

PHARMACY POLICY STATEMENT Marketplace

| DRUG NAME | Cibinqo (abrocitinib) |
|-------------------------|------------------------------|
| BILLING CODE | Must use valid NDC |
| BENEFIT TYPE | Pharmacy |
| SITE OF SERVICE ALLOWED | Home |
| 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 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:

Moderate-to-Severe Atopic Dermatitis (AD)

For *initial* authorization:

- 1. Member must be 18 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 of, intolerance, or contraindication to at least one of the following:
 - a) Medium to high potency topical corticosteroid for at least 4 weeks;
 - b) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) or Eucrisa for at least 4 weeks; AND
- 6. Member has documented trial and failure of, intolerance, or contraindication to one of the following:
 - a) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B));
 - b) At least 12 weeks of one oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine).
- 7. Member has documentation of a trial and failure of, intolerance, or contraindication to at least one preferred product (see Appendix).
- 8. **Dosage allowed/Quantity limit:** 100 mg orally once daily. 200 mg per daily may be used in patients not responding to 100 mg therapy. 50mg once daily can be used for moderate renal impairment or CYP2C19 poor metabolizers.

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. | |

References:

- 1. Cibinqo [prescribing information]. New York, NY: Pfizer Inc.; January 2022.
- 2. Atopic dermatitis clinical guideline (2021). In American Academy of Dermatology. Retrieved from <u>Atopic dermatitis</u> <u>clinical guideline (aad.org)</u>.
- 3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section
- 4. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
- 5. 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.
- 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.
- Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. Exp Ther Med. 2019;17(2):1061-1067

Effective date: 04/01/2022 Revised date: 01/31/2022



| Appendix: Preferred Biologic Products | | |
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| Approved for Rheumatoid Arthritis | Actemra (requires step through Humira) Enbrel Humira | |
| Approved for Juvenile Idiopathic Arthritis | Actemra (requires step through Humira) Enbrel Humira | |
| Approved for Ankylosing Spondylitis | Cosentyx Enbrel Humira Rinvoq | |
| Approved for Non-radiographic Axial | CimziaCosentyx | |
| Approved for Atopic Dermatitis | Rinvoq | |
| Approved for Psoriatic Arthritis | Cosentyx Enbrel Humira Otezla Skyrizi Stelara Tremfya | |
| Approved for Psoriasis | Cosentyx Enbrel Humira Otezla Skyrizi Stelara Tremfya | |
| Approved for Crohn's Disease | HumiraStelara | |
| Approved for Ulcerative Colitis | HumiraStelaraRinvoq | |