Cibinqo

CRITERIA FOR INITIAL APPROVAL

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual has a confirmed diagnosis of moderate to severe atopic dermatitis supported by the submitted medical records**; AND**
2. Individual is ≥ 12 years of age**; AND**
3. Individual has chronic or relapsing history that has been present for at least 6 months **AND**
4. Individual has a history of pruritus associated with atopic dermatitis; **AND**
5. Individual has at least one of the following:
    a. Early age of onset (≤5 years of age); **OR**
    b. Atropy; **OR**
    c. Family history; **OR**
    d. Xerosis; **AND**
6. Individual has involvement of >10% of body surface area **OR** involvement of critical areas (e.g., palms, face, etc) **AND**
7. Individual must have documentation of one of the following:
    a. For children: facial, neck or extensor involvement; **OR**
    b. For any age group: current or previous flexural lesions; sparing of groin and axillary regions; **AND**
8. Individual has a skin biopsy consistent with the diagnosis of atopic dermatitis OR documentation is provided that other skin conditions have been excluded or adequately treated (such as scabies, seborrheic dermatitis, contact dermatitis (irritant or allergic), ichthyoses, cutaneous T-cell lymphoma, psoriasis, photosensitivity dermatoses, immune deficiency disease, and erythroderma of other causes) **AND**
9. The drug is authorized and managed by a physician with expertise in the treatment of atopic dermatitis (e.g., allergist/immunologist or dermatologist) **AND**
10. Topical therapy failure. The patient has either failed a trial, proved intolerant of a medication, or has contraindications to both below topical treatments (in accordance with AAD Guidelines:
    a. A topical calcineurin inhibitor with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks; **AND**
    b. A topical corticosteroid with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks of a moderate-to-high-potency topical corticosteroid, unless involvement is limited to the face and intertriginous areas in which a lower-potency corticosteroid may be used; **AND**

11. 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 are not advisable for the member.

12. The drug will NOT be used in combination with a janus kinase (JAK) inhibitor or another biologic agent for the treatment of atopic dermatitis [e.g., omalizumab (e.g., Xolair), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry) and rituximab (e.g., Rituxan)] for another atopic condition; **AND**
13. Individual has an Investigator's Global Assessment (IGA) score ≥ 3; **AND**

14. Individual has at least one of the following:

    a. Eczema Area and Severity Index (EASI) score ≥21; **OR**
    b. Weekly-average baseline worst itch score ≥4; **AND**

15. Must be dosed in accordance with the FDA label

CONTINUATION OF THERAPY

Continued approval for up to 1 year:

Requirement of documentation in the medical records that the member has achieved and maintains a clinically meaningful benefit as defined below:

1. Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting); **AND**
2. Reduction in the frequency or intensity of pruritus associated with atopic dermatitis; **AND**
3. Reduction in the frequency of disease exacerbations/flairs; **AND**
4. Reduction in the amount of Body Surface Area involvement relative to pretreatment baseline; **AND**
5. Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.);
   AND
6. Must be dosed in accordance with the FDA label.

OTHER

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 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.

APPENDIX

Table. 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	Amcinonide	Cream, Lotion	0.1%

Potency	Drug	Dosage form	Strength
potency (group 3)	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,	0.1%

Potency	Drug	Dosage form	Strength
		Solution	
	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 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, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	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%