

PHARMACY POLICY STATEMENT

Georgia Medicaid

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:

Moderate to Severe Atopic Dermatitis

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: Initiate 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. Quantity Limit: 4 syringes per 28 days.
 - b) 12 to 17 years of age: Initiate 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) administered every other week. Quantity Limit: 2 syringes per 28 days.

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.

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.

References:

1. Adbry [prescribing information]. North Chicago, IL: AbbVie Inc.; 2023.
2. Eichenfield LF, Tom WL, Chamlin SL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol*. 2014;70(2):338-351. doi:10.1016/j.jaad.2013.10.010
3. 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
4. Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. *Exp Ther Med*. 2019;17(2):1061-1067
5. Wollenberg A, Kinberger M, Arents B, et al. European guideline (EuroGuiDerm) on atopic eczema: part I - systemic therapy. *J Eur Acad Dermatol Venereol*. 2022;36(9):1409-1431. doi:10.1111/jdv.18345
6. Tollefson MM, Bruckner AL; Section On Dermatology. Atopic dermatitis: skin-directed management. *Pediatrics*. 2014;134(6):e1735-e1744. doi:10.1542/peds.2014-2812
7. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102
8. 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

Effective date: 07/01/2024

Revised date: 01/17/2024