

PHARMACY – 5.01.637

Pharmacologic Treatment of Alopecia

Effective Date: Sept. 1, 2023

Last Revised: Aug. 8, 2023

Replaces: N/A

RELATED MEDICAL POLICIES:

None

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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-threatening, it can have psychosocial effects on individuals. The FDA has approved Olumiant (baricitinib) and Litfulo (ritlicitinib) 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
Olumiant (baricitinib) oral	<p>Olumiant (baricitinib) may be considered medically necessary for adult individuals when the following criteria are met:</p> <ul style="list-style-type: none"> Individual has a diagnosis of severe alopecia areata <p>AND</p> <ul style="list-style-type: none"> Individual has $\geq 50\%$ of scalp hair loss <p>AND</p> <ul style="list-style-type: none"> Individual has had an inadequate response or relapse after at least one of the following for alopecia areata: <ul style="list-style-type: none"> Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP)) Topical corticosteroid (e.g., betamethasone dipropionate) <p>AND</p> <ul style="list-style-type: none"> Individuals has current alopecia areata episodes lasting at least 6 months without spontaneous re-growth <p>AND</p> <ul style="list-style-type: none"> Individual is NOT using Olumiant (baricitinib) in combination with any of the following: <ul style="list-style-type: none"> Janus Kinase (JAK) inhibitors (e.g., Xeljanz/Xeljanz XR (tofacitinib)) Biologic immunomodulators Cyclosporine Potent immunosuppressants (e.g., methotrexate, azathioprine) <p>AND</p> <ul style="list-style-type: none"> The maximum prescribed dosage is 4 mg once daily <p>AND</p> <ul style="list-style-type: none"> Medication is being prescribed by or in consultation with a dermatologist <p>Note: Drugs for alopecia are excluded under many benefit plans. Therefore 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)</p>



Drug	Medical Necessity
Litfulo (ritlecitinib) oral	<p>Litfulo (ritlecitinib) may be considered medically necessary for adults and adolescents 12 years and older when the following criteria are met:</p> <ul style="list-style-type: none"> • Individual has a diagnosis of severe alopecia areata <p>AND</p> <ul style="list-style-type: none"> • Individual has $\geq 50\%$ of scalp hair loss <p>AND</p> <ul style="list-style-type: none"> • Individual has had an inadequate response or relapse after at least one of the following for alopecia areata: <ul style="list-style-type: none"> ○ Topical immunotherapy (e.g., diphenylcyclopropenone (DPCP)) ○ Topical corticosteroid (e.g., betamethasone dipropionate) <p>AND</p> <ul style="list-style-type: none"> • Individuals has current alopecia areata episodes lasting at least 6 months without spontaneous re-growth <p>AND</p> <ul style="list-style-type: none"> • Individual is NOT using Litfulo (ritlecitinib) in combination with any of the following: <ul style="list-style-type: none"> ○ Janus Kinase (JAK) inhibitors (e.g., Xeljanz/Xeljanz XR (tofacitinib)) ○ Biologic immunomodulators ○ Cyclosporine ○ Potent immunosuppressants (e.g., methotrexate, azathioprine) <p>AND</p> <ul style="list-style-type: none"> • The maximum prescribed dose is 50mg orally once daily <p>AND</p> <ul style="list-style-type: none"> • Medication is being prescribed by or in consultation with a dermatologist <p>Note: Drugs for alopecia are excluded under many benefit plans. Therefore use of Litfulo (ritlecitinib) 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)</p>



Drug	Investigational
Olumiant (baricitinib) Litfulo (ritlecitinib)	All other uses of drug name for conditions not outlined in this policy and policy 5.01.550 are considered investigational.

Length of Approval	
Approval	Criteria
Initial authorization	Olumiant (baricitinib) and Litfulo (ritlecitinib) may be approved up to 12 months.
Re-authorization criteria	Future re-authorization of Olumiant (baricitinib) and Litfulo (ritlecitinib) may be approved up to 1 year in duration when clinical benefit/response at the time of re-authorization show: <ul style="list-style-type: none"> • Chart notes documenting \geq 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: <ul style="list-style-type: none"> • 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 Olumiant (baricitinib) and Litfulo (ritlecitinib) 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

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.

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 $\geq 50\%$ 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.

References

1. Litfulo (ritlecitinib) [Prescribing Information]. New York, NY; Pfizer Labs. Revised June 2023.
2. Olumiant (baricitinib). [Prescribing Information]. Eli Lilly 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.



Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2023 Premera All Rights Reserved.

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.



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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/online-services/cc/pub/complaintinformation.aspx>.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

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MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totagi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

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