09-J4000-27

Original Effective Date: 07/01/22

Reviewed: 11/12/25

Revised: 01/01/26

Subject: Abrocitinib (Cibinqo®) Tablets

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DESCRIPTION:

Abrocitinib (Cibinqo) is an oral Janus kinase (JAK) inhibitor approved by the US Food and Drug Administration (FDA) in January 2022 for "the treatment of adults 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". Abrocitinib was approved on the same date the FDA approved an additional indication for upadacitinib (Rinvoq) for the treatment of atopic dermatitis (AD). Both had identically worded indications at that time. In February 2023, the AD indication for abrocitinib was expanded to include pediatric patients 12 years of age and older. Many mediators in autoimmune inflammation (e.g., interleukins 2, 6, 12, 15, and 23; interferons; and granulocyte-macrophage colony-stimulating factor [GM-CSF]) signal through the JAK family (JAK1, JAK2, JAK3, and tyrosine kinase 2 [Tyk2]). Both abrocitinib and upadacitinib are selective JAK1 inhibitors. In a cell-free isolated enzyme assay, abrocitinib was selective for JAK1 over JAK2 (28-fold), JAK3 (>340-fold), and tyrosine kinase (TYK) 2 (43-fold). Tofacitinib (Xeljanz) has the greatest affinity for JAK3, but it is generally considered a pan-JAK inhibitor, while baricitinib (Olumiant) inhibits JAK1 and JAK2. *In vitro* research suggests that JAK1 inhibition might be largely responsible for the *in vivo* efficacy of JAK inhibitors in immune-inflammatory diseases. However, the overall clinical significance of the different JAK affinity profiles among the various JAK inhibitors has yet to be fully determined.

Atopic dermatitis, also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and approximately 7% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of

the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children, flexure involvement in any age group, with sparing of groin and axillary regions.

Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks. Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with topical emollient/ moisturizer use and conventional topical therapies (including corticosteroids and calcineurin inhibitors). Moisturizers reduce signs, symptoms, and inflammation in AD, and can improve severity while also increasing time between flares. Moisturizers are considered generally safe and are strongly recommended to be used as part of a treatment regimen for AD, either as monotherapy or as concurrent use with pharmacologic treatments.

Topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile. They can be utilized individually or in combination with other topical, physical, and/or systemic treatments; as different classes of treatment have different mechanisms of action, combining therapies allows for the targeting of AD via multiple disease pathways. The American Academy of Dermatology (AAD) strongly recommends the following topical agents:

- Topical corticosteroids (TCS)
- Calcineurin inhibitors (TCIs) (e.g., tacrolimus, pimecrolimus)
- Topical phosphodiesterase (PDE)-4 inhibitors (e.g., crisaborole) [mild to moderate AD]
- Topical Janus kinase (JAK) inhibitors (e.g., ruxolitinib) [mild to moderate AD]

TCS are the most commonly utilized FDA-approved therapies in AD and are commonly used as first-line treatment for mild-to severe dermatitis in all skin regions. TCS target a variety of immune cells and suppress the release of proinflammatory cytokines. High to very high (super) potency TCS can be used to control flares and treat severe disease, while medium potency TCS are utilized for longer courses and as maintenance therapy. Lower potency TCS may be used, and it is important to consider the anatomical site (i.e., using lower potency agents on the face, neck, genitals, and body folds) and severity of the disease when choosing a steroid potency. Clinical trials assessing efficacy generally had a duration of 2 to 6 weeks, and response to TCS therapy should be evaluated by week 4 in clinical practice. Most studies of TCS in AD management involve twice daily application, but some studies (particularly for potent TCS) suggest once daily use may be sufficient. Traditionally, TCS were stopped once AD signs and symptoms of an AD flare were controlled. Maintenance in between AD flares with once to twice weekly use of TCS is another approach.

