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PHARMACY – 5.01.637

Pharmacologic Treatment of Alopecia

Effective Date:	Apr. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 24, 2025	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Alopecia areata is a chronic, immune-mediated disorder characterized by a sudden loss of patches of hair on the scalp and other body area. Typically, this condition does not result in permanent harm to the hair follicles. While most individuals experience regrowth of hair in the affected areas over time, the process can take a long time. It is estimated that about 1 out of 50 people will suffer from the alopecia area at some point in their life. This condition affects both men and women equally and can occur at any age. While alopecia areata is non-life-threating, it can have psychosocial effects on individuals. The FDA has approved Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), and Olumiant (baricitinib) for the indication of severe alopecia areata. This policy describes when these drugs for alopecia may be considered medically necessary. Even though drug treatment exists, it does not mean it is covered; the member's contract determines this. This policy describes when drugs used in alopecia may be considered medically necessary if covered by the member's contract.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity

Leqselvi (deuruxolitinib) oral	**Leqselvi (deuruxolitinib) may be considered medically necessary for adult individuals when the following criteria are met:**
	• The individual is aged 18 years or older
	AND
	• Has a diagnosis of severe alopecia areata
	AND
	• Has had greater than or equal to 50% of scalp hair loss
	AND
	• Has had an inadequate response or relapse after at least one of the following for alopecia areata:
	  ○ Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP))
	  ○ Topical corticosteroid (e.g., betamethasone dipropionate)
	AND
	• Has current alopecia areata episodes lasting at least 6 months without spontaneous re-growth
	AND
	• Is NOT using Leqselvi (deuruxolitinib) in combination with any of the following:
	  ○ Janus Kinase (JAK) inhibitors (e.g., Xeljanz/Xeljanz XR (tofacitinib))
	  ○ Biologic immunomodulators
	  ○ Cyclosporine
	  ○ Potent immunosuppressants (e.g., methotrexate, azathioprine)
	AND
	• Maximum prescribed dose is 16 mg daily
	AND
	• Medication is being prescribed by or in consultation with a dermatologist
	
	Note: Drugs for alopecia are excluded under many benefit plans. Therefore, the use of Leqselvi (deuruxolitinib) for alopecia areata may not be covered.

Drug	Medical Necessity
	Please refer to the applicable benefit plan document to determine benefit availability (see **Benefit Application** for further information)
Litfulo (ritlecitinib) oral	**Litfulo (ritlecitinib) may be considered medically necessary for adult and adolescent individuals when the following criteria are met:** • The individual is aged 12 years or older **AND** • Has a diagnosis of severe alopecia areata **AND** • Has had greater than or equal to 50% of scalp hair loss **AND** • Has had an inadequate response or relapse after at least one of the following for alopecia areata: ○ Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP)) ○ Topical corticosteroid (e.g., betamethasone dipropionate) **AND** • Has current alopecia areata episodes lasting at least 6 months without spontaneous re-growth **AND** • Is NOT using Litfulo (ritlecitinib) in combination with any of the following: ○ Janus Kinase (JAK) inhibitors (e.g., Xeljanz/Xeljanz XR (tofacitinib)) ○ Biologic immunomodulators ○ Cyclosporine ○ Potent immunosuppressants (e.g., methotrexate, azathioprine) **AND** • Maximum prescribed dose is 50 mg orally once daily **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** Drugs for alopecia are excluded under many benefit plans. Therefore, the use of Litfulo (ritlecitinib) for alopecia areata may not be covered. Please

Drug	Medical Necessity
	refer to the applicable benefit plan document to determine benefit availability (see **Benefit Application** for further information)
Olumiant (baricitinib) oral	**Olumiant (baricitinib) may be considered medically necessary for adult individuals when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has a diagnosis of severe alopecia areata **AND** • Has had greater than or equal to 50% of scalp hair loss **AND** • Has had an inadequate response or relapse after at least one of the following for alopecia areata: ○ Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP)) ○ Topical corticosteroid (e.g., betamethasone dipropionate) **AND** • Has current alopecia areata episodes lasting at least 6 months without spontaneous re-growth **AND** • Is NOT using Olumiant (baricitinib) in combination with any of the following: ○ Janus Kinase (JAK) inhibitors (e.g., Xeljanz/Xeljanz XR (tofacitinib)) ○ Biologic immunomodulators ○ Cyclosporine ○ Potent immunosuppressants (e.g., methotrexate, azathioprine) **AND** • Maximum prescribed dosage is 4 mg once daily **AND** • Medication is being prescribed by or in consultation with a dermatologist **Note:** Drugs for alopecia are excluded under many benefit plans. Therefore, the use of Olumiant (baricitinib) for alopecia areata may not be covered. Please refer to the applicable benefit plan document to determine benefit availability (see **Benefit Application** for further information)

