Commercial/Healthcare Exchange PA Criteria

Effective: May 12, 2022

Prior Authorization: Adbry

Products Affected: Adbry (Tralokinumab-ldrm) Subcutaneous solution

Medication Description: Tralokinumab-ldrm is a human IgG4 monoclonal antibody that binds to human interleukin-13 (IL-13) thereby inhibiting its bioactivity and IL-13-induced responses, including the release of proinflammatory cytokines, chemokines, and IgE

Covered Uses: 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.

Exclusion Criteria:

1. Concurrent use with another Monoclonal Antibody Therapy.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Prescriber Restriction: Prescribed by, or in consultation with, an allergist, immunologist, or dermatologist

Age Restriction: 18 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Atopic Dermatitis

- **A.** Patient meets **ONE** of the following (i **OR** ii)
  - i. Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber **AND** meets **ALL** of the following criteria (a, b, **AND** c):
    - a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; **AND**
    - b. This topical corticosteroid was applied daily for at least 28 consecutive days; **AND**
    - c. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; **OR**
  - ii. Patient has atopic dermatitis involvement estimated to be < 10% of the body surface area according to the prescriber and meets **ALL** of the following criteria (a, b, c **AND** d):
    - a. Patient has atopic dermatitis affecting **ONLY** the following areas: face, eyes/eyelids, skin folds, and/or genitalia; **AND**

b. Patient has tried tacrolimus ointment; **AND**
c. Tacrolimus ointment was applied daily for at least 28 consecutive days; **AND**
d. Inadequate efficacy was demonstrated with tacrolimus ointment, according to the prescriber

Renewal Criteria

1. Atopic Dermatitis

A. Patient has already received at least 4 months of therapy with Adbry; **AND**
Note: A patient who has received < 4 months of therapy or who is restarting therapy with Adbry should be considered under criterion 1A (Atopic Dermatitis, Initial Therapy).

B. Patient has responded to therapy as determined by the prescriber
Note: Examples of a response to Adbry therapy are marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other responses observed

References:

1. Adbry™ [package insert]. Madison, NJ, Leo Pharma, Inc. Updated January 2022. Accessed March 16th, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/12/2022
2	Policy Update	Exclusion Criteria to include concurrent use with another Monoclonal Antibody Therapy.	Exclusion Criteria	12/2022