PFIZER DERMATOLOGY
patient access™

Litfulo® (ritlecitinib)

Navigating the Prior Authorization (PA) & Appeals Process

This guide is designed to work through the policies of a patient's health plan for coverage of LITFULO® (ritlecitinib). This process may involve submitting a PA or an appeal, which you can learn about below.

Prior Authorization

Before you submit, it's best to check with your patient's health plan to ensure you have a list of their specific criteria.

Step 1 – Obtain necessary PA forms through any of the following:

✔ Patient's health plan website, calling a health plan representative, or Pharmacy Benefit Manager (PBM)
✔ CoverMyMeds
✔ Pfizer Dermatology Patient Access™ (Hub) or Field Reimbursement Manager (FRM)
✔ Specialty Pharmacy

Step 2 – Include all required information when submitting a PA

Complete all sections of the PA form(s) including:

✔ **Patient Information:** Name, address, DOB, SSN

✔ **Insurer Information:** Name of policy holder, ID #, Group #, plan address, plan phone, copy of front and back of insurance card, completed and signed PA form

✔ **HCP info:** HCP name, specialty, Tax ID #, office address, phone/fax #, NPI #

✔ **Clinical Documentation:** Patient's disease severity and progression rate (e.g., moderate, severe*), location and/or percent of patient's scalp hair loss due to diagnosis (SALT score)

*Severity such as low, moderate, severe is defined as chart or medical record documentation with or without SALT score >50% scalp hair loss measured > 6 months.

Refer to the chart below for additional information to include for your patient with alopecia areata.

Example of PA criteria	Example information that MAY be appropriate to provide
Patient's current medical history	✔Date of diagnosis ✔History of alopecia areata ✔Duration of disease ✔Length of time the patient has gone without spontaneous hair regrowth
Patient's current diagnosis indicated with appropriate ICD-10 code†	L63 (Alopecia Areata); L63.0: Alopecia (Capitis) Totalis; L63.1: Alopecia Universalis; L63.2: Ophiasis; L63.8: Other Alopecia Areata; L63.9: Alopecia Areata, Unspecified. You are solely responsible for determining the billing and coding information. The use of this information does not guarantee payment or that any payment received will cover the costs.
Patient's disease severity and progression rate	✔Hair loss: location and/or percent of patient's scalp hair loss due to the diagnosis (SALT score). For additional information on SALT scores, see page 4
Testing results for clinical parameters (if required by health plan)	✔Tuberculosis (TB) test ✔Liver enzymes ✔Complete blood count (CBC) ✔Hepatitis panel
Medication treatment history	Please list names, doses, plan-specific duration of previous therapies and treatment period requirements (e.g., within the last 12 months), and administration dates of ALL previously tried and failed therapies, including but not limited to: ✔Topical ✔Oral ✔Systemic
Confirmation of discontinuation of previous treatments	List the medication(s) and reason(s) for discontinuation including inadequate responses, contraindications, inadvisable therapies, failed therapies, intolerance, and patient adherence or compliance issues
Any additional relevant clinical information	Clinical studies or relevant literature justifying treatment

†The information available here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. This information is subject to change. Payer coding requirements may vary or change over time, so it is important to regularly check with each payer as to payer-specific requirements. Codes are provided for informational purposes only. List may not be comprehensive. Codes are not intended to encourage or suggest a medication use that is inconsistent with FDA-approved uses.

INDICATION

LITFULO is a kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), AND THROMBOSIS
SERIOUS INFECTIONS
Patients treated with LITFULO are at increased risk of serious bacterial, fungal, viral and opportunistic infections that may lead to hospitalization or death, including tuberculosis (TB). The most frequent serious infections reported with LITFULO have been appendicitis, COVID-19 infection (including pneumonia), and sepsis. Among opportunistic infections, multi-dermatomal herpes zoster was reported with LITFULO.

(cont'd on page 2)

Please see full Important Safety Information for LITFULO® on page 5 and full Prescribing Information, including BOXED WARNING, and Medication Guide at LITFULOHCP.com.

Prior Authorization (cont.)

