Original Effective Date: 04/28/2022
Current Effective Date: 05/31/2023
Last P&T Approval/Version: 4/26/2023
Next Review Due By: 04/2024
Policy Number: C23363-A

Cibinqo (abrocitinib)

PRODUCTS AFFECTED

Cibinqo (abrocitinib)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe atopic dermatitis (AD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
   1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
      AND
   2. (a) Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) according to the prescribing physician; AND meets all of the following criteria:
      i. Member has used at least TWO of the following: a medium potency prescription topical

corticosteroid, a medium-high potency prescription topical corticosteroid, a high potency prescription topical corticosteroid, OR a superhigh- potency prescription topical corticosteroid;
AND

ii. Each topical corticosteroid was applied daily for at least 14 consecutive days;
AND

iii. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescribing physician
AND

iv. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to ONE of the following: trial (6 weeks) of preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus) OR trial (4 weeks) of crisaborole (Eucrisa) OR trial (8 weeks) of Opzelura (ruxolitinib)

OR

(b) Member has atopic dermatitis involvement estimated to be < 10% of the BSA according to the prescribing physician and meets ALL of the following criteria:

i. Member has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skin folds, and/or genitalia.
AND

ii. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to BOTH of the following: trial (6 weeks) of tacrolimus ointment (Protopic, generics) AND trial (8 weeks) of Opzelura (ruxolitinib)

AND

3. FOR ADULTS ONLY (≥18 YEARS OF AGE): Documented compliant short course of at least ONE systemic immunosuppressant OR documentation of FA label contraindication to systemic immunosuppressants
AND
4. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritis, BSA affected, topical requirement, etc.)
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Cibinqo (abrocitinib) include: Antiplatelet therapies except for low-dose aspirin (≤81 mg daily) during the first 3 months of treatment, use of live vaccines prior to, during, and immediately after Cibinqo treatment, severe hepatic impairment (Child Pugh C), severe renal impairment (eGFR <30 mL/min) and end-stage renal disease including patients on renal replacement therapy, and concomitant use of Cibinqo with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9 or concomitant use of CIBINQO with strong CYP2C19 or CYP2C9 inducers.]
AND
6. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND
7. Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
8. Member is not on concurrent treatment or will be used in combination with other TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib), or potent

immunosuppressants such as azathioprine or cyclosporine, as verified by prescriber attestation, member medication fill history, or submitted documentation
AND

9. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
10. Prescriber attest that the following tests have been performed prior to initiation of therapy and based on FDA label recommendations member does not have any of the following in which therapy is NOT recommended: a platelet count <150,000/mm3, an absolute lymphocyte count <500/mm3, an absolute neutrophil count <1,000/mm3, a hemoglobin value <8 g/d, or active hepatitis B or hepatitis C
AND
11. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE ATOPIC DERMATITIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation member has responded to therapy as determined by the prescribing physician (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed)
AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
OR
5. (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified allergist, immunologist, or dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

12 years of age and older

QUANTITY:

100 mg orally once daily
If an adequate response is not achieved with CIBINQO 100 mg orally daily after 12 weeks, consider increasing dosage to 200 mg orally once daily

FOR APPROVAL OF 200MG ONCE DAILY DOSING:

Prescriber must provide medical chart note documentation to support a member's initial inadequate response to a compliant 12-week consecutive course of 100mg daily (or appropriate starting dose per necessary modification) and therapeutic plan for evaluating the response to the 200mg dosing. Discontinue therapy if inadequate response is seen after dosage increase to 200 mg once daily.

Maximum of ANY dose 30 tabs/30 days

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Antirheumatic-Janus Kinase Inhibitors

FDA-APPROVED USES:
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.
Limitation of Use: CIBINQO is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Dosage Recommendations in Patients with Renal Impairment

Renal Impairment Stage	Estimated Glomerular Filtration (eGFR)	Dosage
Mild	60 – 89 mL/minute	CIBINQO 100 mg once daily
Moderate	30 – 59 mL/minute	CIBINQO 50 mg once daily
Severe Renal Impairment and End-Stage Renal Disease include patients on renal replacement therapy.	≤ 29 ml/minute	Not recommended for use

Recommended Dosage in CYP2C19 Poor Metabolizers

In patients who are known or suspected to be CYP2C19 poor metabolizers, the recommended dosage of CIBINQO is 50 mg once daily. If an adequate response is not achieved with CIBINQO 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily.

Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.

Dosage Modifications due to Strong Inhibitors

In patients taking strong inhibitors of cytochrome P450 (CYP) 2C19 reduce the dosage to 50 mg once daily. If an adequate response is not achieved with CIBINQO 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Atopic dermatitis (AD), also known as atopic eczema, is a chronic inflammatory skin condition associated with dry skin, intense itching, rash, cracks in the skin, oozing/crusting, skin discoloration, and, over time, thickening of the skin. The disease itself causes skin damage, and scratching can increase the risk for skin infections. Symptoms of AD can be chronic, or they can chronically relapse. In milder forms of AD, the latter is more common. AD is the result of skin barrier dysfunction and immune dysregulation. Individuals with AD often have comorbid atopic conditions such as food allergies, allergic rhinitis, and asthma. Itching is a primary symptom that negatively impacts quality of life for patients with AD, in addition to the social, academic, and occupational consequences of the disease (absenteeism from work and school are common, along with decreased productivity and daytime fatigue caused by a lack of sleep due to itching). Individuals with more severe AD are at risk for depression, anxiety, and sleep disturbance due to itching. AD commonly onsets in the first year of life and by 5 years of age in most patients. AD can continue into adulthood. Onset occurs in adulthood in about 25% of patients. Individuals with a family history of atopic diseases are at higher risk of developing AD.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cibinqo (abrocitinib) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Cibinqo (abrocitinib) include: Antiplatelet therapies except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment, use of live vaccines prior to, during, and immediately after Cibinqo treatment, severe hepatic impairment (Child Pugh C), severe renal impairment (eGFR < 30 mL/min) and end-stage renal disease including patients on renal replacement therapy, and concomitant use of Cibinqo with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9 or concomitant use of Cibinqo with strong CYP2C19 or CYP2C9 inducers.

OTHER SPECIAL CONSIDERATIONS:

Cibinqo (abrocitinib) has a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Cibinqo TABS 50MG (30ct bottle)
Cibinqo TABS 100MG (30ct bottle)
Cibinqo TABS 200MG (30ct bottle)

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations	Q2 2023
NEW DEVELOPMENT	Q2 2022