PFIZER DERMATOLOGY
patient access™

CIBINQO®
(abrocitinib) tablets

Navigating the Prior Authorization (PA) & Appeals Process

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

INDICATION

CIBINQO is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Limitations of Use: CIBINQO is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators or other immunosuppressants.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with CIBINQO may be at increased risk for developing serious infections that may lead to hospitalization or death. The most frequent serious infections reported with CIBINQO were herpes simplex, herpes zoster, and pneumonia.

If a serious or opportunistic infection develops, discontinue CIBINQO and control the infection.

Reported infections from JAK inhibitors used to treat inflammatory conditions:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral (including herpes zoster), and other infections due to opportunistic pathogens.**

(cont'd on page 3)

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

CoverMyMeds

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 atopic dermatitis.

Example of PA Criteria	Example information that MAY be appropriate to provide
Patient's current medical history	✔ Date of diagnosis ✔ Symptoms ✔ Clinical signs
Patient's current diagnosis indicated with appropriate ICD-10 code(s)*	L20 (Atopic Dermatitis), L20.8 (Other Atopic Dermatitis), L20.9 (Atopic Dermatitis, Unspecified)
Patient's disease severity and progression rate (moderate to severe)	✔ Percentage of body surface affected (BSA) ✔ Any sensitive areas affected (e.g., hands, feet, genitals/groin, head/neck, other) ✔ Eczema Area and Severity Index (EASI) score, Numerical Rating Scale (NRS) for itch severity, Investigator Global Assessment (IGA), or other methods of disease assessment
Testing results for clinical parameters (if required by health plan)	✔ Tuberculosis (TB) test ✔ Complete blood count (CBC) ✔ Viral hepatitis screening
Medication treatment history	List of all failed therapies
Confirmation of discontinuation of previous treatments	List the medication(s) and reason(s) for discontinuation including any 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. A sample letter of medical necessity and **patient narrative letter** can be found in the Forms and Resources section of the PDPA website.

PDPA Forms and Resources

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

Step 5 – Receive a decision

If approved, the patient's CIBINQO prescription will be fulfilled by a Specialty Pharmacy. **If denied**, continue to page 3. If the patient is enrolled in PDPA, send the appeal response to the Hub.

Appeal

Step 1 – Review the reason(s) for denial

If the PA is denied, submit to PDPA. To appeal the decision, begin by reading the common causes for denial below, then follow steps 2–4 if you choose to continue with the appeals process.

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 CIBINQO 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:

Scan the QR code or visit PDPAresources.com for helpful materials and resources

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

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SERIOUS INFECTIONS

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If a serious or opportunistic infection develops, discontinue CIBINQO and control the infection.

Reported infections from Janus kinase (JAK) inhibitors used to treat inflammatory conditions:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
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Avoid use of CIBINQO in patients with an active, serious infection, including localized infections. The risks and benefits of treatment with CIBINQO should be carefully considered prior to initiating therapy in patients with chronic or recurrent infections or those who have resided or traveled in areas of endemic tuberculosis or endemic mycoses.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIBINQO, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Consider yearly screening for patients in highly endemic areas for TB. CIBINQO is not recommended for use in patients with active TB. For patients with a new diagnosis of latent TB or prior untreated latent TB, or for patients with a negative test for latent TB but who are at high risk for TB infection, start preventive therapy for latent TB prior to initiation of CIBINQO.

Viral reactivation, including herpes virus reactivation (eg, herpes zoster, herpes simplex), was reported in clinical studies with CIBINQO. If a patient develops herpes zoster, consider interrupting CIBINQO until the episode resolves. Hepatitis B virus reactivation has been reported in patients receiving JAK inhibitors. Perform viral hepatitis screening in accordance with clinical guidelines before starting therapy and monitor for reactivation during therapy with CIBINQO. CIBINQO is not recommended for use in patients with active hepatitis B or hepatitis C.