Step 3 – Consider providing supplemental documentation

To make the strongest case for your patient, consider including a **letter of medical necessity** summarizing your professional opinion of why the patient's recent symptoms, severity of condition, and/or impact of disease warrant treatment. Your patient can also write their own letter of medical necessity to provide additional support. A sample patient narrative letter can be found **here**.

✔ Photos ✔ Impact on daily life ✔ Pull test

Step 4 – Submit the PA to the patient's health plan

PA available faster* through CoverMyMeds

CoverMyMeds is a no-cost solution to help support providers through a Pfizer Dermatology PA request.

*Compared to phone and fax

Step 5 – Receive a decision

If the patient is enrolled in Pfizer Dermatology Patient Access™ (PDPA), send the response to the Hub. **If approved,** the patient's LITFULO prescription will be fulfilled by a Specialty Pharmacy. **If denied,** continue to the reverse side.

To receive additional information from Pfizer during the PA and appeal process:

Visit PDPAresources.com for helpful materials and resources

Scan the QR code to contact your local Field Reimbursement Manager (FRM)

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS (cont.)

Avoid use of LITFULO in patients with an active, serious infection. Consider the risks and benefits of treatment prior to initiating LITFULO in patients:

- with chronic or recurrent infection
- who have been exposed to tuberculosis (TB)
- with a history of serious infection or an opportunistic infection
- who have resided or traveled in areas of endemic TB or mycoses, or
- with underlying conditions that may predispose them to infection

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with LITFULO. Interrupt treatment if a patient develops a serious or opportunistic infection. A patient who develops a new infection during treatment with LITFULO should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient, appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored. LITFULO may be resumed once the infection is controlled.

(cont'd on page 3)

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Appeals

Step 1 – Review the reason(s) for denial

If the PA is denied, submit to PDPA. Please refer to the denial letter to find the reason for denial, as this may help with your appeal.

Examples of denial reasons due to the omission of:

- ✗ Documentation supporting diagnosis and disease severity
- ✗ Documentation on prior failed therapies with duration and information for discontinuation for step therapy payer requirements
- ✗ Missing lab work results
- ✗ Missing TB test
- ✗ Missing SALT score
- ✗ Clinical testing results
- ✗ Accurate ICD-10 diagnosis code information
- ✗ Notes on contraindications to prior therapies or inappropriate therapies based on prescriber's clinical judgment
- ✗ Ruling out other causes of hair loss

Step 2 – Include supporting documentation with the appeal

✔ Photos ✔ Impact on daily life ✔ Pull test

A successful appeal may include information found in the resources below:

- Sample letter of medical necessity
  - This can be used as a reference when submitting an appeal letter
- Patient narrative letter
  - An example letter that a patient could use to support an appeal

Step 3 – Submit the appeal to your patient's health plan

Step 4 – Receive a decision

If approved, the patient's LITFULO prescription will be fulfilled by a Specialty Pharmacy.

If denied, consider any additional materials noted in Step 1 to submit another appeal, and contact Pfizer Dermatology Patient Access™ at 1-833-956-3376 for questions about the appeals process.

Step 5 – Reauthorization

Your patient's health plan may require reauthorization after a period of time (3–18 months), including a request for documentation of improvement in hair growth in the patient chart, improved SALT score, or photographs.

(cont'd on page 5)

Understanding SALT scores in patients with alopecia areata[2,3]

