



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

DRUG POLICY

Cibinqo (abrocitinib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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 are inadvisable

POLICY

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

Atopic Dermatitis

1. Criteria for initial approval for atopic dermatitis will only apply when at least ONE of the following criteria are met:
 - a) Member has had an inadequate response to treatment or intolerable adverse event with TWO of the preferred products (Dupixent and Rinvoq)
 - b) Member has refractory atopic dermatitis and has failed the preferred product (Rinvoq)

- c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Required Documentation

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

Atopic dermatitis

A. Initial requests:

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

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:

- 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 has had an inadequate treatment response to both of the following in the last 180 days:
 - i. A high potency or super-high potency topical corticosteroid (TCS) (see Appendix), or the use of topical corticosteroids is not advisable for the member (e.g., due to contraindications, prior intolerances).
 - ii. A topical calcineurin inhibitor (TCI) [e.g., tacrolimus], or the use of a topical calcineurin inhibitor is 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 (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil), or a biologic (e.g., Dupixent, Adbry), indicated for the treatment of atopic dermatitis, or use of these therapies is not advisable for the member.
- d. Member is 18 years of age or older.
- e. Must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

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).

Other

For all indications: Member has had a documented negative 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 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 drugs, targeted synthetic drugs, or potent immunosuppressants such as azathioprine or cyclosporine.

Dosage and Administration

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

Quantity Limits Apply

Cibinqo - 30 tablets per 30 days

Appendix

Relative potency of select topical corticosteroid products			
Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	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 potency (group 2)	Amcinonide	Ointment	0.1%
	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%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
Halobetasol propionate	Lotion	0.01%	
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	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 potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	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-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
		Triamcinolone acetonide	Lotion
	Ointment		0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, Lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
		Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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.
- Fishbein AB, Silverberg, JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. *J Allergy Clin Immunol Pract.* 2020;8(1): 91-101.
- Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. *J Eur Acad Dermatol Venereol.* 2020;34(12):2717-2744.
- Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on July 21, 2022 from: <https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm>.
- Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; December 1, 2021. Accessed July 28, 2022.

*Some content reprinted from CVSHealth

POLICY HISTORY

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