more chronic disease course with little to no remission periods. Hair is an important aspect of self-image, so the psychosocial impact of AA can be significant and often affects work and school life and attendance. Patients with AA are also at higher risk of developing other autoimmune and inflammatory conditions (e.g. atopic dermatitis, psoriasis, lupus erythematosus).

Intralesional corticosteroid injections are the preferred first-line treatment option in patients with limited (<25%) patchy hair loss. For larger areas and for patients who cannot tolerate the injection site pain, topical corticosteroids are another acceptable first-line therapy for AA.

For patients with extensive hair loss, topical immunotherapy with diphenylcyclopropenone (DPCP) or squaric acid dibutyl ester (SADBE) is generally the first-line therapy. The topical immunotherapy agents are potent contact allergens that are applied to the skin weekly to trigger an immune reaction, and it usually takes about 3 months for the hair to start to regrow. DPCP and SADBE are not commercially available in ready-to-use dosage forms. The chemicals are purchased from a chemical distributor, and then the product is compounded into a solution of the desired strength. For both agents, the maximum

strength typically used is 2%. Treatment with DPCP or SADBE usually starts with a low concentration and is slowly worked up to a higher concentration to obtain a mild dermatitis reaction.

Systemic treatments are used in patients who are refractory to topical and intralesional therapies or for whom these therapies are inappropriate or infeasible.

Severity of Alopecia Tool

The Severity of Alopecia Tool (SALT) is a standardized tool to quantify hair loss on the scalp and is commonly used in clinical trials and in clinical practice. The SALT score ranges from 0 (no scalp hair loss) to 100 (total scalp hair loss); hair regrowth is reflected by a decrease in the SALT score. For example, a SALT score of 20 equates to 20% scalp hair loss, or
in other words, 80% scalp hair coverage. The SALT score indicates disease severity using the following ranges: no hair loss = 0; limited = 1–20; moderate = 21–49; severe = 50–94; and very severe = 95–100.

Leqselvi (deuruxolitinib)

The safety and efficacy of deuruxolitinib was evaluated in two multicenter, randomized, double blind, placebo-controlled trials (n=1209 total). The phase 3 THRIVE-AA1 trial enrolled patients aged 18-65 years with at least 50 percent hair loss. Patients (n=706) were randomized to receive 12 mg twice daily, 8 mg twice daily or placebo, in a 3:5:2 ratio for 24 weeks with the primary end point of the achieving a SALT score of 20 or less. Deuruxolitinib utilization resulted in significantly higher proportions of patients meeting the primary end point. 94 (29.6%) achieved the end point in the 12 mg group; 83 (41.5%) achieved the end point in the 8 mg group. Treatment emergent adverse events were reported in all groups: 61.5% (8 mg group), 63.7% (12 mg group) and 55.7% (placebo). TEAEs were more frequent in the treatment groups compared to placebo. The second trial, THRIVE-AA2 [NCT04797650] was also evaluated deuruxolitinib in patients 18 to 65 years with severe alopecia areata lasting at least 6 months and not more than 10 years. Assessment of treatment
response using SALT for efficacy occurred at 4, 8, 12, 16, 20 and 24 weeks. Following the 24 week treatment, patients were eligible to continue receiving treatment in an open label extension study.
Key exclusion criteria included:

- Treatment with other medications or agents within 1 month of Baseline or during the study that may affect hair regrowth or immune response, including but not limited to: corticosteroids administered orally, intravenously or intramuscularly, or applied to areas of skin affected by alopecia (intranasal and inhaled corticosteroids are allowed, eye and ear drops containing corticosteroids are also allowed); oral retinoids, oral cyclines (minocin, tetracycline); platelet rich plasma injections; topical application to affected areas of retinoids, anthralin, squaric acid, diphenylcyclopropenone, or minoxidil.
- Treatment with systemic immunosuppressive medications within 3 months of screening
- Treatment with biologics within 6 months of screening
- History of lymphoproliferative disease or malignancy
- Abnormal screening labs, including A1C, lipids, liver function, and thyroid function.

