Pharmacy Policy Bulletin: J-1166 Adbry (tralokinumab-ldrm) – Commercial and Healthcare Reform	
Number: J-1166	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Quantity Limits = Safety/Specialty **2.** Quantity Limits = Safety/Specialty + Dose Opt **3.** Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1166-010	**Original Date:** 01/26/2022
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Adbry (tralokinumab-ldrm)
FDA-Approved Indication(s):	• 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.

Background:	• Adbry is a self-administered, subcutaneous (SC), human immunoglobulin G4 (IgG4) monoclonal antibody that specifically binds to human interleukin-13 (IL-13), a naturally occurring cytokine of the Type 2 immune response, inhibiting its interaction with the IL-13 receptor α1 and α2 subunits. Inhibiting IL-13-induced responses blocks the release of proinflammatory cytokines, chemokines, and immunoglobulin E (IgE). • Atopic dermatitis (AD) is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum IgE levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification. • According to the 2023 American Academy of Dermatology (AAD) guidelines for AD, topical corticosteroids are first-line treatment for mild-to-severe AD in all skin areas (strong recommendation, high evidence) along with non-prescription

	therapies such as moisturizers (strong recommendation, moderate evidence). Initial treatment may be followed by topical calcineurin inhibitors, a topical phosphodiesterase-4 (PDE-4) inhibitor (crisaborole), or a topical JAK inhibitor (ruxolitinib), as alternative treatments due to adverse effects or patient preference (strong recommendation; high evidence- for all except topical JAK inhibitors: moderate evidence). • For systemic therapies in AD, the AAD makes strong recommendations for the use of dupilumab, tralokinumab, abrocitinib, baricitinib, and upadacitinib. Conditional recommendations are made in favor of using phototherapy, azathioprine, cyclosporine, methotrexate, and mycophenolate, and against the use of systemic corticosteroids. • Topical corticosteroids should be avoided if a patient has damaged skin, such as infected skin (unless advised by a doctor), rosacea, acne, and skin ulcers (open sores). • Severity of atopic dermatitis is defined by the Validated Investigator's Global Assessment (v-IGA) o 0 - Clear: No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present. o 1 - Almost Clear: Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting. o 2 - Mild: Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting. o 3 - Moderate: Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present. o 4 - Severe: Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present. • Examples of positive clinical response in AD therapy include improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with AD. • Prescribing Considerations: o Prior to Adbry initiation, complete all age-appropriate vaccinations as recommended by current immunization guidelines. Avoid use of live vaccines while on treatment. o Treat patients with pre-existing helminth infections before initiating treatment with Adbry. o Patients should report new onset or worsening eye symptoms of conjunctivitis or keratitis to their healthcare provider. o For adults, an initial dose is recommended of 600 mg (four x 150 mg or two x 300 mg injections), followed by 300 mg (two x 150 mg or 1 x 300 mg injections) administered every other week. For patients 12-17 years, an initial dose is recommended of 300 mg (two 150 mg injections), followed by 150 mg administered every other week using only the prefilled syringe. o For adults after 16 weeks of treatment, if the patient has a body weight below 100 kg and achieves clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered. Adbry reauthorization enforces dose de-escalation if clinically appropriate.

	○ In pediatric patients 12 – 17 years of age, it is recommended that Adbry be given by or under supervision of an adult.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Adbry may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 12 years of age or older.

B. The specialist (dermatologist, allergist, or immunologist) submits attestation that the member has a diagnosis of atopic dermatitis (ICD-10: L20) that is moderate-to-severe.

C. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has experienced therapeutic failure or intolerance to one (1) of the following **(a. or b.)**:

a. One (1) generic topical corticosteroid

b. One (1) generic topical calcineurin inhibitor (specifically, tacrolimus or pimecrolimus)

2. The prescriber submits documentation that the member has severe atopic dermatitis and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(a. or b.)**:

a. The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.

b. Topical therapies are contraindicated due to severely damaged skin.

D. The requested quantity does not exceed the recommended dosing regimen per FDA label.

II. Reauthorization

When a benefit, reauthorization of Adbry may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

B. If the member is 18 years of age or older, the prescriber has assessed the member for dose de-escalation and one (1) of the following criteria are met **(1., 2., or 3.):**

1. Adbry is requested at a dosing interval of every 4 weeks.

2. The prescriber attests that the member has not achieved clear or almost clear skin and dose de-escalation to an every 4-week dosing interval would not be appropriate.

3. The prescriber attests that an every 4-week dosing interval would not be appropriate (for example, weight above 100 kg).

III. Quantity Limitations

When prior authorization is approved, Adbry may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
Atopic Dermatitis (≥ 18 years of age)	Six (6) 150 mg syringes -OR- three (3) 300 mg autoinjectors within the first four (4) weeks of therapy	Two (2) or four (4) 150 mg syringes -OR- one (1) or two (2) 300 mg autoinjectors every four (4) weeks
Atopic Dermatitis (12 – 17 years of age)	Three (3) 150 mg syringes within the first four (4) weeks of therapy	Two (2) 150 mg syringes every four (4) weeks

IV. If the patient has already had a trial of at least one biologic agent for the same indication, the patient is not required to “step back” and try a non-biologic agent.

V. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted. *Note*: For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #5467 (Exam Authority #53287-22-701).

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; June 2024.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics. 2025.
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 Jul;89(1):e1-e20.
4. 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*. 2017;5(6):1519-1531.
5. Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg J, Farrar JR. Atopic dermatitis yardstick: Practical recommendations for an evolving therapeutic landscape. *Ann Allergy Asthma Immunol*. 2018;120(1):10-22.e2.
6. NHS choices. Topical corticosteroids. Available at: https://www.nhs.uk/conditions/topical-steroids/. Accessed February 4, 2025.
7. International Eczema Council. Validated investigator global assessment scale for atopic dermatitis. Available at: https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf. Accessed February 4, 2025.
8. 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.