

5.90.053

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Topical Products	Original Policy Date:	April 29, 2022
Subject:	Adbry	Page:	1 of 6

Last Review Date: March 8, 2024

Adbry

Description

Adbry (tralokinumab-ldrm)

Background

Adbry (tralokinumab-ldrm) is a human monoclonal IgG4 antibody that specifically binds to interleukin-13 (IL-13) and blocks its interaction with the IL-13 receptor $\alpha 1$ and $\alpha 2$ subunits (IL-13R $\alpha 1$ and IL-13R $\alpha 2$). This blocks the IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, and IgE (1).

Regulatory Status

FDA-approved indication: Adbry is an interleukin-13 antagonist 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 (1).

Adbry has warnings for hypersensitivity reactions, conjunctivitis, keratitis, and parasitic (helminth) infections. Patients should be monitored and Adbry treatment should be discontinued if appropriate (1).

Prior to initiation of Adbry, patients should complete all age-appropriate vaccinations as recommended by current immunization guidelines. Live vaccines should be avoided while using Adbry (1).

The safety and effectiveness of Adbry in pediatric patients less than 12 years of age have not been established (1).

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Topical Products	Original Policy Date:	April 29, 2022
Subject:	Adbry	Page:	2 of 6

Related policies

Cibinqo, Dupixent, Rinvoq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Adbry may be considered **medically necessary** if the conditions indicated below are met.

Adbry may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

Moderate-to-severe atopic dermatitis (eczema)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to **ONE** medication in **EACH** of the following categories:
 - a. 18 years of age or older:
 - i. Topical calcineurin inhibitor (see Appendix 1)
 - ii. **High** potency topical corticosteroid (see Appendix 2)
 - b. 12 to 17 years of age:
 - i. Topical calcineurin inhibitor (see Appendix 1)
 - ii. Topical corticosteroid (see Appendix 2)
2. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
3. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Topical Products	Original Policy Date:	April 29, 2022
Subject:	Adbry	Page:	3 of 6

Patient must have the following:

Atopic dermatitis (eczema)

AND ALL of the following:

1. Condition has improved or stabilized
2. **NOT** used in combination with another non-topical Prior Authorization (PA) medication for atopic dermatitis (see Appendix 3)
3. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 18 syringes

Duration 16 weeks

Prior – Approval *Renewal* Limits

Quantity 12 syringes every 84 days

Duration 12 months

Rationale

Summary

Adbry (tralokinumab-ldrm) is an interleukin-13 receptor antagonist indicated for the treatment of atopic dermatitis (eczema). Adbry has warnings for hypersensitivity reactions, conjunctivitis, keratitis, and parasitic (helminth) infections. Patients should be monitored and Adbry treatment should be discontinued if appropriate. The safety and effectiveness of Adbry in patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Adbry while maintaining optimal therapeutic outcomes.

Section: Prescription Drugs

Effective Date: April 1, 2024

Subsection: Topical Products

Original Policy Date: April 29, 2022

Subject: Adbry

Page: 4 of 6

References

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; December 2023.

Policy History

Date	Action
April 2022	Addition to PA
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.90.053
January 2024	Per PI update, updated age to 12 and older from 18 and older
March 2024	Annual review

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Section: Prescription Drugs**Effective Date:** April 1, 2024**Subsection:** Topical Products**Original Policy Date:** April 29, 2022**Subject:** Adbry**Page:** 5 of 6**Appendix 1**

Relative Potency of Topical Calcineurin Inhibitors		
Drug	Dosage Form	Strength
Medium Potency		
Tacrolimus	Ointment	0.1%
Low Potency		
Tacrolimus	Ointment	0.03%
Pimecrolimus	Cream	1%

Appendix 2

Relative Potency of Selected Topical Corticosteroids		
Drug	Dosage Form	Strength
Very high Potency		
Augmented betamethasone dipropionate	Ointment, Gel	0.05%
Clobetasol propionate	Cream, 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, Ointment	0.05%
Betamethasone valerate	Ointment	0.1%
Desoximetasone	Cream, Ointment	0.25%
	Gel	0.05%
Diflorasone diacetate	Cream, Ointment	0.05%
	(emollient base)	
Fluocinonide	Cream, Ointment, Gel	0.05%
Halcinonide	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment	0.5%
Medium Potency		
Betamethasone dipropionate	Lotion	0.05%
Betamethasone valerate	Cream	0.1%
Clocortolone pivalate	Cream	0.1%
Desoximetasone	Cream	0.05%
Fluocinolone acetonide	Cream, Ointment	0.025%

Section: Prescription Drugs

Effective Date: April 1, 2024

Subsection: Topical Products

Original Policy Date: April 29, 2022

Subject: Adbry

Page: 6 of 6

Flurandrenolide	Cream, Ointment, Lotion	0.05%
	Tape	4 mcg/cm ²
Fluticasone propionate	Cream	0.05%
	Ointment	0.005%
Hydrocortisone butyrate	Ointment, Solution	0.1%
Hydrocortisone valerate	Cream, Ointment	0.2%
Mometasone furoate	Cream, Ointment, Lotion	0.1%
Prednicarbate ²	Cream, Ointment	0.1%
Triamcinolone acetonide	Cream, Ointment, Lotion	0.025%
	Cream, Ointment, Lotion	0.1%
<i>Low Potency</i>		
Alclometasone dipropionate	Cream, Ointment	0.05%
Desonide	Cream	0.05%
Fluocinolone acetonide	Cream, Solution	0.01%
Hydrocortisone	Lotion	0.25%
	Cream, Ointment, Lotion,	0.5%
	Aerosol	
	Cream, Ointment, Lotion,	1%
	Solution	
Cream, Ointment, Lotion	2.5%	
Hydrocortisone acetate	Cream, Ointment	0.5%
	Cream, Ointment	1%

Appendix 3 - List of Non-Topical PA Medications for Atopic Dermatitis

Generic Name	Brand Name
abrocitinib	Cibinqo
dupilumab	Dupixent
tralokinumab-ldrm	Adbry
upadactinib	Rinvoq