Effective Date **1/1/2024**
Next Review Date… **1/1/2025**
Coverage Policy Number **IP0589**

Ritlecitinib

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for ritlecitinib (**Litfulo**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Ritlecitinib (Litfulo) is considered medically necessary when the following are met:

Alopecia Areata (includes alopecia universalis and alopecia totalis). Individual meets **ALL** of the following criteria:

A. Age 12 years or older
B. Documentation of a current episode of alopecia areata lasting for at least 6 months
C. Documentation of at least 50% scalp hair loss prior to initiating ritlecitinib
D. **ONE** of the following:
    i. Documentation of failure, contraindication or intolerance to **ONE** of the following:

a. Conventional systemic therapy used for at least 3 months (for example, corticosteroids, methotrexate, cyclosporine)
b. Prescription topical corticosteroids used for at least 28 days
c. Intralesional corticosteroids used for at least 3 months

ii. Already tried Olumiant (baricitinib tablets)

E. Medication is prescribed by, or in consultation with, a dermatologist

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of ritlecitinib (Litfulo) is considered medically necessary for Alopecia Areata when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 6 months
Reauthorization approval duration: up to 6 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Causes of hair loss other than alopecia areata.** Olumiant is not indicated for the treatment of other causes of hair loss other than alopecia areata.[1]

2. **Concurrent Use with a Biologic, Targeted Synthetic DMARD or potent immunosuppressant.** The use of ritlecitinib is not recommended for use in combination with biologic immunomodulators, cyclosporine or other potent immunosuppressants (see Appendix for examples)[1]. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of evidence for additive efficacy.

3. **Concurrent Use with a Biologic Immunomodulator.** Litfulo is not recommended in combination with biologic immunomodulators (for example, Adbry [tralokinumab-ldrm subcutaneous injection], Cinqair [reslizumab intravenous], Dupixent [dupilumab subcutaneous injection], Fasenra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection], Tezspire [tezepelumab-ekko subcutaneous injection], and Xolair [omalizumab subcutaneous injection]).[1]

4. **Concurrent Use with an Oral or Topical Janus Kinase Inhibitor (JAKi).**[1]
Litfulo should not be administered in combination with another JAKi (for example, Olumiant [baricitinib tablets], Rinvoq [upadacitinib tablets], Xeljanz [tofacitinib tablets], and Opzelura [ruxolitinib cream]). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.

Background

OVERVIEW
Litfulo, a kinase inhibitor, is indicated for the treatment of **severe alopecia areata** in patients ≥ 12 years of age.[1] It inhibits the janus kinase 3 (JAK) and tyrosine kinase expressed in hepatocellular carcinoma (TEC) pathways.

Guidelines
Although specific drugs are not mentioned, JAK inhibitors (JAKis) as a therapeutic class are addressed in an international expert opinion on treatments for alopecia areata (2020).[2] JAKis are identified among the therapies for treatment of extensive hair loss. First-line treatments for adults include topical and/or systemic corticosteroids. Steroid-sparing therapies to mitigate the risk associated with prolonged use of corticosteroids include cyclosporine, methotrexate, azathioprine, and JAKis. Based on the expert opinion, JAKis are considered the ideal option amongst systemic, steroid-sparing agents.

References

1. Litfulo® capsules [prescribing information]. New York, NY: Pfizer; June 2023.
2. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. *J Am Acad Dermatol*. 2020;83:123-30.

APPENDIX

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Ankylosing Spondylitis**	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Ulcerative Colitis**
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Opzelura	--	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√[#]	√	--	√	--	√
Xeljanz oral solution	--	√[#]	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; [#] Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√[^]	--
Actemra Subcutaneous	√	√[^]	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√[#]	√
Orencia Subcutaneous	√	√[#]	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; [#] Indicated in polyarticular JIA.