Drug Coverage Policy

Effective Date……09/01/2025
Coverage Policy Number……IP0680
Policy Title……Litfulo Prior Authorization Policy

Inflammatory Conditions – Litfulo Prior Authorization Policy

- Litfulo™ (ritlecitinib capsules – Pfizer)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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
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 high- or super-high potency topical corticosteroids and/or systemic corticosteroids. Steroid-sparing therapies to mitigate the risks associated with prolonged use of corticosteroids include cyclosporine, methotrexate, azathioprine, and JAKis. Based on expert opinion, JAKis are considered the ideal option amongst systemic, steroid-sparing agents.

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Policy Statement
Prior Authorization is recommended for benefit coverage of Litfulo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Litfulo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Litfulo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Litfulo is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Alopecia Areata.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   Note: Alopecia universalis and alopecia totalis are subtypes of alopecia areata.
   A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
      i. Patient is ≥ 12 years of age; AND
      ii. Patient has a current episode of alopecia areata lasting for ≥ 6 months; AND
      iii. Patient has ≥ 50% scalp hair loss; AND
      iv. Patient has tried at least ONE of the following for alopecia areata (a or b):
         a) Conventional systemic therapy; OR
            Note: Examples of conventional systemic therapies include corticosteroids, methotrexate, and cyclosporine. An exception to the requirement for a trial of one conventional systemic agent can be made if the patient has already tried Leqselvi (deuruxolitinib tablets) or Olumiant (baricitinib tablets).
         b) High- or super-high potency topical corticosteroid; AND
      v. The medication is prescribed by or in consultation with a dermatologist; OR
   B) Patient is Currently Receiving Litfulo. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
      i. Patient is ≥ 12 years of age; AND
      ii. Patient has been established on Litfulo for at least 6 months; AND
         Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

iii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss; AND

iv. According to the prescriber, the patient continues to require systemic therapy for treatment of alopecia areata.
Note: International consensus states that systemic treatment is best discontinued once complete regrowth has been achieved and maintained for 6 months or when regrowth is sufficient to be managed topically.

Conditions Not Covered

Litfulo for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

2. **Concurrent Use with a Topical Janus Kinase Inhibitor (JAKi).**[1] Litfulo should not be administered in combination with a topical JAKi. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects and lack of evidence for additive efficacy.
Note: Examples include Opzelura (ruxolitinib cream).

3. **Concurrent Use with a Biologic Immunomodulator.** Litfulo is not recommended in combination with biologic immunomodulators.[1]
Note: Examples include 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).

4. **Concurrent Use with Other Potent Immunosuppressants** (e.g., cyclosporine, azathioprine).[1] Co-administration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

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

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC

Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO, AS, nr-axSpA, PsA
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, CD, UC

Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Annual Revision	No criteria changes.	09/01/2025

The policy effective date is in force until updated or retired.