Effective Date: 6/2022
Reviewed: 6/2022, 4/2023, 3/2024, 2/2025 Scope: Medicaid

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 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 is inadvisable.

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

II. 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 the following criteria are met:
1. Member is 12 years of age or older
2. Prescribed by, or in consultation with dermatologist or allergist/immunologist
3. Documentation that the 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. Documentation that the member has had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or use of a topical corticosteroid is not advisable for the member (e.g., due to contraindications, prior intolerances)
5. Documentation that the member has had an inadequate treatment response to pimecrolimus cream or tacrolimus ointment for ≥ 6 consecutive weeks, experienced an intolerance or is contraindicated to topical calcineurin inhibitors
6. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Dupixent
7. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Adbry or Nemluvio
8. Member will not use Cibinqo concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.
9. 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.]*

III. CONTINUATION OF THERAPY

Moderate-to-severe atopic dermatitis

A. Authorization of 12 months may be granted for members 12 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 with documentation (e.g., chart notes) 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). Member will not use Cibinqo concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

IV. 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.

V. APPENDIX

Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

VI. REFERENCES

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.
2. 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.
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;70:338-51.
4. 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.