Cibinqo (abrocitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cibinqo (abrocitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Cibinqo (abrocitinib) for the treatment of atopic dermatitis may be approved if the following criteria are met:

I. Individual is age 12 years of age or older with refractory, moderate to severe atopic dermatitis; **AND**

II. Documentation is provided that a non-corticosteroid systemic immunosuppressant (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of low or mild disease activity state or contraindications to all non-corticosteroid systemic immunosuppressants for atopic dermatitis;

OR

III. Documentation is provided that a biologic therapy for atopic dermatitis has failed to achieve and maintain remission of low or mild disease activity state or contraindications to all biologics for atopic dermatitis;

AND

IV. Documentation is provided that individual has had a trial and inadequate response or intolerance to Rinvoq (upadacitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial);

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried; **OR**
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

V. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cibinqo (abrocitinib). Medication samples/coupons/discount cards are excluded from consideration as a trial.

Continuation requests for Cibinqo for atopic dermatitis may be if approved if the following criterion is met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cibinqo. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. Treatment with Cibinqo has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased pruritis, inflammation, dermatitis, or exacerbations).

Cibinqo (abrocitinib) may not be approved for the following:

I. In combination with other oral or topical JAK inhibitors; **OR**
II. In combination with dupilumab, lebrikizumab-lbkz, nemolizumab-ilto, or tralokinumab; **OR**
III. In combination with other immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
IV. Individuals with severe hepatic impairment (Child-Pugh C); **OR**
V. Individual with baseline creatinine clearance less than 40mL/min; **OR**
VI. Individual is currently taking an antiplatelet medication (except for doses of aspirin 81mg or less daily) during the first three (3) months of treatment with Cibinqo; **OR**
VII. Individual is at increased risk of thrombosis.

NOTE:
Cibinqo contains a black box warning related to JAK-inhibitors. Cibinqo has a black box warning for serious infections that can lead to hospitalization or death, malignancies, higher rate of all-cause mortality, higher rate of major adverse cardiovascular events (MACE), and thrombosis. It is noted that these events have occurred in patients receiving JAK-inhibitors for inflammatory conditions. Serious infections included active tuberculosis, invasive fungal infections, bacterial, viral, and other opportunistic infections. Patients with an active, serious infection should avoid use of Cibinqo. Higher rate of all-cause mortality including sudden cardiovascular death and MACE, which also includes sudden cardiovascular death, myocardial infarction, and stroke, were also observed in those using JAK-inhibitors for inflammatory conditions. Lymphoma and other malignancies have also been observed.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102
6. Sidbury, Robert et al. “Guidelines of care for the management of atopic dermatitis in adults with topical therapies.” Journal of the American Academy of Dermatology vol. 89,1 (2023): e1-e20. doi:10.1016/j.jaad.2022.12.029

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.