Effective Date: 8/1/2022
Reviewed: 06/2022, 06/2023, 03/2024, 11/2024, 2/2025, 10/2025 Scope: Medicaid

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 of age or older
2. Documentation of member's weight
3. Prescribed by, or in consultation with dermatologist or allergist/immunologist
4. 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
5. Documentation that the member had an inadequate treatment response to at least one medium to super-high potency topical corticosteroid for ≥ 2 consecutive weeks (see Appendix) or use of a topical corticosteroid is not advisable for the member (e.g., due to contraindications, prior intolerances)
6. Documentation that the member has had an inadequate treatment response to pimecrolimus cream or tacrolimus ointment for ≥ 6 consecutive weeks, experienced an intolerance or is contraindicated to topical calcineurin inhibitors
7. Documentation that the member has had an inadequate treatment response with a 4-month trial, intolerance or contraindication to Dupixent
8. Member will not use Adbry concomitantly with any other biologic drug or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

III. CONTINUATION OF THERAPY

Moderate-to-severe atopic dermatitis

Requests for 300mg every 4 weeks:
Authorization of 12 months may be granted for adult members who are using the requested medication for moderate-to-severe atopic dermatitis when all of the following are met:

A. Member has achieved or maintained a positive clinical response with Adbry therapy with documentation (e.g., chart notes) 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).
B. Documentation that member weighs less than 100 kg (for members that weigh 100kg or more, please see the section below for requests for 300mg every other week) .
C. Member will not use Adbry concomitantly with any other biologic or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

Requests for 300mg every other week:
Authorization of 12 months may be granted for adult members who are using the requested medication for moderate-to-severe atopic dermatitis when all of the following are met:

A. Member has achieved or maintained a positive clinical response with Adbry therapy with documentation (e.g., chart notes) as evidenced by low disease activity or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
B. Documentation of member weighs greater than or equal to 100 kg OR if member weighs <100 kg, medical rationale provided for continuing every 2-week dosing frequency.
C. Member will not use Adbry concomitantly with any other biologic or targeted synthetic drug, including JAK inhibitors, indicated for atopic dermatitis.

Requests for 150mg every other week (adolescents)
Authorization of 12 months may be granted for members 12-17 years of age 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 with documentation (e.g., chart notes) 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).
B. Member will not use Adbry concomitantly with any other biologic or targeted synthetic drug, including 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: 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. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Gel	0.05%
	Clobetasol propionate	Cream, Ointment, Solution, Cream (emollient)	0.05%
	Fluocinonide	Cream	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
	Betamethasone valerate	Ointment	0.1%
	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)	Fluocinolone acetonide	Ointment	0.025%
	Mometasone furoate	Cream	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%

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. Eichenfield LF, Tom WL, Berger TG, 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;71:116-132.
5. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol.* 2024;90(2):e43-e56.
6. Chu DK, Schneider L, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE− and Institute of Medicine−based recommendations. Ann Allergy Asthma Immunol 132(2024) 274−312.
7. Topical Corticosteroids. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; January 15, 2020. Accessed October 2, 2024.