Drug	Investigational
Leqselvi (deuruxolitinib) **Litfulo (ritlecitinib)** **Olumiant (baricitinib)**	**All other uses of drug name for conditions not outlined in this policy and policy 5.01.550 are considered investigational.** **The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), and Olumiant (baricitinib) may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), and Olumiant (baricitinib) may be approved up to 12 months when clinical benefit/response at the time of re-authorization show:** • Chart notes documenting greater than or equal to 50% hair regrowth

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain diagnosis of alopecia areata, prior treatments for alopecia areata,

Coding

N/A

Related Information

Consideration of Age

The age stated in this policy for which Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), and Olumiant (baricitinib) are considered medically necessary are based on the ages approved in the FDA labeling.

Benefit Application

Many benefit plans exclude drugs for alopecia. Please refer to the applicable benefit plan to determine benefit availability and the terms, conditions, and limitations of coverage. For questions about benefit information, providers should contact customer service using the telephone number on the back of the member's identification card.

Evidence Review

Summary of Evidence

Leqselvi (deuruxolitinib)

Deuruxolitinib is a Janus kinase inhibitor. JAKs mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. JAK signaling involves recruitment of STATs (signal transducers and activators of transcription) to cytokine receptors, activation and subsequent localization of STATs to the nucleus leading to modulation of gene expression.

The efficacy and safety of deuruxolitinib was evaluated in two multicenter, randomized, double-blind, placebo-controlled phase 3 clinical trials (AA-1 and AA-2), which evaluated a total of 1,209 adult subjects with alopecia areata (AA), who had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than six months. In both trials, subjects received Leqselvi 8 mg twice daily, deuruxolitinib 12 mg twice daily, or placebo twice daily for 24 weeks.

The primary efficacy endpoint for both trials assessed the proportion of subjects who achieved at least 80% hair coverage (SALT score of ≤20) at Week 24. Key secondary outcomes included the percentage of responders (defined as "satisfied" or "very satisfied") at Week 24 on the

Satisfaction of Hair Patient-Reported Outcome (SPRO) and the percentage of subjects achieving an absolute SALT score of ≤20 at Week 20, 16, 12, and 8.

At the end of week 24, a greater proportion of subjects had a SALT ≤20 response (80% or more scalp hair) and SALT ≤10 response (90% or more scalp hair) with Leqselvi 8 mg twice daily compared to placebo.

Safety

The safety of Leqselvi was evaluated in three randomized, placebo-controlled clinical trials, two open-label trials, and two long-term extension trials in adult subjects with severe alopecia areata. In these clinical trials, the most common adverse effects were headache, acne, nasopharyngitis, increased blood creatinine phosphokinase, hyperlipidemia, fatigue, and skin/soft tissue infections.

Leqselvi is not recommended for use in individuals with severe renal impairment or hepatic impairment.

Leqselvi is contraindicated in individuals who are CYP2C9 poor metabolizers or who are using moderate or strong CYP2C9 inhibitors.

Litfulo (ritlecitinib)

Ritlecitinib is a kinase inhibitor and irreversibly inhibits Janus Kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEX) kinase family by inhibiting the adenosine triphosphate (ATP) binding site. Ritlecitinib also inhibits the phosphorylation and activation of STATs. Also, ritlecitinib inhibits the signaling of immune receptors dependent on TEC kinase family members.

The efficacy and safety of Litfulo was evaluated in a randomized, double-blind, placebo-controlled trial where 718 individuals aged 12 years and older with alopecia areata with ≥ 50% scalp hair loss, including alopecia totalis (AT) and alopecia universalis (AU).

In this trial, the individuals were randomized to receive either Litfulo 200 mg once daily for 4 weeks and then 50 mg once daily for 44 weeks, or Litfulo 200 mg once daily for 4 weeks and then 30 mg once daily for 44 weeks, or Litfulo 50 mg once daily for 48 weeks, or Litfulo 30 mg once daily for 48 weeks, or Litfulo 10 mg once daily for 48 weeks, or placebo for 24 weeks and

then Litfulo 200 mg once daily for 4 weeks and 50 mg once daily for 20 weeks, or placebo for 24 weeks followed by 50 mg once daily for 24 weeks.

The primary efficacy endpoint was based on the SALT score. The primary efficacy endpoint was a proportion of individuals with SALT $\leq$ 20 response (20% or less scalp hair loss) at week-24 and proportion of individuals with SALT $\leq$ 10% (10% or less scalp hair loss) at week-24.

