Coding and Billing Information

for EUCRISA® (crisaborole), CIBINQO™ (abrocitinib), and LITFULO™ (ritlecitinib)

The tables below provide an overview of the codes that may be appropriate when billing for:

EUCRISA® or CIBINQO™

ICD-10-CM Codes for Atopic Dermatitis[1,a]	
ICD	**Description**
L20	Atopic Dermatitis
L20.8	Other Atopic Dermatitis
L20.9	Atopic Dermatitis, Unspecified

EUCRISA

INDICATION

EUCRISA is indicated for topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

EUCRISA is contraindicated in patients with known hypersensitivity to crisaborole or any component of the formulation.

Warnings and Precautions

Hypersensitivity reactions, including contact urticaria, have occurred in patients treated with EUCRISA and should be suspected in the event of severe pruritus, swelling, and erythema at the application site or at a distant site. Discontinue EUCRISA immediately and initiate appropriate therapy if signs and symptoms of hypersensitivity occur.

Adverse Reactions

The most common treatment-related adverse reaction occurring in clinical trials was application site pain, such as burning or stinging

Ointment: 20 mg of crisaborole per gram (2%) of white to off-white ointment

CIBINQO

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 Janus kinase (JAK) inhibitors, biologic immunomodulators, or with 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.

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LITFULO™

ICD-10-CM Codes for Alopecia Areata[1,a]	
ICD	**Description**
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

LITFULO

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.

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[a] The information provided in this table is intended for informational purposes only and is not a comprehensive description of potential coding requirements for the product. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her patients. The information provided in this sectionshould not be considered a guarantee of coverage or reimbursement for the product. The codes shown above are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use.

Reference: 1. Patterson L, Green L. *ICD-10-CM Expert for Physicians: the complete official code set 2022.* Draper, UT: Optum 360; 2022.

Please see full Prescribing Information and Patient Information for EUCRISA at EUCRISAHCP.com.

Please see additional Important Safety Information for CIBINQO on page 2 and full Prescribing Information, including BOXED WARNING, and Medication Guide at CIBINQOHCP.com.

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

IMPORTANT SAFETY INFORMATION FOR CIBINQO (cont'd)

SERIOUS INFECTIONS (cont'd)

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.**
- **Bacterial, viral (including herpes zoster), and other infections due to opportunistic pathogens.**

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 and monitoring for reactivation in accordance with clinical guidelines before starting therapy and 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 vein 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%) in subjects receiving 100 mg and 200 mg include: nasopharyngitis, nausea, headache, herpes simplex, increased blood creatine phosphokinase, dizziness, urinary tract infection, fatigue, acne, vomiting, oropharyngeal pain, influenza, gastroenteritis.

Most common adverse reactions (≥1%) in subjects receiving either 100 mg or 200 mg also include: impetigo, hypertension, contact dermatitis, 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 females of reproductive potential 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 women not to breastfeed during treatment with CIBINQO and for one day after the last dose.

Tablets: 50 mg, 100 mg, and 200 mg

Please see full Prescribing Information and Patient Information for EUCRISA at EUCRISAHCP.com.

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

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

IMPORTANT SAFETY INFORMATION FOR LITFULO (cont'd)

SERIOUS INFECTIONS (cont'd)

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.

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

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.

Capsules: 50 mg of ritlecitinib

Please see full Prescribing Information and Patient Information for EUCRISA at EUCRISAHCP.com.

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