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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	April 29, 2022
Subject:	Cibinqo	**Page:**	1 of 7

Last Review Date: March 7, 2025

Cibinqo

Description

Cibinqo (abrocitinib)

Background
Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Cibinqo modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

Regulatory status
FDA-approved indication: Cibinqo is a Janus kinase (JAK) inhibitor 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 are inadvisable (1).

Limitations of Use: (1)
Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Cibinqo carries several boxed warnings: (1)

1. Serious infections
    a. Serious infections, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infection leading to hospitalization or death. If a serious infection develops, discontinue Cibinqo until the infection is controlled. Prior to starting Cibinqo, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting Cibinqo. Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative.
2. Mortality
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor showed a higher rate of all-cause mortality, including sudden cardiovascular death, in patients treated with JAK inhibitors compared to TNF blockers.
    b. Cibinqo is not approved for use in RA patients.
3. Malignancies
    a. Lymphoma and other malignancies have been observed in patients treated with Cibinqo.
    b. In RA patients treated with a JAK inhibitor, a higher rate of malignancies was observed when compared with TNF blockers.
4. Major adverse cardiovascular events (MACE)
    a. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor showed a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) when compared to TNF blockers. Patients who are current or past smokers are at increased risk. Cibinqo should be discontinued in patients that have experienced a myocardial infarction or stroke.
5. Thrombosis
    a. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.
    b. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with a JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers.

Cibinqo is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment (1).

The safety and effectiveness of Cibinqo in pediatric patients less than 12 years of age have not been established (1).

Related policies
Adbry, Dupixent, Rinvoq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cibinqo may be considered **medically necessary** if the conditions indicated below are met.

Cibinqo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Moderate-to-severe atopic dermatitis (eczema)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to at least **TWO** systemic atopic dermatitis medications, including biologics (e.g., oral corticosteroids, hydroxyzine, Adbry, Dupixent, Rinvoq, etc.)
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that Cibinqo therapy is appropriate
3. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB

AND NONE of the following:

1. Antiplatelet therapy (excluding low-dose aspirin ≤81 mg daily) during the first 3 months of treatment
2. Active bacterial, invasive fungal, viral, and other opportunistic infections
3. Severe hepatic impairment (Child Pugh C)
4. A lymphocyte count less than 500 cells/mm3
5. An absolute neutrophil count less than 1000 cells/mm3
6. A hemoglobin less than 8 g/dL
7. History of thrombotic events including deep vein thrombosis (DVT) or pulmonary embolism (PE)
8. Used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 1)
9. Given concurrently with live vaccines

Prior-Approval Renewal Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Atopic dermatitis (eczema)

AND ALL of the following:

1. Condition has improved or stabilized
2. Prescriber has considered the risks for malignancy and major adverse cardiovascular events (MACE) (e.g., advanced age, smoking history, cardiovascular risk factors etc.) and determined that continuation of Cibinqo therapy is appropriate

AND NONE of the following:

1. Active bacterial, invasive fungal, viral, and other opportunistic infections
2. Used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 1)
3. Development of thrombotic events (including DVTs or PEs)
4. Given concurrently with live vaccines

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Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 90 tablets per 90 days

Duration 4 months

Prior–Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 12 months

Rationale

Summary

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor indicated for patients with atopic dermatitis. Cibinqo has several boxed warnings including risk of serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Cibinqo in pediatric patients less than 12 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cibinqo while maintaining optimal therapeutic outcomes.

References

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.

Policy History

Date	Action
April 2022	Addition to PA

June 2022	Annual review. Per SME, added example names of biologics to the atopic dermatitis t/f requirement
March 2023	Per PI update, changed age requirement to 12 and older from 18 and older. Changed policy number to 5.90.055
June 2023	Annual review
March 2024	Annual review and reference update
September 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

Appendix 1 - List of Non-Topical PA Medications for Atopic Dermatitis

Generic Name	Brand Name
abrocitinib	Cibinqo
dupilumab	Dupixent
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq