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PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Adbry (tralokinumab-ldrm)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Adbry is an interleukin-13 antagonist initially approved by the FDA in 2022. It is 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. This human IgG4 monoclonal antibody specifically binds to IL-13, inhibiting its interaction with the IL-13 receptor. IL-13 is a naturally occurring cytokine that is involved in inflammatory and immune responses.

Adbry (tralokinumab-ldrm) will be considered for coverage when the following criteria are met:

Atopic Dermatitis (AD)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by a dermatologist, allergist, or immunologist; AND
3. Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure to **ONE** of the following:
   a) **TWO** trials of medium to very high potency topical corticosteroids for 2 weeks;
   Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
   b) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both or UV-B1 (narrow-band UV-B)) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks;
   Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
   c) **ONE** 12-week trial of an oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks.
   Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
6. **Dosage allowed/Quantity limit:**
   a) 18 years of age and older: administer a loading dose of 600 mg subcutaneously followed by 300 mg subcutaneously administered every other week. A dosage of 300 mg every 4 weeks may be

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considered for adult patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. Quantity limit: 4 syringes or 2 autoinjectors per 28 days after loading dose.

b) 12 to 17 years of age: administer a loading dose of 300 mg subcutaneously (two 150 mg injections), followed by 150 mg (one 150 mg injection) subcutaneously administered every other week. Quantity limit: 2 syringes per 28 days after loading dose.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Adbry (tralokinumab-ldrm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/31/2022	New policy for Adbry created.
11/20/2023	Changed trials to two topicals, one topical and phototherapy or one immunomodulator and one topical; changed duration of steroid topicals to 2 weeks, added duration of 6 weeks for TCI, 4 weeks for Eucrisa; added option of Opzelura for 8 weeks duration; changed steroid requirement from high to very high; updated references.
01/17/2024	Lowered age limit to 12 years of age. Added pediatric dosing. Updated references. Added QL.
10/14/2024	Added autoinjector dosing/quantity limit.

References:

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3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71(1):116-132
4. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol.* 2023;89(1):e1-e20. doi:10.1016/j.jaad.2022.12.029
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7. Tollefson MM, Bruckner AL; Section On Dermatology. Atopic dermatitis: skin-directed management. *Pediatrics.* 2014;134(6):e1735-e1744. doi:10.1542/peds.2014-2812
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9. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel, Chu DK, Schneider L, 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.* Published online December 18, 2023. doi:10.1016/j.anai.2023.11.009
10. Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. *J Allergy Clin Immunol Pract*. 2017;5(6):1519-1531.

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