Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Adbry™ (tralokinumab-ldrm)

Effective: March 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Adbry (tralokinumab-ldrm) is an interleukin-13 antagonist indicated for:

- **Atopic dermatitis**
  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.

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Adbry for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Documentation the patient's condition meets **one (1)** of the following:
   a. Body Surface Area (BSA) of at least 10%
   b. Eczema Area and Severity Index EASI score of at least 16
   c. Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3

AND

3. Patient is at least 12 years of age

AND

4. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

5. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to one (1) of the following: a medium or high potency topical corticosteroid, a calcineurin inhibitor, or crisaborole
   b. Contraindication to all of the following: medium and high potency topical corticosteroids, topical calcineurin inhibitors, and crisaborole

Reauthorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Patient is at least 12 years of age

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Reduction in body surface area involvement relative to pretreatment baseline
    b. Improvement in atopic dermatitis symptoms as evidenced by marked improvements in symptoms such as pruritus, xerosis, crusting, or lichenification
    c. Reduction in the use of other topical or systemic therapies

Limitations

1. Initial approval of Adbry will be authorized for six (6) months. Reauthorization of Adbry will be provided in 12-month intervals.
2. Patients new to the plan stable on Adbry should be reviewed against Reauthorization Criteria.

Codes

None

References

1. AAAAI/ACAA JTF Atopic Dermatitis Guideline Panel, 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. 2023 Dec; S1081-1206(23)01455-2.
2. Boguniewicz MD, et al. Atopic dermatitis yardstick update. Ann Allergy Asthma Immunol. 2023 June;130(6):811-20.
3. Dawn MR Davis, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Journal of the American Academy of Dermatology. 2023 Nov;08(102):e1-e14.
4. Adbry (tralokinumab-ldrm) [prescribing information]. Madison, NJ: LEO Pharma Inc.; Dec 2023.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes
- February 13, 2024: Updated age requirements to at least 12 years of age based on expanded indication (effective 3/1/2024).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.