09-5000-01

Original Effective Date: 01/01/26

Reviewed: 10/08/25

Revised: 00/00/00

Subject: Deuruxolitinib (Leqselvi) Tablet

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions
Definitions	Related Guidelines	Other	References	Updates

DESCRIPTION:

Deuruxolitinib (Leqselvi) is an oral Janus kinase (JAK) inhibitor approved by the United States (US) Food and Drug Administration (FDA) in July 2024 for “the treatment of adults with severe alopecia areata”. Deuruxolitinib is the third JAK inhibitor to be approved by the FDA for the treatment of alopecia areata (AA); the first being baricitinib (Olumiant) in June 2022 and the second being ritlecitinib (Litfulo) in June 2023. Of note, as of September 2025, deuruxolitinib and baricitinib are only approved for use in adults with AA, while ritlecitinib is approved for use in adolescents and adults. In an in vitro kinase activity assay, deuruxolitinib had greater inhibitory potency for JAK1, JAK2 and TYK2 relative to JAK3. Various JAK inhibitors are still in development, and each has a unique inhibitory profile among the various JAK proteins. The clinical significance in terms of safety and efficacy of the different affinity profiles among the JAK inhibitors has yet to be determined. Unique to deuruxolitinib, as compared to other JAK inhibitors, is its significant CYP2C9 metabolism. As a result, deuruxolitinib is contraindicated in patients who are CYP2C9 poor metabolizers or are using moderate or strong CYP2C9 inhibitors. Patient should be tested for CYP2C9 variants to determine CYP2C9 genotype prior to initiation of treatment. Like other JAK inhibitors, deuruxolitinib includes a Boxed Warning regarding risk of serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.

DERMATOLOGICAL DISORDERS

Alopecia Areata

Alopecia areata (AA) is a chronic autoimmune disease characterized by non-scarring hair loss of the scalp. The most common pattern of presentation of hair loss is the patch subtype, with circular patches seen on the scalp or beard areas. Hair loss may also affect other parts of the body, including the eyebrows, eyelashes, beard, and axillary. AA may also affect the nails and cause nail pitting, or in severe cases cause brachyonychia. During early stages of the disease spontaneous hair regrowth is common,

but this becomes rarer as the hair loss becomes more extensive. Patients may have a decreased quality-of-life or psychological burden associated with the disease. Patients with AA tend to have a higher risk of both depression and anxiety.

AA is diagnosed based off of clinical presentation and patient history, but sometimes a biopsy is required. Active AA can be assessed with a pull test. A pull test involves firmly pulling 50 to 60 hairs close to the scalp, and a positive test is defined as greater than 10% of hairs being pulled out. Severity of the disease is a strong predictor of long-term outcomes of the disease and can assist in guiding treatment. The Severity of Alopecia Tool (SALT) involves splitting the scalp into four quadrants and determining the percentage of scalp area devoid of terminal hairs to provide a total affected area. One limitation of SALT is it does not account for hair loss of facial hair (eyelashes, eyebrows, beard) or body hair. Severity of AA has been defined as follows:

- Mild AA: 20% or less scalp hair loss
- Moderate AA: 21%-49% scalp hair loss
- Severe AA: 50%-100% scalp hair loss

Pharmacologic treatment of AA includes topical/intralesional/systemic corticosteroids, systemic immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate), and minoxidil, with the use of each intervention dependent on the severity of the disease and the area of the body affected. Janus kinase (JAK) inhibitors have been shown to be effective in adults and young people with severe AA and are strongly recommended for these patients.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of deuruxolitinib (Leqselvi) **meets the definition of medical necessity** when **ALL** of the following criteria are met (“1” to “5”):

1. **ONE** of the following (“a”, “b”, or “c”):
    a. The member has been treated with deuruxolitinib (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with deuruxolitinib (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following (‘i” and “ii”):
        i. Deuruxolitinib will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met
        ii. **EITHER** of the following if the member has an FDA-approved indication (“I” or “II”):

I. The member's age is within FDA labeling for the requested indication for deuruxolitinib

II. There is support for using deuruxolitinib for the member's age for the requested indication

2. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for alopecia areata) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. The member does **NOT** have any FDA-labeled contraindications to Leqselvi
4. The member will **NOT** be using deuruxolitinib in combination with a biologic immunomodulator agent (full list in "Other" section); another Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a, "b", "c", or "d"):
    a. The dosage does **NOT** exceed 8 mg twice daily
        - QL: 60 tablets/30 days (two per day)
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
        ii. **ALL** of the following ("1", "2", and "3"):
            1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
            2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
            3. **EITHER** of the following ("a" or "b"):
    a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
    b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
    c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a

lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

Table 1

Indication	Criteria
Alopecia areata (AA)	**BOTH** of the following ("1" and "2"): 1. Member has a diagnosis of severe alopecia areata **AND** 2. Member has at least 50% scalp hair loss that has lasted 6 months or more
Other indications	The member has another FDA-labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, American Hospital Formulary Service (AHFS), or National Comprehensive Cancer Network (NCCN) compendium recommended use 1 or 2A

Continuation of deuruxolitinib (Leqselvi) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "6"):

