



Federal Employee Program.

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5.90.055

Section:	Prescription Drugs	Effective Date:	January 1, 2026
Subsection:	Topical Products	Original Policy Date:	April 29, 2022
Subject:	Cibinco	Page:	1 of 8

Last Review Date: December 12, 2025

Cibinco

Description

Cibinco (abrocitinib)

Background

Cibinco (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. Cibinco modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs (1).

Regulatory status

FDA-approved indication: Cibinco 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)

Cibinco is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Cibinco carries several boxed warnings: (1)

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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 Cibinco until the infection is controlled. Prior to starting Cibinco, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting Cibinco. 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. Cibinco is not approved for use in RA patients.
3. Malignancies
 - a. Lymphoma and other malignancies have been observed in patients treated with Cibinco.
 - 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. Cibinco 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.

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

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The safety and effectiveness of Cibinco 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.

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

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

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Moderate-to-severe atopic dermatitis (eczema)

AND ALL of the following with provided documentation (e.g., medical records, laboratory reports):

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. Baseline evaluation of the condition using **ONE** of the following scoring tools:
 - a. Investigator's Static Global Assessment (ISGA) with a score > 3
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - b. Eczema Area and Severity Index (EASI) with a score ≥ 16
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - c. Patient-Oriented Eczema Measure (POEM) with a score ≥ 8
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - d. Scoring Atopic Dermatitis (SCORAD) index with a score ≥ 15

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(e.g., <https://dermnetnz.org/topics/scorad/>)

3. 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 Cibinquo therapy is appropriate
4. 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
5. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior-Approval Renewal Requirements

Age 12 years of age or older

Diagnosis

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Patient must have the following:
Atopic dermatitis (eczema)

AND ALL of the following with provided documentation (e.g., medical records, laboratory reports):

1. Documented improvement of the condition using **ONE** of the following scoring tools:
 - a. ISGA – decrease from baseline by at least 2 points
(e.g., https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf)
 - b. EASI – decrease from baseline by at least 75%
(e.g., <https://dermnetnz.org/topics/easi-score/>)
 - c. POEM – decrease from baseline by at least 3 points
(e.g., <https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png>)
 - d. SCORAD – decrease from baseline by at least 50%
(e.g., <https://dermnetnz.org/topics/scorad/>)
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 Cibinco therapy is appropriate
3. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre-PA Allowance

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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

Cibinvo (abrocitinib) is a Janus kinase (JAK) inhibitor indicated for patients with atopic dermatitis. Cibinvo has several boxed warnings including risk of serious infections, mortality, malignancies, MACE, and thrombosis. The safety and effectiveness of Cibinvo 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 Cibinvo while maintaining optimal therapeutic outcomes.

References

1. Cibinvo [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

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June 2023	Annual review
March 2024	Annual review and reference update
September 2024	Annual review
March 2025	Annual review
December 2025	Annual review. Added documentation and t/f requirement. Added Appendix 2

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

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

Generic Name	Brand Name
abrocitinib	Cibinco
dupilumab	Dupixent
lebrikizumab-lbkz	Ebglyss
tralokinumab-ldrm	Adbry
upadacitinib	Rinvoq

Appendix 2 - List of Preferred Products

List of preferred products:

https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>