UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2269-3
Program	Prior Authorization/Medical Necessity
Medications	Adbry™ (tralokinumab-ldrm)
P&T Approval Date	2/2022, 7/2022, 3/2023
Effective Date	6/1/2023; Oxford only: 16/1/2023

1. Background:

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist 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.

2. Coverage Criteria[a]:

A. Atopic Dermatitis

1. **Initial Authorization**

a. **Adbry** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe chronic atopic dermatitis

-AND-

(2) History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication)^:

(a) Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
(b) Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]*
(c) Eucrisa (crisaborole)*

-AND-

(3) Patient is **not** receiving Adbry in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(4) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adbry** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Adbry therapy

-AND-

(2) Patient is **not** receiving Adbry in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Dupixent (dupilumab)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(3) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.
***** Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

Table 1: Relative potencies of topical corticosteroids

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids

Adults and adolescents (12 years of age and older)			
Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	n.a	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limitations may be in place

4. References:

1. Adbry [package insert]. Madison, NJ: Leo Pharma Inc.; November 2022.
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(1):338-51.
3. 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(1):116-32.
4. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.

Program	Prior Authorization/Medical Necessity - Adbry (tralokinumab-ldrm)
Change Control	
2/2022	New program.
7/2022	Removed age requirement from initial authorization. Updated reference.
3/2023	Annual review. Updated not used in combination criteria and reference.