

## SPECIALTY GUIDELINE MANAGEMENT

### Cibinqo (abrocitinib)

## POLICY

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication

Cibinqo is 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.

All other indications are considered experimental/investigational and not medically necessary.

### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

#### A. Initial requests:

1. Chart notes or medical records showing affected areas and affected body surface area
2. Chart notes or medical record documentation and claims history of prerequisite therapies including dosage, duration, and response to therapy. If therapy is not advisable, documentation of why therapy is not advisable.

B. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

### III. CRITERIA FOR INITIAL APPROVAL

#### **Moderate-to-severe atopic dermatitis**

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis when all of the following criteria are met:

1. Member is 18 years of age or older;
2. Prescribed by, or in consultation with dermatologist or allergist/immunologist
3. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
4. Member has tried and failed or had an inadequate response for at least 2-3 months to at least one medium-high to very high potency topical corticosteroid;
5. Member has tried and failed or had an inadequate response for at least 2-3 months to pimecrolimus, tacrolimus ointment or crisaborole (Eucrisa)
6. Member has a documented inadequate response, intolerance or contraindication to Dupixent or Adbry
7. Member will not use Cibinqo concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received Cosentyx or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.]*

#### IV. CONTINUATION OF THERAPY

##### **Moderate-to-severe atopic dermatitis**

Authorization of 12 months may be granted for members 18 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

#### V. QUANTITY LIMIT/DOSAGE AND ADMINISTRATION

##### **Cibinqo 50mg, 100mg, or 200mg: 1 tablet per day**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### VI. REFERENCES

- Cibinqo [package insert]. New York, NY: Pfizer Inc.; January 2022.
- Simpson EL, Sinclair R, Forman S, et al. Efficacy and safety of abrocitinib in adults and adolescents with moderate-to-severe atopic dermatitis (JADE MONO-1): a multicentre, double-blind, randomised, placebo-controlled, phase 3 clinical trial. *Lancet*. 2020;396:255-266.
- 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;70:338-51.
- Eichenfield LF, Tom WL, 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;71:116-32.