SALT measures scalp hair loss on a scale of 0 to 100

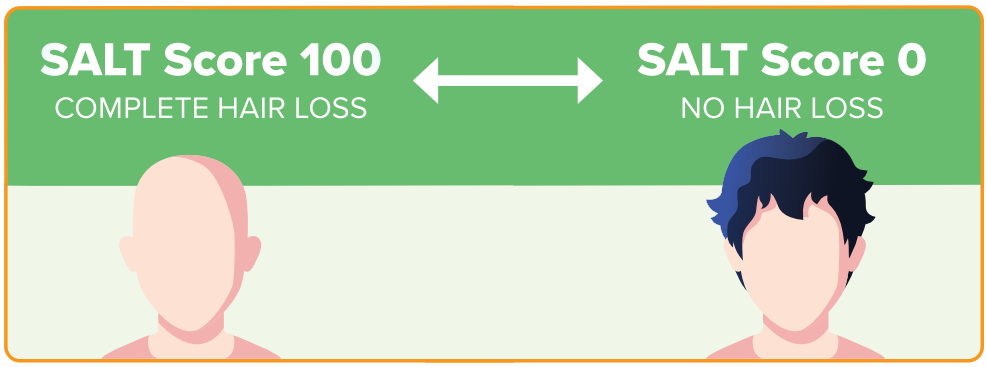


Image is for illustrative purposes only and is not representative of specific patients or efficacy data.

SALT score

Interpretation of SALT scores:

SALT score 100: Complete hair loss

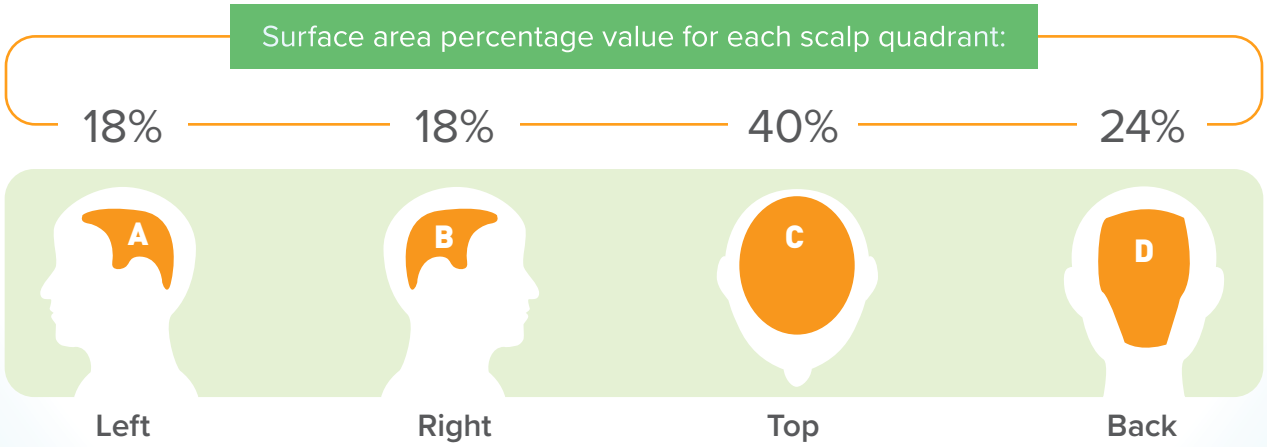
SALT score 50: 50% hair loss

SALT score ≤20: 20% or less hair loss

SALT score 0: No hair loss

Calculating SALT scores

SALT score = percentage of scalp hair loss in the respective quadrant multiplied by percentage of scalp surface area of the respective quadrant. The product of each quadrant is then added together to determine a total score.



SALT=Severity of Alopecia Tool.

For example, if a patient has 20% hair loss on the left quadrant, 25% on the right, 30% on top, and 35% on the back, the SALT score would be: (18 * 0.20) + (18 * 0.25) + (40 * 0.30) + (24 * 0.35) = 28.5

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SERIOUS INFECTIONS

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Tuberculosis

LITFULO should not be given to patients with active TB. Screen patients for TB before starting and monitor during therapy. Anti-TB therapy should be started prior to initiating therapy with LITFULO in patients with a new diagnosis of latent TB or previously untreated latent TB. In patients with a negative latent TB test, consider anti-TB therapy before initiating treatment with LITFULO in those at high risk and consider screening patients at high risk for TB during treatment with LITFULO.

Viral Reactivation

Viral reactivation, including cases of herpes virus reactivation (eg, herpes zoster), was reported in clinical trials. If a patient develops herpes zoster, consider interrupting treatment until the episode resolves. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with LITFULO. Patients with evidence of HIV infection or hepatitis B or C infection were excluded from clinical trials.

