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	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Cibinqo (abrocitinik	o)	Page:	1 of 5
Effective D	ate: 4/1/2023		Last Review Date	: 4/2023
A	□Illinois	□Florida	□Virgin	ia
Applies to:	☐New Jersey	⊠Maryland	□Michi	gan
ιο.	⊠Pennsylvania Kids	⊠Florida Kids	□Texas	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Cibingo under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Cibingo

Policy/Guideline:

Documentation for all indications:

The patient is unable to take Dupixent and Rinvoq, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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 area(s) and affected body surface area (where applicable).
- 2. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
- 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.

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Prescriber Specialties:

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Criteria for Initial Approval:

Atopic dermatitis

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:

- A. 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.
- B. Member meets one of the following:
 - 1. Member has had an inadequate treatment response with one of the following in the past year:
 - i. A medium potency to super-high potency topical corticosteroid (see Appendix)
 - ii. A topical calcineurin inhibitor
 - 2. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
- C. Member has had an inadequate response to treatment with a systemic drug product or a biologic indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.

Criteria for Continuation of Therapy: Atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained 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).

Note: For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB

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infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Approval Duration and Quantity Restrictions:

Approval:

Initial: 4 monthsRenewal: 12 months

Quantity Level Limit:

30 tablets per 30 days

Appendix:

Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super- high	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High	Amcinonide	Ointment	0.1%
potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%

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Potency	Drug	Dosage form	Strength
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
Potency	Drug	Dosage form	Strength
III. High	Amcinonide	Cream, Lotion	0.1%
potency	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
(group 3)	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium	Betamethasone dipropionate	Spray	0.05%
potency	Clocortolone pivalate	Cream	0.1%
(group 4)	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2- second spray
V. Lower-	Betamethasone dipropionate	Lotion	0.05%
mid	Betamethasone valerate	Cream	0.1%
potency	Desonide	Ointment, Gel	0.05%
(group 5)	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%

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Potency	Drug	Dosage form	Strength
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low	Alclometasone dipropionate	Cream, Ointment	0.05%
potency	Betamethasone valerate	Lotion	0.1%
(group 6)	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
	Hydrocortisone (base, greater than or	Cream, Ointment, Solution	2.5%
	equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

References:

- 1. Cibingo [package insert]. New York, NY: Pfizer Inc.; February 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, 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;71:116-132.
- 5. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 15, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
- 6. Topical Corticosteroids. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; December 1, 2021. Accessed November 7, 2022.