Original Effective Date: 04/28/2022
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Last P&T Approval/Version: 4/30/2025
Next Review Due By: 04/2026
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. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
   AND
2. Documentation of ONE of the following:
   i. Member has atopic dermatitis involvement estimated to be ≥10% of the body surface area

(BSA) according to the prescribing physician
ii. Member has atopic dermatitis involvement estimated to be <10 % of the BSA affecting face, eyes/eyelids, skin folds, and/or genitalia according to the prescribing physician

AND

3. Documentation of inadequate response, serious side effects, or contraindication to TWO of the following: topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus)
AND
4. Documentation of inadequate response, serious side effects, or contraindication to ONE of the following: Eucrisa (crisaborole), Opzelura (ruxolitinib), Vtama (tapinarof), or Zoryve (roflumilast)
AND
5. FOR ADULTS ONLY (≥18 YEARS OF AGE): Documented compliant short course of at least ONE systemic immunosuppressant (e.g., methotrexate, azathioprine, cyclosporine, mycophenolate, etc.) OR documentation of FDA labeled contraindication to systemic immunosuppressants
AND
6. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritis, BSA affected, topical requirement, etc.)
AND
7. 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, avoid use of live vaccines prior to, during, and immediately after Cibinqo treatment, avoid use in patients with severe hepatic impairment (Child Pugh C), avoid use in patients with severe renal impairment (eGFR <30 mL/min) and end- stage renal disease including patients on renal replacement therapy, and avoid 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
8. Member is not on concurrent treatment or will be used in combination with 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 or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
AND
10. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL 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, or held for laboratory abnormalities
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (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. Prescriber attests to ongoing monitoring for development if infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

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 1 tab/day

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:
Atopic Dermatitis - 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, avoid use of live vaccines prior to, during, and immediately after Cibinqo treatment, avoid use in patients with severe hepatic impairment (Child Pugh C), avoid use in patients with severe renal impairment (eGFR < 30 mL/min) and end-stage renal disease including patients on renal replacement therapy, and avoid 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.

Exclusions/Discontinuation:

Cibinqo initiation is not recommended in patients with active TB.
Cibinqo initiation is not recommended in patients with active hepatitis B or hepatitis C.
Cibinqo initiation is not recommended in patients with a platelet count <150,000/mm3, an absolute lymphocyte count <500/mm3, an absolute neutrophil count <1,000/mm3, or a hemoglobin value <8 g/dL.
Perform a complete blood count (CBC) prior to initiation. CBC to be performed at baseline, 4 weeks after treatment initiation and 4 weeks after dosage increase. Follow FDA labeled recommendations for discontinuation for hematologic abnormalities.
If a patient develops a serious or opportunistic infection, discontinue Cibinqo and control the infection. The risks and benefits of treatment with Cibinqo should be carefully considered prior to reinitiating therapy with Cibinqo.
Discontinue Cibinqo in patients that have experienced a myocardial infarction or stroke.
If symptoms of thrombosis occur, discontinue Cibinqo and treat appropriately.
Discontinue Cibinqo if an adequate response is not achieved with 200 mg once daily, or with maximum modified dose.

OTHER SPECIAL CONSIDERATIONS:

Cibinqo (abrocitinib) has a Black Box Warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

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 Contraindications/Exclusions/ Discontinuation References	Q2 2025
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Quantity Drug Class Contraindications/Exclusions/ Discontinuation References	Q2 2024
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