MORTALITY

In a large, randomized, postmarketing safety study of another Janus kinase (JAK) inhibitor in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in RA patients treated with the JAK inhibitor compared with tumor necrosis factor (TNF) blockers. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with LITFULO. **LITFULO is not approved for use in RA patients.**

MALIGNANCIES AND LYMPHOPROLIFERATIVE DISORDERS

Malignancies, including non-melanoma skin cancer (NMSC), were observed in clinical trials of LITFULO.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding NMSC) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers. In this study, current or past smokers had an additional increased risk of overall malignancies.

The risks and benefits of ritlecitinib treatment should be considered prior to initiating or continuing therapy in patients with a known malignancy other than successfully treated NMSC or cervical cancer.

Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of MACE (defined as cardiovascular death, non-fatal myocardial infarction [MI], and non-fatal stroke) was observed with the JAK inhibitor compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with LITFULO, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue LITFULO in patients that have experienced an MI or stroke.

THROMBOEMBOLIC EVENTS

Thrombosis has occurred in patients treated with LITFULO. An event of pulmonary embolism (PE) was reported in a patient receiving LITFULO. In a ritlecitinib higher dosing group, 1 patient reported an event of retinal artery occlusion.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of overall thrombosis, deep vein thrombosis, arterial thrombosis and PE were observed with the JAK inhibitor compared to those treated with TNF blockers.

Avoid LITFULO in patients who may be at increased risk of thrombosis. If symptoms of thrombosis or embolism occur, patients should interrupt LITFULO and be evaluated promptly and treated appropriately.

CONTRAINDICATION

LITFULO is contraindicated in patients with known hypersensitivity to ritlecitinib or any of its excipients.

HYPERSENSITIVITY

Serious reactions, including anaphylactic reactions, urticaria, and rash have been observed in patients receiving LITFULO in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue LITFULO and institute appropriate therapy.

LABORATORY ABNORMALITIES

Treatment with LITFULO was associated with decreases in lymphocytes and platelets. Prior to LITFULO initiation, perform absolute lymphocyte count (ALC) and platelet count. After initiating treatment with LITFULO, treatment interruption or discontinuation is recommended based on ALC and platelet count abnormalities.

Liver Enzyme Elevations: Treatment with LITFULO was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) and aspartate aminotransferase (AST) ≥5 times the upper limit of normal were observed in patients in LITFULO clinical trials. Evaluate at baseline and thereafter according to routine patient management. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt LITFULO until this diagnosis is excluded.

Creatine Phosphokinase (CPK) Elevations: Treatment with LITFULO was associated with increased incidence of CPK elevation compared to placebo.

VACCINATIONS

No data are available on the response to vaccination in patients receiving LITFULO. Use of live attenuated vaccines should be avoided during or shortly prior to initiating treatment. Prior to initiating LITFULO, it is recommended that patients be brought up to date with all immunizations, including prophylactic herpes zoster vaccinations, in agreement with current immunization guidelines.

HEPATIC IMPAIRMENT

LITFULO is not recommended in patients with severe hepatic impairment.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥1%) are headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood creatine phosphokinase increased, herpes zoster, red blood cell count decreased, and stomatitis.

DRUG INTERACTIONS

LITFULO can increase plasma concentrations of CYP3A and CYP1A2 substrates. Consider additional monitoring and dose adjustment of CYP3A and CYP1A2 substrates where small concentration changes may lead to serious adverse reactions when used with LITFULO.

Coadministration with strong inducers of CYP3A is not recommended.

USE IN PREGNANCY

Available clinical trial data on LITFULO use in pregnant women are insufficient to identify a drug-associated risk from major birth defects, miscarriage or other adverse maternal or fetal outcomes. Advise pregnant females and females of reproductive potential to inform their healthcare providers if they are pregnant or intend to become pregnant during treatment with LITFULO.

If a patient becomes pregnant while receiving LITFULO, healthcare providers should report LITFULO exposure by calling 1-877-390-2940.

LACTATION

Advise women not to breastfeed during treatment with LITFULO and for 14 hours after the last dose.

Please see full Important Safety Information for LITFULO® on this page and full Prescribing Information, including BOXED WARNING, and Medication Guide at LITFULOHCP.com.