At the end of week-24, SALT $\leq$ 20 response was 23% in Litfulo 50 mg QD group and 1.6% in the placebo group. At the end of week-24, SALT $\leq$ 10 response was 13.4% in the Litfulo 50 mg QD group compared to 1.5% in the placebo group.

Safety

The safety of Litfulo was evaluated in one clinical trial – AA1. In this clinical trial, the most common adverse effects were headache, diarrhea, acne, rash, urticaria, folliculitis, atopic dermatitis, pyrexia, dizziness, increased level of blood creatine phosphokinase, herpes zoster, reduced level of red blood cell count and stomatitis.

Litfulo also includes the black box warning related to serious infection, mortality, malignancy, thrombosis, and major adverse cardiovascular events.

Litfulo is not recommended for individuals with severe hepatic impairment.

Olumiant (baricitinib)

Olumiant (baricitinib) belongs to the drug class of Janus Kinase (JAK) Inhibitors. JAKs are intracellular enzymes which transmit signals from cytokines or other growth factor-receptor interactions on the cellular membrane to enhance the process of hematopoiesis and immune cell function. Also, JAKS phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression.

Baricitinib works by modulating the JAKs signaling pathway and preventing the activation of STATs. Baricitinib also inhibits the JAKs potency at JAK1, JAK2 and TYK2 compared to JAK3.

The safety and efficacy of baricitinib was evaluated in the randomized, double-blind, placebo-controlled trials (AA-1 and AA02), where 1200 individuals with alopecia areata (AA), with at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months. In both trials, the individuals were randomized to receive either Olumiant 2 mg, Olumiant 4 mg or placebo.

The primary efficacy endpoint of these trials was the proportion of individuals who achieved at least 80% scalp hair coverage at week 36. The secondary efficacy endpoint was to evaluate proportion of individuals who achieved at least 90% scalp hair coverage at week 36, assessments of eyebrow and eyelash hair loss, and individuals with Scalp Hair Assessment PRO score of 0 or 1 with at least 2-point reduction on the 5-point scale.

At the end of week 36, the proportion of individuals who achieved at least 80% scalp hair coverage was 5% in the placebo group, 22% in the Olumiant 2 mg/day group, and 35% in the Olumiant 4 mg/day group in clinical trials. At the end of week 36, the proportion of individuals who achieved at least 90% scalp hair coverage was 4% in the placebo group, 13% in the Olumiant 2 mg/day group, and 26% in the Olumiant 4 mg/day group.

At the end of week 36, the individuals with Scalp Hair Assessment PRO score 0 or 1 with at least 2-point reduction on the 5-point scale was 5% in the placebo group, 16% in the Olumiant 2 mg/day group, and 33% in the Olumiant 4 mg/day group. Also, the individuals with substantial eyebrow and eyelash hair loss at baseline, a great improvement in the eyebrow and eyelash hair growth was seen in Olumiant 4 mg group at week-36.

Safety

The safety of Olumiant was evaluated in two clinical trials – AA1 and AA2. In these trials, the most common adverse effects were upper respiratory tract infections (URTI), headache, acne, hyperlipidemia, increased level of blood creatine phosphokinase and urinary tract infection.

Olumiant also includes the black box warning related to serious infection, mortality, malignancy, thrombosis, and major adverse cardiovascular events.

Olumiant is not recommended to be used in individuals with hepatic impairment and renal impairment.

2024 Update

Reviewed prescribing information for all drugs listed in policy. Added coverage criteria for Leqselvi (deuruxolitinib) for the treatment of severe alopecia areata. Added summary of evidence for Leqselvi.

2025 Update

Reviewed prescribing information for all drugs listed in policy. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

References

1. Leqselvi (deuruxolitinib) [Prescribing Information]. Whippany, NJ; Sun Pharmaceutical Industries, Inc. Revised July 2024.
2. Litfulo (ritlecitinib) [Prescribing Information]. New York, NY; Pfizer Labs. Revised June 2023.
3. Olumiant (baricitinib). [Prescribing Information]. Eli Lily and Company. Revised June 2022.

History

Date	Comments
09/01/23	New policy, approved August 8, 2023. Added coverage criteria for Olumiant (baricitinib) and Litfulo (ritlecitinib) for the treatment of severe alopecia areata.
12/01/24	Annual Review, approved November 12, 2024. Added coverage criteria for Leqselvi (deuruxolitinib) for the treatment of severe alopecia areata.
04/01/25	Annual Review, approved March 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to

the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.