Adverse events reported for study participants which occurred more frequently than placebo included: acne, headache, nasopharyngitis, increased blood creatinine phosphatase, hyperlipidemia, fatigue, skin and soft tissue infections, anemia, wight increase, neutropenia, lymphopenia, thrombocytosis, and herpes. Though 8 mg and 12 mg doses were studied, only the 8 mg dose is FDA approved. During the study period up to 52 weeks, 1 subject treated with the 12 mg dose developed bilateral pulmonary embolism. During the period of weeks 52-98, 4 subjects treated with the 12 mg dose experienced 7 thrombotic events.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Leqselvi (deuruxolitinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Leqselvi (deuruxolitinib) include: use in members who are CYP2C9 poor metabolizers, use with moderate or strong CYP2C9 inhibitors, and avoid use of live vaccines during or immediately prior to treatment with deuruxolitinib.

Exclusions/Discontinuation:
Due to the increased risk of serious bacterial, fungal, viral and opportunistic infections including tuberculosis (TB), that may lead to hospitalization or death, treatment with Leqselvi (deuruxolitinib) should be interrupted until the infection is controlled. Additionally, patients should be tested for latent TB before and during therapy. Latent TB should be treated prior to use.

Perform a CBC prior to treatment with Leqselvi. Leqselvi treatment is not recommended in patients with an absolute lymphocyte count (ALC) < 500 cells/mm3, absolute neutrophil count (ANC) <1,000 cells/mm3, or hemoglobin level <8 g/dl.

Leqselvi (deuruxolitinib) therapy should be interrupted for the following hematologic abnormalities and can be resumed upon resolution: absolute lymphocyte count (ALC) <500 cells/mm3, absolute neutrophil count (ANC) <1,000 cells/mm3, or hemoglobin level <8 g/dl.

OTHER SPECIAL CONSIDERATIONS:
Leqselvi (deuruxolitinib) has a Black Box Warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE) and thrombosis. There is an increased risk of serious bacterial, fungal, viral and opportunistic infections including tuberculosis (TB), that may lead to hospitalization or death. There is a higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients. Leqselvi (deuruxolitinib) is not approved for use in RA patients. Malignancies have occurred in patients treated with Leqselvi (deuruxolitinib). There is a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients. Thrombosis has occurred in patients treated with Leqselvi (deuruxolitinib).

Additionally, there is an increased risk for gastrointestinal perforation. Patients that present with new onset abdominal pain should be evaluated promptly. Lipid elevations, anemia, neutropenia and lymphopenia can occur. Patients should be monitored for changes in lipids, hemoglobin, neutrophils and lymphocytes.

Leqselvi (deuruxolitinib) is not recommended for use in patients who are lactating, have severe renal impairment or have severe hepatic impairment.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is*

included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Leqselvi TABS 8MG

REFERENCES

1. Leqselvi (deuruxolitinib) tablets, for oral use [prescribing information]. Whippany,NJ: Halo Pharmaceutical, Inc (for Sun Pharmaceutical Industries, Inc); July 2024.
2. Lee S, et al. Comorbidities in alopecia areata: a systematic review and meta analysis. J Am Acad Dermatol. 2019;80(2):466-477.e16.
3. King, B., Senna, M. M., Mesinkovska, N. A., Lynde, C., Zirwas, M., Maari, C., Prajapati, V. H., Sapra, S., Brzewski, P., Osman, L., Hanna, S., Wiseman, M. C., Hamilton, C., & Cassella, J. (2024). 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). Journal of the American Academy of Dermatology, 91(5), 880–888. https://doi.org/10.1016/j.jaad.2024.06.097
4. NCT04797650, Study to Evaluate the Efficacy and Safety of CTP-543 in Adults With Moderate to Severe Alopecia Areata (THRIVE-AA2) (THRIVE-AA2), Sponsor Concert Pharmaceuticals, https://clinicaltrials.gov/study/NCT04797650, accessed August 14, 2025
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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2025