Adbry (tralokinumab-ldrm)

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 Adbry drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. The criteria will require the use of both of the health plan's preferred products, Dupixent and Rinvoq, before the use of the targeted product, Adbry, unless there are clinical circumstances that exclude the use of all the preferred products and may be based on previous use of a product.

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 Indication

Adbry is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.

POLICY

Required Documentation

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

A. Initial requests:
    1. Member's chart notes or medical records showing affected areas and affected body surface area

2. Member's chart notes or medical record documentation and claims history of prerequisite therapies (including topical calcineurin inhibitors and topical corticosteroids) including dosage, duration, and response to therapy. If 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.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval when applicable.

Preferred Drug Plan Design

A. Criteria for initial approval for Adbry (tralokinumab-ldrm) will only apply when ONE of the following criteria are met:
   1. The patient has had an inadequate response to treatment, intolerable adverse event, or has a contraindication to therapy with BOTH preferred products, Dupixent and Rinvoq.
   2. The patient is currently receiving therapy with Adbry, excluding when Adbry is obtained as samples or via manufacturer's patient assistance programs, and experiencing a positive therapeutic outcome

Criteria for Initial Approval

A. 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. Affected body surface area is greater than or equal to 10% OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member has had an inadequate treatment response to both of the following in the past 180 days:
   a. 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).
   b. 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).
3. Member is 18 years of age or older
4. Member will not use Adbry concomitantly with other biologics or targeted synthetic drug indicated for atopic dermatitis
5. This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist

Continuation of Therapy

A. Moderate-to-severe atopic dermatitis

Authorization of **6 months** may be granted for members 18 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when all of the following criteria is met:

1. 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).
2. Member will not use Adbry concomitantly with other biologics or targeted synthetic drugs indicated for atopic dermatitis.

Adbry is considered **not medically necessary** for members who do not meet the criteria set forth above.

Quantity Limits Apply

Medication	Quantity Limit	FDA-recommended dosing
Adbry 150 mg/mL prefilled syringe	Initiation of therapy: Six 150 mg injections per first 28 days Maintenance: Four 150 mg injections per 28 days	Atopic Dermatitis • Initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week • After 16 weeks of treatment, for patients with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered

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%

Relative potency of select topical corticosteroid products			
Potency	**Drug**	**Dosage form**	**Strength**
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	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, 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.

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POLICY HISTORY

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