Effective Date: 8/1/2022
Reviewed: 06/2022, 06/2023, 03/2024, 11/2024 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

Adbry (tralokinumab-ldrm)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia 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 Indications

Adbry is 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.

II. 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:

1. Member is 12 years or older
2. Prescribed by, or in consultation with dermatologist or allergist/immunologist
3. Documentation of the affected body surface that 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
4. Documentation that the member has tried and failed or had an inadequate response for at least 2-3 months to at least one medium-high to very high potency topical corticosteroid
5. Documentation that member has tried and failed or had an inadequate response for at least 2-3 months to pimecrolimus, tacrolimus ointment or crisaborole (Eucrisa)
6. Documenattion that the member has tried and failed, had an inadequate response or contraindication for at least 3 months to Dupixent
7. Member will not use Adbry concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

III. CONTINUATION OF THERAPY

Moderate-to-severe atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older who are using the requested medication for moderate-to-severe atopic dermatitis when both of the following are met:

A. Member has achieved or maintained a positive clinical response with Adbry therapy 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).
B. Documentation that the provider has considered de-escalating therapy for adult members with a body weight below 100 kg who achieve clear or almost clear skin, from every 2 weeks to every 4 weeks
C. Member will not use Adbry concomitantly with other biologics or JAK inhibitors indicated for atopic dermatitis.

IV. QUANTITY LIMIT/DOSAGE AND ADMINISTRATION

Age	Initial Loading Dose	Subsequent Dose
Adults: • 18 years of age and older	Prefilled syringe: 600mg (four 150mg injections) Autoinjector: 600mg (two 300mg injections)	Prefilled syringe: 300mg (two 150mg injections) every other week Autoinjector: 300mg (one 300mg injection) every other week ** After 16 weeks of treatment, for adult patients with body weight below 100 kg who achieve clear or almost clear skin, the patient's dose must be de-escalated to 300 mg every 4 weeks.
Pediatric patients: • 12-17 years of age	Prefilled syringe: 300mg (two 150mg injections)	Prefilled syringe: 150mg (one 150mg injection) every other week

Adbry 150mg/ml prefilled syringe: 4 syringes per 28 days or daily dose of 0.143 with an exception for the loading dose of 4 syringes per 14 days or daily dose of 0.29

Adbry 300mg/2ml autoinjector pen: 2 pens per 28 days or daily dose of 0.143 with an exception for the loading dose of 2 pens per 14 days or daily dose of 0.29

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

V. APPENDIX

Relative potency of select topical corticosteroid products.

Potency	Drug	Dosage form	Strength
I. Very high potency	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment	0.05%
II. High potency	Augmented betamethasone dipropionate	Cream, Lotion	0.05%
	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	Fluocinonide	Ointment, Gel	0.05%
	Triamcinolone acetonide	Cream, Ointment	0.5%
III. Medium potency	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Fluocinolone acetonide	Cream, Ointment	0.025%
	Fluticasone propionate	Cream	0.05%
		Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%, 0.1%
IV. Low potency	Desonide	Cream	0.05%
	Fluocinolone acetonide	Cream, Solution	0.01%
	Hydrocortisone	Cream, Ointment	0.5%
		Cream, Ointment	1%
		Cream, Ointment	2.5%

VI. REFERENCES

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; May 2024.
2. Eichenfield LF, Tom WL, 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.
3. Utilization Management (UM) Criteria Review CVS Caremark P&T Subgroup. Dermatology – Biologic Agents – UM Criteria. April 2019.
4. Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; January 15, 2020. Accessed January 11, 2022.