MORTALITY

In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing another JAK inhibitor to TNF blocker treatment, a higher rate of all-cause mortality (including sudden cardiovascular death) was observed with the JAK inhibitor. CIBINQO is not approved for use in RA patients.

MALIGNANCIES

Malignancies, including non-melanoma skin cancer (NMSC), were reported in patients treated with CIBINQO. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. Perform periodic skin examination for patients who are at increased risk for skin cancer. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. CIBINQO is not approved for use in RA patients. 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. **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 CIBINQO, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

Major adverse cardiovascular events were reported in patients treated with CIBINQO. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. CIBINQO is not approved for use in RA patients. **Patients who are current or past smokers are at additional increased risk. Discontinue CIBINQO in patients that have experienced a myocardial infarction or stroke.**

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with CIBINQO, 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.

THROMBOSIS

Deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with CIBINQO. Thrombosis, including PE, DVT, and arterial thrombosis, have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of overall thrombosis, DVT, and PE were observed when compared with TNF blockers. CIBINQO is not approved for use in RA patients.

Avoid CIBINQO in patients that may be at increased risk of thrombosis. If symptoms of thrombosis occur, discontinue CIBINQO and treat patients appropriately.

CONTRAINDICATION

CIBINQO is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment.

LABORATORY ABNORMALITIES

Hematologic Abnormalities: Treatment with CIBINQO was associated with an increased incidence of thrombocytopenia and lymphopenia. Prior to CIBINQO initiation, perform a complete blood count (CBC). CBC evaluations are recommended at 4 weeks after initiation and 4 weeks after dose increase of CIBINQO. Discontinuation of CIBINQO therapy is required for certain laboratory abnormalities.

Lipid Elevations: Dose-dependent increase in blood lipid parameters were reported in patients treated with CIBINQO. Lipid parameters should be assessed approximately 4 weeks following initiation of CIBINQO therapy, and thereafter patients should be managed according to clinical guidelines for hyperlipidemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

IMMUNIZATIONS

Prior to initiating CIBINQO, complete all age-appropriate vaccinations as recommended by current immunization guidelines, including prophylactic herpes zoster vaccinations. Avoid vaccination with live vaccines immediately prior to, during, and immediately after CIBINQO therapy.

RENAL IMPAIRMENT

Avoid use in patients with severe renal impairment or end stage renal disease, including those on renal replacement therapy.

HEPATIC IMPAIRMENT

Avoid use in patients with severe hepatic impairment.

ADVERSE REACTIONS

Most common adverse reactions (≥1% with CIBINQO 100 mg) are nasopharyngitis, nausea, headache, herpes simplex, increased blood creatine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, impetigo, oropharyngeal pain, hypertension, influenza, gastroenteritis, and dermatitis contact.

Most common adverse reactions (≥1% with CIBINQO 200 mg and greater than CIBINQO 100 mg) are nausea, headache, herpes simplex, increased blood creatine kinase, dizziness, urinary tract infection, acne, vomiting, gastroenteritis, upper abdominal pain, abdominal discomfort, herpes zoster, and thrombocytopenia.

Inform patients that retinal detachment has been reported in CIBINQO clinical trials. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision.

DRUG INTERACTIONS

Monitor appropriately or dose titrate P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities when coadministered with CIBINQO. See Prescribing Information for clinically relevant drug interactions.

USE IN PREGNANCY

Available data from pregnancies reported in clinical trials with CIBINQO are not sufficient to establish a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Advise patients who can become pregnant that CIBINQO may impair fertility.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to CIBINQO during pregnancy. Pregnant women exposed to CIBINQO and health care providers are encouraged to call 1-877-311-3770 or visit CIBINQOPregnancyRegistry.com.

LACTATION

Advise patients not to breastfeed during treatment with CIBINQO and for one day after the last dose.

Please see full Prescribing Information, including BOXED WARNING, and Medication Guide for CIBINQO®.