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

***Last Review Date:*** June 16, 2022

# 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 α1 and α2 subunits (IL-13Rα1 and IL-13Rα2). 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 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 (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 patients less than 18 years of age have not been established (1).

**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** in patients 18 years of age or older with atopic dermatitis and if the conditions indicated below are met.

Adbry may be considered **investigational** in patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 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. Topical calcineurin inhibitor (see Appendix 1)
    b. **High** potency 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** 18 years of age or older

**Diagnosis**

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 18 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.

**References**

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; January 2022.

## Policy History

| Date | Action |
|---|---|
| April 2022 | Addition to PA |
| June 2022 | Annual review |

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**

## 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 (emollient base) | 0.05% |
| 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% |

| | | |
|---|---|---|
| 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% |
| ***Low Potency*** | | |
| Alclometasone dipropionate | Cream, Ointment | 0.05% |
| Desonide | Cream | 0.05% |
| Fluocinolone acetonide | Cream, Solution | 0.01% |
| Hydrocortisone | Lotion | 0.25% |
| | Cream, Ointment, Lotion, Aerosol | 0.5% |
| | Cream, Ointment, Lotion, Solution | 1% |
| | 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 |