Clinical Policy: Tralokinumab-ldrm (Adbry)

Reference Number: CP.PCH.60
Effective Date: 12.01.25
Last Review Date: 11.25
Line of Business: Commercial, HIM

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Tralokinumab-ldrm (Adbry®) is an interleukin-13 antagonist.

FDA Approved Indication(s)

Adbry 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Adbry is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all)**:**

1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
   a. At least 10% of the member's body surface area (BSA);
   b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age ≥ 12 years;
4. Failure of both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced:
   a. Two formulary medium to very high potency topical corticosteroids of different molecular identities, each used for ≥ 2 weeks;
   b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®;
   **These agents may require prior authorization*
5. Failure of Dupixent® or Rinvoq®, used for ≥ consecutive 4 months, unless clinically significant adverse effects are experienced or both are contraindicated;^
   ^For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395
6. Adbry is not prescribed concurrently with another biologic medication (e.g., Dupixent, Cinqair®, Fasenra®, Nucala®, Tezspire™, Xolair®) or a Janus kinase (JAK) inhibitor (e.g., Olumiant®, Rinvoq, Cibinqo®, Opzelura™);

7. Dose does not exceed one of the following (a or b):
   a. Adults (both i and ii):
      i. Initial (one-time) dose of 600 mg (1 or 2):
         1) For prefilled syringe: four injections;
         2) For autoinjector: two injections;
      ii. Maintenance dose of 300 mg every 2 weeks (1 or 2):
         1) For prefilled syringe: two injections;
         2) For autoinjector: one injection;
   b. Age 12 to 17 years for prefilled syringe (both i and ii):
      i. Initial (one-time) dose of 300 mg (two injections);
      ii. Maintenance dose of 150 mg (one injection) every 2 weeks.

Approval duration:
HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Atopic Dermatitis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. Adbry is not prescribed concurrently with another biologic medication (e.g., Dupixent, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. For adult members with weight < 100 kg: Request is for 300 mg every 4 weeks, unless documentation supports member has not achieved clear or almost clear skin;

5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Adults: 300 mg every 2 weeks (i or ii):
      i. For prefilled syringe: two injections;
      ii. For autoinjector: one injection;
   b. Age 12 to 17 years: 150 mg (one injection of prefilled syringe) every 2 weeks.

Approval duration:
HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BSA: body surface area
FDA: Food and Drug Administration
JAK: Janus kinase

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Very High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene®) ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Apexicon E®) ointment		
fluocinonide 0.1% (Vanos®) cream		
halobetasol propionate 0.05% (Ultravate®) cream, foam, lotion, ointment		
High Potency Topical Corticosteroids		
amcinonide 0.1% cream, ointment, lotion	Apply topically to the affected area(s) BID	Varies
betamethasone 0.05% (Diprolene® AF) cream (augmented formulation), ointment		
betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam		
clobetasol propionate 0.025% (Impoyz®) cream		
diflorasone 0.05% (Apexicon E®, Psorcon®) cream		
fluocinonide 0.05% cream, ointment, gel, solution		
halcinonide 0.1% cream, ointment, solution (Halog®)		
halobetasol propionate 0.01% lotion (Bryhali®)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mometasone furoate 0.1% ointment		
triamcinolone acetonide 0.5% (Triderm®) cream, ointment		
Medium Potency Topical Corticosteroids		
clocortolone pivalate 0.1% cream	Apply topically to the affected area(s) BID	Varies
desoximetasone 0.05%, 0.025% (Topicort®) cream, ointment, gel		
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
flurandrenolide 0.05% (Cordran®, Nolix®) cream, lotion, ointment		
fluticasone propionate 0.005%, 0.05% cream, ointment		
hydrocortisone valerate 0.2% cream		
Mometasone furoate 0.1% cream, lotion, solution		
triamcinolone acetonide 0.025%, 0.05%, 0.1% cream, lotion, ointment		
Other Classes of Agents		
tacrolimus (Protopic®), Elidel® (pimecrolimus)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa® (crisaborole)	Apply to the affected areas BID	Varies
Dupixent® (dupilumab)	*Adults*: Initial dose of 600 mg SC followed by 300 mg SC every other week *Adolescents 6-17 years of age*: • Body weight 15 to < 30 kg: Initial dose of 600 mg SC followed by 300 mg SC every 4 weeks	See regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• Body weight 30 kg to < 60 kg: Initial dose of 400 mg SC followed by 200 mg SC every other week • Body weight ≥ 60 kg: Initial dose of 600 mg SC followed by 300 mg SC every other week *Pediatrics 6 months - 5 years of age*: • Body weight 5 to < 15 kg: 200 mg SC every 4 weeks • Body weight 15 to < 30 kg: 300 mg SC every 4 weeks	
Rinvoq® (upadacitinib)	Age ≥ 12 years and ≥ 40 kg but < 65 years: 15 mg PO QD; if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD Age ≥ 65 years: 15 mg PO QD	Age ≥ 12 years and ≥ 40 kg but < 65 years: 30 mg/day Age ≥ 65 years: 15 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to tralokinumab-ldrm or any excipients in Adbry
- Boxed warning(s): none

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate-to-severe atopic dermatitis	*Adult:* Initial dose of 600 mg SC followed by 300 mg SC every other week After 16 weeks of treatment, for adult patients with body weight < 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered *Pediatric 12-17 years of age:* Initial dose of 300 mg SC followed by 150 mg SC every other week	*Adult:* 300 mg every other week (maintenance dose) *Pediatric 12-17 years of age:* 150 mg every other week (maintenance dose)

VI. Product Availability

- Pre-filled syringe: 150 mg/mL
- Autoinjector: 300 mg/2 mL

VII. References

1. Adbry Prescribing Information. Madison, NJ: LEO Pharma, Inc.; June 2024. Available at: https://www.adbry.com/. Accessed January 16, 2025.
2. Micromedex® DRUGDEX® [Internet database]. Ann Arbor, Michigan: Merative™. Updated periodically. Accessed February 21, 2025.
3. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier. Updated periodically. Available at: http://www.clinicalkey.com/pharmacology. Accessed February 21, 2025.
4. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020 Dec;34(12):2717-2744.
5. 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 Mar;184(3):437-449.
6. 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 Mar;184(3):450-463.
7. 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.
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. 2023 Nov 3:S0190-9622(23)02878-5.
9. Chu DK, Schneider L, Asiniwasis RN, 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. 2023 Dec 18:S1081-1206(23)01455-2.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per August SDC (adapted from CP.PHAR.577 with the following revisions: for atopic dermatitis initial approval criteria, added redirection to preferred agents Dupixent or Rinvoq.)	08.20.25	11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.