TCIs are a safe anti-inflammatory option for mild-to-severe AD, particularly when there is concern for adverse events secondary to corticosteroid use. Both tacrolimus and pimecrolimus have been shown to be effective in treating AD, but pimecrolimus may be more appropriate for patients who have milder disease or are sensitive to local reactions. Prescribing information for pimecrolimus cream and tacrolimus ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.

When AD is more severe or refractory to topical treatment, advanced treatment with phototherapy or systemic medications can be considered. Phototherapy is conditionally recommended by the AAD as a

treatment for AD based on low certainty evidence. The AAD strongly recommends the following systemic therapies:

- Monoclonal antibodies (biologics) (e.g., dupilumab, tralokinumab)
- JAK inhibitors (e.g., upadacitinib, abrocitinib, baricitinib)

In a change from the 2014 AAD AD guidelines the use of systemic antimetabolites such as methotrexate, immunosuppressants such as systemic corticosteroids, mycophenolate mofetil, azathioprine, and cyclosporine are now conditionally recommended for AD only in a small number of select patients due to low or very low certainty of evidence and need for monitoring. The most favored first-line systemic is dupilumab.

There is no clear consensus on how to operationalize a definition of the FDA indication for treatment of patients with "moderate to severe" AD. The severity of AD can vary substantially over time and, from a patient's perspective, can include a complex combination of intensity of itch, location, body surface area (BSA) involvement, and degree of skin impairment. Given the variability of patient phenotype and lack of familiarity among clinicians with scoring systems used in clinical trials, it is advisable to create a broad clinically relevant definition inclusive of multiple specific measures of disease intensity for example:

- One of the following:
  - Affected BSA greater than or equal to 10%
  - Investigator Global Assessment (IGA) greater than or equal to 3
  - Eczema Area and Severity Index (EASI) greater than or equal to 16

  OR
- One of the following:
  - Affected BSA greater than or equal to 10%
  - Involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds)
  - Severe itch that has been unresponsive to topical therapies

<u>Efficacy</u>

The efficacy of abrocitinib as monotherapy and in combination with background topical corticosteroids were evaluated in 3 randomized, double-blind, placebo-controlled trials [Trial-AD-1 (NCT03349060), Trial-AD-2 (NCT03575871), and Trial-AD-3 (NCT03720470)] in 1,615 subjects 12 years of age and older (Cibinqo is not approved for use in pediatric patients) with moderate-to-severe atopic dermatitis as defined by Investigator's Global Assessment (IGA) score greater than or equal to 3, Eczema Area and Severity Index (EASI) score greater than or equal to 16, body surface area (BSA) involvement greater than or equal to 10%, and Peak Pruritus Numerical Rating Scale (PP-NRS) greater than or equal to 4 at the baseline visit prior to randomization. Overall, 53% of subjects were male, 69% of subjects were white, 64% of subjects had a baseline IGA score of 3 (moderate AD), and 36% of subjects had a baseline IGA score of 4 (severe AD). The baseline mean EASI score was 30. The baseline mean age was 36 years old with 8% of subjects 12 to less than 18 years old and 92% of subjects 18 years of age or older. Subjects in these trials were those who had an inadequate response to previous topical therapy or were subjects for whom topical treatments were medically inadvisable, or who had received systemic

therapies including dupilumab (Dupixent). In each of the trials, over 40% of subjects had prior exposure to systemic therapy. In Trial-AD-1 and Trial-AD-2, 6% of the subjects had received dupilumab, whereas prior use of dupilumab was not allowed in Trial-AD-3. Trial-AD-1, Trial-AD-2, and Trial-AD-3 assessed the co-primary endpoints of IGA and EASI-75 responses at Week 12 (results below). IGA responders were subjects with IGA score of clear (0) or almost clear (1) (on a 5-point scale) and a reduction from baseline of ≥2 points. EASI-75 was based on ≥75% improvement in EASI from baseline.

