CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Adbry (tralokinumab-ldrm)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Adbry is an interleukin-13 antagonist initially approve by the FDA in 2022. It is indicated for the 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. 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 18 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 of, intolerance, or contraindication to at least one of the following:
   a) Medium to high potency topical corticosteroid for at least 4 weeks;
   b) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) or Eucrisa for at least 4 weeks; AND
6. Member has documented trial and failure of, intolerance, or contraindication to one of the following:
   a) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B));
   b) At least 12 weeks of one oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine).
7. **Dosage allowed/Quantity limit:** 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.

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.

References:

1. Adbry [prescribing information]. North Chicago, IL: AbbVie Inc.; December 2021.
2. Atopic dermatitis clinical guideline (2021). In American Academy of Dermatology. Retrieved from Atopic dermatitis clinical guideline (aad.org).
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section
4. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
5. 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.
6. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
7. Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. Exp Ther Med. 2019;17(2):1061-1067

Effective date: 04/01/2022
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