Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: October 13, 2026

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

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:

Disease State	
Atopic Dermatitis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Adbry **(tralokinumab-ldrm)** 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 or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation of history of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: medium or high potency topical corticosteroids, calcineurin inhibitor, crisaborole, ruxolitinib *(Note: document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderate to severe atopic dermatitis

AND

3. Patient is at least 12 years of age or older

AND

4. Prescribed by a dermatologist, allergist, or immunologist

AND

5. Documentation the patient has experienced a beneficial clinical response, defined as improvement from baseline in at least **one (1)** of the following:
    a. Estimated body surface area affected by atopic dermatitis, erythema, induration/thickness, and/or scale of areas affected by atopic dermatitis
    b. Reduction in the use of other topical or systemic therapies

AND

6. Documentation that compared to baseline, the patient has experienced an improvement in at least one symptom of atopic dermatitis such as pruritus, xerosis, crusting, or lichenification

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Initial approval of Adbry will be authorized for six (6) months. Reauthorization of Adbry will be provided in 12-month intervals.
2. A patient who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
3. Members new the plan stable on the requested medication should be reviewed against Initial Authorization 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.; December 2025.

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).
- January 14, 2025: No changes (eff 1/14/25)
- October 14, 2025: Initial approvals limited to 6 months with annual reauthorization coverage criteria added. Provider requirements no longer allow with in consultation with the specialist. Added a minimum 30-day supply of prerequisite topical therapies. Added coverage criteria to prevent duplicative targeted immunomodulator therapy (eff 1/1/26).
- October 13, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

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.