	Trial-AD-1 (Monotherapy)			**Trial-AD-2 (Monotherapy)**			**Trial-AD-3 (With Topical Corticosteroid)**		
	Cibinqo		Placebo (n=77)	Cibinqo		Placebo (n=78)	Cibinqo		Placebo (n=131)
	200 mg daily (n=154)	100 mg daily (n=156)		200 mg daily (n=155)	100 mg daily (n=158)		200 mg daily (n=226)	100 mg daily (n=238)	
IGA 0 or 1	44%	24%	8%	38%	28%	9%	47%	36%	14%
Difference from Placebo (95% CI)	36% (26%, 46%)	16% (7%, 25%)	-	29% (19%, 39%)	19% (9%, 29%)	-	34% (25%, 42%)	23% (15%, 31%)	-
EASI-75	62%	40%	12%	61%	44%	10%	68%	58%	27%
Difference from Placebo (95% CI)	51% (40%, 61%)	28% (18%, 39%)	-	50% (40%, 61%)	33% (23%, 44%)	-	41% (32%, 51%)	32% (22%, 41%)	-

The proportion of subjects achieving PP-NRS4 at week 2 (defined as an improvement of greater than or equal to 4 points from baseline in PP-NRS) was higher in subjects treated with Cibinqo monotherapy 200 mg once daily (28% in Trial-AD-1 and 24% in Trial-AD-2) and 100 mg once daily (11% in both trials) compared to placebo (2% in both trials). A higher proportion of subjects in the Cibinqo monotherapy 100 mg or 200 mg once daily arm compared to placebo achieved improvement in itching at week 12. The proportions of subjects achieving PP-NRS4 at week 2 was higher in subjects treated with Cibinqo 200 mg once daily (30%) and 100 mg once daily (14%) in combination with background medicated topical therapies compared to placebo (8%). Examination of age, gender, race, weight, and previous systemic AD therapy treatment did not identify differences in response to Cibinqo 100 mg or 200 mg once daily among these subgroups in Trial-AD-1, Trial- AD-2, and Trial-AD-3.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of abrocitinib (Cibinqo) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "7"):

1. **ONE** of the following ("a", "b", or "c"):
    a. The member has been treated with abrocitinib (starting on samples is not approvable) within the past 90 days

b. The prescriber states the member has been treated with abrocitinib (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed

c. **BOTH** of the following ("i" and "ii"):

i. Abrocitinib will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met

ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II"):

I. The member's age is within FDA labeling for the requested indication for abrocitinib

II. The prescriber has provided information in support of using abrocitinib for the member's age for the requested indication

2. If the member has a diagnosis of atopic dermatitis, then **BOTH** of the following ("a" and "b"):

a. The member is currently treated with topical emollients and practicing good skin care

b. The member will continue the use of topical emollients and good skin care practices in combination with abrocitinib

3. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis

4. Member does **NOT** have any FDA labeled contraindications to abrocitinib

5. Member will **NOT** be using abrocitinib in combination with a biologic immunomodulator agent [including dupilumab (Dupixent) and tralokinumab (Adbry), see full list in "Other" section]; another Janus kinase (JAK) inhibitor [Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

6. **ANY** of the following ("a", "b", or "c"):

a. The dosage does not exceed 200 mg once daily

- QL: 50 mg tablet - 1 tablet/day
- QL: 100 mg tablet - 1 tablet/day
- QL: 200 mg tablet - 1 tablet/day

b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** there is support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 6 months

