

PHARMACY POLICY STATEMENT

Georgia Medicaid

DRUG NAME	Cibinqo (abrocitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Cibinqo was initially approved by the FDA in 2022. It is a Janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric patients 12 years of age or 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. Cibinqo works by inhibiting the activity of one or more of the Janus kinase family of enzymes, interfering with the JAK-STAT signaling pathway.

Cibinqo (abrocitinib) will be considered for coverage when the following criteria are met:

Atopic Dermatitis (AD)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by a dermatologist, allergist, or immunologist; AND
3. Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure to **ONE** of the following:
 - a) **TWO** trials of medium to very high potency topical corticosteroids for 2 weeks;
Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
 - b) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both or UV-B1 (narrow-band UV-B)) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks;
Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
 - c) **ONE** 12-week trial of an oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks.
Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
6. Member has documentation of a trial and failure of, intolerance, or contraindication to Dupixent or Adbry. Treatment failure requires at least 12 weeks of therapy.
7. **Dosage allowed/Quantity limit:** 100 mg orally once daily. If an adequate response is not achieved after 12 weeks, consider increasing to 200 mg orally once daily. (Quantity Limit: 30 tablets per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Cibinqo (abrocitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/31/2022	New policy for Cibinqo created.
02/24/2023	Updated References. Age indication expanded to include patients as young as 12 years of age. Added trial duration for biologics. Simplified disease state header to exclude moderate to severe. Simplified dosing to include standard population dosing only.
11/16/2023	Changed trials to two topicals, one topical and phototherapy or one immunomodulator and one topical; changed duration of steroid topicals to 2 weeks, added duration of 6 weeks for TCI, 4 weeks for Eucrisa; added option of Opzelura for 8 weeks duration; changed steroid requirement from high to very high; added reference.

References:

1. Cibinqo [prescribing information]. New York, NY: Pfizer Inc.; February 2023.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies [published online ahead of print, 2023 Jan 11]. *J Am Acad Dermatol*. 2023;S0190-9622(23)00004-X. doi:10.1016/j.jaad.2022.12.029
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol*. 2014; 70(1):338-51.
4. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014;71(1):116-132.
5. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014 Aug;71(2):327-49.
6. Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. *Exp Ther Med*. 2019;17(2):1061-1067
7. Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. *J Allergy Clin Immunol Pract*. 2017;5(6):1519-1531. doi:10.1016/j.jaip.2017.08.005
8. Wollenberg A, Kinberger M, Arents B, et al. European guideline (EuroGuiDerm) on atopic eczema: part I - systemic therapy. *J Eur Acad Dermatol Venereol*. 2022;36(9):1409-1431. doi:10.1111/jdv.18345

Effective date: 04/01/2024

Revised date: 11/16/2023