AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Adbry (tralokinumab-ldrm)	Page:	1 of 5
Effective Date:	11/15/2024	Last Review Date:	7/2024, 8/19/2024
Applies to:	☒Illinois ☐New Jersey ☐Pennsylvania Kids	☐Florida ☐Maryland ☐Florida Kids	☐Virginia ☐Michigan ☐Texas

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Adbry 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
Indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older 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.

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

Applicable Drug List:

Adbry

Policy/Guideline:

Documentation for all indications:
The patient is unable to take Dupixent, 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. For initial requests:
   1. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
   2. Member's chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapy is not advisable for the member.

B. For 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.

Prescriber Specialties:

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

Criteria for Initial Approval:

Atopic dermatitis

A. Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic or targeted synthetic drug indicated for moderate-to-severe atopic dermatitis in the past year.

B. Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when both 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).

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: Member cannot use Adbry concomitantly with any other biologic drug or targeted synthetic drug for the same indication**.**

Approval Duration and Quantity Restrictions:

Approval:

- **Initial:** 4 months
- **Renewal:** 12 months

Quantity Level Limit:
Adbry (tralokinumab-ldrm) 150 mg/mL prefilled syringe: 4 syringes per 28 days
Adbry (tralokinumab-ldrm) 300 mg/2 mL autoinjector: 2 autoinjectors per 28 days

FDA-Recommended Dosing:

- Adults: Initial dose of 600 mg (four 150 mg injections or two 300 mg injections), followed by 300 mg (two 150 mg injections or one 300 mg injection) 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.
- 12 to 17 years old: Initial dose of 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) every other week.

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%
	Amcinonide	Ointment	0.1%

Potency	**Drug**	**Dosage form**	**Strength**
II. High 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%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
Potency	**Drug**	**Dosage form**	**Strength**
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

Potency	Drug	Dosage form	Strength
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, 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%

References:

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; December 2023.
2. 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;70:338-351.
3. Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; September 1, 2023. Accessed November 2, 2023.