Table 1

Diagnosis	Criteria
Moderate-to-severe atopic dermatitis (AD)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has at least 10% body surface area involvement **OR** b. The member has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** c. The member has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **OR** d. The member has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. **EITHER** of the following ("a" or "b"): a. **BOTH** of the following ("i" and "ii"): i. **ONE** of the following: • The member has tried and had an inadequate response to **ONE** at least medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy **OR** • The member has an intolerance or hypersensitivity to **ONE** at least a medium- potency topical corticosteroid used in the treatment of AD **OR** • The member has an FDA labeled contraindication to **ALL** medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **AND** ii. **ONE** of the following: • The member has tried and had an inadequate response to **ONE** topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the

	treatment of AD after at least a 6-week duration of therapy **OR** • The member has an intolerance or hypersensitivity to **ONE** topical calcineurin inhibitor **OR** • The member has an FDA labeled contraindication to **ALL** topical calcineurin inhibitors **OR** b. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AD
Other indications	The member has another FDA approved indication, or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of abrocitinib (Cibinqo) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "7"):

1. An authorization or reauthorization for abrocitinib has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. The member has had clinical benefit with abrocitinib
3. If the member has a diagnosis of moderate to severe atopic dermatitis, the member will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with abrocitinib
4. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis
5. Member does **NOT** have any FDA labeled contraindications to abrocitinib
6. Member will **NOT** be using abrocitinib in combination with a biologic immunomodulator agent [including dupilumab (Dupixent) and tralokinumab (Adbry), see full list in "Other" section]; another Janus kinase (JAK) inhibitor [Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
7. **ANY** of the following ("a", "b", or "c"):
    a. The dosage does not exceed 200 mg once daily
        - QL: 50 mg tablet - 1 tablet/day
        - QL: 100 mg tablet - 1 tablet/day

- QL: 200 mg tablet - 1 tablet/day

b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** there is support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 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 (per product labeling): Abrocitinib is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.
    - The recommended dose is 100 mg orally once daily. If an adequate response is not achieved with 100 mg orally daily after 12 weeks, consider increasing dosage to 200 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 200 mg once daily. Abrocitinib can be used with or without topical corticosteroids.

Dose Adjustments

- Renal Impairment
    - Mild (eGFR 60 to 89 mL/min) - 100 mg once daily. If an adequate response is not achieved after 12 weeks, the dose can be doubled.
    - Moderate (eGFR 30 to 59 mL/min) - 50 mg once daily. If an adequate response is not achieved after 12 weeks, the dose can be doubled.
    - Severe or End-Stage Renal Disease (eGFR <30 mL/min) - Not recommended for use.
- Hepatic Impairment - Not recommended for use in patients with severe hepatic impairment.
- CYP2C19 Poor Metabolizers - In patients who are known or suspected to be CYP2C19 poor metabolizers, the recommended dosage is 50 mg once daily. If an adequate response is not achieved after 12 weeks, the dose can be doubled.

- Drug Interactions - In patients taking strong inhibitors of cytochrome P450 (CYP) 2C19, the recommended dosage is 50 mg once daily. If an adequate response is not achieved after 12 weeks, the dose can be doubled.
- Adverse Effects
    - Serious or opportunistic infection - discontinue treatment and control the infection
    - Absolute Neutrophil Count (ANC) <1,000 cells/mm^3 - interrupt therapy until ANC ≥1,000 cells/mm^3
    - Absolute Lymphocyte Count (ALC) <500 cells/mm^3 - interrupt therapy until ALC ≥500 cells/mm^3
    - Hg <8 g/dL - interrupt therapy until Hg ≥8 g/dL

Drug Availability

- 50 mg, 100 mg, and 200 mg tablets in 30-count bottles
- Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (59°F to 86°F). Keep in original package. The container closure system is child resistant.

PRECAUTIONS:

Boxed Warning

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 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.
    - 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.
- 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 were reported in patients treated with Cibinqo. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

- MAJOR ADVERSE CARDIOVASCULAR EVENTS
  - 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. Patients who are current or past smokers are at additional increased risk. Discontinue CIBINQO in patients that have experienced a myocardial infarction or stroke.
- 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 thrombosis was observed when compared with TNF blockers. Avoid Cibinqo in patients at risk. If symptoms of thrombosis occur, discontinue Cibinqo and treat appropriately.