1. An authorization or reauthorization for deuruxolitinib has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. The member has had clinical benefit with deuruxolitinib therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for alopecia areata) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. The member does **NOT** have any FDA-labeled contraindications to Leqselvi
5. The member will **NOT** be using deuruxolitinib in combination with a biologic immunomodulator agent (full list in "Other" section); another Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

6. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does **NOT** exceed 8 mg twice daily
        - QL: 60 tablets/30 days (two per day)
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
        ii. **ALL** of the following ("1", "2", and "3"):
            1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
            2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
            3. **EITHER** of the following ("a" or "b"):
                a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
                b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
    c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
        ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)
    d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):
        i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
        ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Treatment of adult patients with severe alopecia areata (AA)
    - Limitations of Use (per product labeling): Leqselvi is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.
- The recommended dosage is 8 mg orally twice daily, with or without food.
- Perform the following prior to treatment:
    - CYP2C9 genotype determination, as use is contraindicated in patients who are CYP2C9 poor metabolizers
    - Evaluation for use of concomitant CYP2C9 inhibitors, as use is contraindicated in patients taking moderate or strong CYP2C9
    - Active and latent tuberculosis (TB) evaluation, viral hepatitis screening in accordance with clinical guidelines, and a complete blood count (CBC). Treatment is not recommended in patients with an absolute lymphocyte count (ALC) <500 cells/mm^3, absolute neutrophil count (ANC) <1,000 cells/mm^3, or hemoglobin (Hgb) level <8 g/dL. Treatment is not recommended in patients with active hepatitis B or hepatitis C. Treatment is not recommended in patients with active TB. For patients with latent TB or those with a negative latent TB test who are at high risk for TB, start preventive therapy for latent TB prior to initiation of deuruxolitinib.

Dose Adjustments

- Adverse effects: Treatment should be interrupted if ALC is <500/mm^3, ANC <1,000 cells/mm^3, or Hgb level <8 g/dL; and may be restarted once they return above these respective values.
- Hepatic impairment: No dosage adjustment is needed for mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment. Use is not recommended for patients with severe (Child Pugh C) hepatic impairment.
- Renal impairment: No dosage adjustment is needed for mild or moderate renal impairment. Use is not recommended for patients with severe (eGFR less than 30 mL/minute) renal impairment.

Drug Availability

- 8 mg purple, round, immediate-release tablets in a 60-count bottle.
- Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). Store in the original bottle to protect from moisture.

PRECAUTIONS:

Boxed Warning

- WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS
    - Increased risk of serious bacterial, fungal, viral and opportunistic infections, including tuberculosis (TB), that may lead to hospitalization or death. Interrupt treatment with Leqselvi if a serious infection occurs until the infection is controlled. Leqselvi treatment is not recommended in patients with active tuberculosis. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.
    - Higher rate of all-cause mortality, including sudden cardiovascular death, was observed with another Janus kinase (JAK) inhibitor vs. TNF blockers in rheumatoid arthritis (RA) patients. Leqselvi is not approved for use in RA patients.
    - Malignancies were reported in patients treated with Leqselvi. Higher rate of lymphomas and lung cancers was observed with another JAK inhibitor vs. TNF blockers in RA patients.
    - Higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with another JAK inhibitor vs. TNF blockers in RA patients.
    - Thrombosis, including cerebral venous sinus thrombosis (CVT), deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with Leqselvi. Increased incidence of pulmonary embolism, venous and arterial thrombosis was observed with another JAK inhibitor vs. TNF blockers.

Contraindications

- Patients who are CYP2C9 poor metabolizers.
- Patients who are on concomitant moderate or strong CYP2C9 inhibitors.

Precautions/Warnings

- **Serious Infections** - see boxed warning.
- **Mortality** - see boxed warning.
- **Malignancy and Lymphoproliferative Disorders** - see boxed warning.
- **Major Adverse Cardiovascular Events (MACE)** - see boxed warning.
- **Thrombosis** - see boxed warning.
- **Increased Risk of Leqselvi-Associated Serious Adverse Reactions in CYP2C9 Poor Metabolizers or with Concomitant Use of Moderate or Strong CYP2C9 Inhibitors** - Leqselvi is contraindicated in patients who are CYP2C9 poor metabolizers or patients taking a moderate or strong CYP2C9 inhibitor.
- **Gastrointestinal Perforations** - Monitor patients who may be at increased risk for gastrointestinal perforation. Evaluate promptly patients presenting with new onset abdominal symptoms.

- **Lipid Elevations, Anemia, Neutropenia, and Lymphopenia** - Monitor for changes in lipids, hemoglobin, neutrophils, and lymphocytes.
- **Immunizations** - Avoid use of live vaccines during or immediately prior to Leqselvi treatment.

BILLING/CODING INFORMATION:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

L63.0 – L63.9	Alopecia areata

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None

RELATED GUIDELINES:

Baricitinib (Olumiant), 09-J3000-10
Ritlecitinib (Litfulo), 09-J4000-57

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 10/08/25.

GUIDELINE UPDATE INFORMATION:

01/01/26	New Medical Coverage Guideline.