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 requirements.

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

✔ Patient's health plan website or calling a representative ✔ CoverMyMeds ✔ Pfizer Dermatology Patient Access™ (HUB) ✔ Specialty Pharmacy

### Step 2 – Include all required information when submitting a PA

Complete all sections of the PA form(s) including: ✔ Patient Information ✔ Health Plan Information ✔ Healthcare Provider Information

*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<br>✔ Duration of disease: length of time the patient has experienced hair loss due to the diagnosis |
| **Patient's current diagnosis indicated with appropriate ICD-10 code*** | L63 (Alopecia Areata) |
| **Patient's disease severity and progression rate** (severe) | ✔ Hair loss: location and/or percent of patient's scalp hair loss due to the diagnosis (SALT score) |
| **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 durations 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:<br>✔ Topical ✔ Oral ✔ Systemic ✔ Phototherapy ✔ Biologics |
| **Confirmation of discontinuation of previous treatments** | List the medication(s) and reason(s) for discontinuation including inadequate responses, contraindications, inadvisable therapies, and patient adherence or compliance issues |
| **Any additional relevant clinical information** | Clinical studies or relevant literature justifying treatment |

*Codes are provided for informational purposes only. List may not be comprehensive. The healthcare provider is responsible for determining appropriate coding for treatment of their patients. Codes are not intended to encourage or suggest a medication use that is inconsistent with FDA-approved uses.

### 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.

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

### Step 5 – Receive a decision

**If approved,** the patient's LITFULO prescription will be fulfilled by a Specialty Pharmacy. **If denied,** continue to the reverse side.

## 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.

**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

(*cont'd on page 2*)

**Please see full Important Safety Information for LITFULO™ on page 3 and full Prescribing Information, including BOXED WARNING, and Medication Guide at LITFULOHCP.com.**

# Appeal

## Step 1 – Review the reason(s) for denial

If the PA is denied and you are considering appealing the decision, read the common causes for denial.

**Examples of denial reasons due to the omission of:**

- X Documentation supporting diagnosis and disease severity
- X Documentation on prior failed therapies with duration and information for discontinuation for step therapy payer requirements
- X Clinical testing results
- X Accurate coding information
- X Notes on contraindications to prior therapies or inappropriate therapies based on prescriber's clinical judgment

## Step 2 – Include supporting documentation with the appeal

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. Make sure you reference the denial letter to address denial reason through the appeal process
- Additional letter for support
  - A letter written by the patient could provide appeal support

## 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 assistance.

**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 (cont'd)

**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.

**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.

(*cont'd on page 3*)

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## 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.

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

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- 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.

Tuberculosis

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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.

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