Contraindications

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

Precautions/Warnings

- **Serious Infections** – see Boxed Warning
- **Mortality** – see Boxed Warning
- **Malignancy and Lymphoproliferative Disorders** – see Boxed Warning
- **Major Adverse Cardiovascular Events** – See Boxed Warning
- **Thrombosis** – see Boxed Warning
- **Laboratory Parameters**
  - **Hematologic Abnormalities -** Treatment with abrocitinib was associated with an increased incidence of thrombocytopenia and lymphopenia. Prior to initiation, perform a CBC. CBC evaluations are recommended at 4 weeks after initiation and 4 weeks after dose increase. Discontinuation of therapy is required for certain laboratory abnormalities.
  - **Lipid Elevations** - Dose-dependent increase in blood lipid parameters were reported in patients treated with abrocitinib. Lipid parameters should be assessed approximately 4 weeks following initiation of 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, 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 abrocitinib therapy.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified

REIMBURSEMENT INFORMATION:

Refer to section entitled.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD

Eczema Area Severity Index score (EASI) - assesses severity (severity score) and body surface area affected by erythema, induration/papulation/edema, excoriations, and lichenification (area score), which are graded systematically for each of 4 anatomical regions (head and neck, trunk, upper limbs, lower limbs) and assembled in a composite score, with a score range of 0 to 72.

- EASI 50 - a percentage improvement of EASI score from baseline that is ≥50%
- EASI 75 - a percentage improvement of EASI score from baseline that is ≥75%
- EASI 90 - a percentage improvement of EASI score from baseline that is ≥90%

Helper T cells (a.k.a., CD4+ T cells) – a type of lymphocyte or white blood cell (WBC) that matures in the thymus and play an important role in cell-mediated immunity. T helper cells assist other WBCs in immunologic processes by releasing T cell cytokines. Different types of T helper cells secrete different cytokines (e.g., type 2 release IL-4, IL-5, IL-9, IL-10 and IL-13)

Intertriginous area – an area where two skin areas may touch or rub together (e.g., axilla of the arm, the anogenital region, skin folds of the breasts, between digits)

Lichenified - skin that has become thickened and leathery. This often results from continuously rubbing or scratching the skin.

Patient-Oriented Eczema Measure (POEM) – a validated questionnaire, examining seven items (scored 0 to 4 based on frequency of event), used in clinical settings to assess time spent with symptoms and the impact of symptoms on sleep, with a score range of 0 to 28.

Pruritus – itching

Scoring Atopic Dermatitis (SCORAD) - the extent and severity of AD over the body area and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) are assessed and scored by the investigator. Subjective assessment of itch and sleeplessness is scored by the patient. The SCORAD score is a combined score of body area affected, and investigator and patient symptom scoring, with a score range of 0 to103.

RELATED GUIDELINES:

Dupilumab (Dupixent), 09-J2000-80
Tralokinumab-ldrm (Adbry) Injection, 09-J4000-20
Upadacitinib (Rinvoq) Tablet, 09-J3000-31

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/12/25.

GUIDELINE UPDATE INFORMATION:

07/01/22	New Medical Coverage Guideline.
04/15/23	Revision to guidelines consisting of updating the description section, dosage/administration, and references based on the expanded AD indication to include pediatric patients 12 years of age and older.
01/01/24	Review and revision to guideline consisting of updating the description (atopic dermatitis info), position statement, other section, and references. Added additional parameters for diagnosis of “moderate-to-severe” atopic dermatitis. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
04/01/24	Revision to guidelines consisting of updating the position statement. The requirements for prior use of a systemic immunosuppressant, Adbry, Dupixent, and Rinvoq for members with atopic dermatitis were removed.
07/01/24	Revision to guideline consisting of updating the position statement and other section. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/25	Review and revision to guideline consisting of updating the description, position statement, other section, and references. New drugs added to the list of drugs that are not permitted for use in combination.
01/01/26	Review and revision to guideline consisting of updating the description, position statement, and references.