ALASKA MEDICAID
Prior Authorization Criteria

Adbry™ (tralokinumab-ldrm)

FDA INDICATIONS AND USAGE[1]

Adbry™ is an interleukin-13 antagonist indicated for the treatment of moderate-to-sever 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.

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient meets FDA labeling approved age **AND**;
2. Prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND**;
3. Patient has the diagnosis of atopic dermatitis **AND**;
4. Documentation of the affected baseline body surface area affected and severity of symptoms **AND;**
5. Must have tried and failed or has a contraindication to at least two of the following for a period of 30 days:
    a. Patient > 18 years of age a medium to high potency topical corticosteroid or < 18 years of age a low potency topical corticosteroid
    b. Topical calcineurin inhibitor
    c. Phosphodiesterase 4 inhibitor

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Adbry™ is to be used in conjunction with another biologic medication (eg. Enbrel™, Dupixent™, Xolair®, etc.)

CAUTIONS[1]

- Monitor for hypersensitivity reactions after administration.
- Patients should be monitored for new or worsening eye symptoms.
- Avoid use of live vaccines while on Adbry™.
- Patients with pre-existing helminth infections should be treated before initiating treatment with Adbry™. In patients who become infected while receiving Adbry™ and fail to respond to anti-helminth treatment, discontinue Adbry™ until infection resolves.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- First month dosing up to 1200mg (eight 150mg injections), then up to 600mg (four 150mg injections) monthly thereafter

REFERENCES / FOOTNOTES:

1. Adbry (tralokinumab-ldrm) [prescribing information]. Madison, NJ: Leo Pharma Inc; December 2023.
2. Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). Br J Dermatol. 2021; 184(3): 437–449. DOI: 10.111/bjd.19575. Available at: https://pubmed.ncbi.nlm.nih.gov/33000465/.
3. Silverberg JI, Toth D, Bieber T, et al. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicentre, placebo-controlled phase III ECZTRA 3 trial. Br J Dermatol. 2021; 184(3): 450–463. DOI: 10.1111/bjd.19573. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7986183/.
4. Davis D, Drucker A, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. JAAD November 07, 2023. DOI: https://doi.org/10.1016/j.jaad.2023.08.102.
5. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. JAAD January 11, 2023. DOI: https://doi.org/10.1016/j.jaad.2022.12.029.