Original Effective Date: 04/28/2022
Current Effective Date: 06/06/2026
Last P&T Approval/Version: 04/29/2026
Next Review Due By: 04/2027
Policy Number: C23078-A

Adbry (tralokinumab-ldrm)

PRODUCTS AFFECTED

Adbry (tralokinumab-ldrm)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate-to-severe Atopic Dermatitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
   1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
      AND

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2. Member is not on concurrent treatment with, or Adbry will not be used in combination with TNF-inhibitors, biologic response modifiers or other biologic DMARDs, Janus kinase Inhibitors, Phosphodiesterase 4 inhibitors (i.e., apremilast, tofacitinib, baricitinib), or other potent immunosuppressants such as azathioprine or cyclosporine, as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
3. Documentation of ONE of the following:
   i. Member has atopic dermatitis involvement estimated to be ≥10% of the body surface area (BSA) according to the prescribing physician
   ii. Member has atopic dermatitis involvement estimated to be <10 % of the BSA affecting face, eyes/eyelids, skin folds, and/or genitalia according to the prescribing physician
   AND
4. Documentation of inadequate response, serious side effects, or contraindication to TWO of the following: topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus)
   AND
5. Documentation of inadequate response, serious side effects, or contraindication to ONE of the following: Eucrisa (crisaborole), Opzelura (ruxolitinib), Vtama (tapinarof), or Zoryve (roflumilast)
   AND
6. Documentation by prescriber of baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritis, BSA affected, topical requirement, etc.)
   AND
7. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE ATOPIC DERMATITIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of adverse effects or drug toxicity (e.g., hypersensitivity or ocular adverse effects)
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed)

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an allergist, immunologist, or dermatologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests.]

AGE RESTRICTIONS:

12 years of age and older

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QUANTITY:
Adult (18 years and older):
Initial loading dose: 600 mg
Maintenance dose: 300 mg every other week
Note: After 16 weeks of treatment, for adult members with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered.

Pediatric (12-17 years old):
Initial loading dose: 300 mg
Maintenance dose: 150 mg every other week
NOTE: The Adbry autoinjector (300mg/2mL) is for use in adults only. The Adbry prefilled syringe (150mg/1mL) is for use in adults and pediatric patients 12 years of age and older.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Atopic Dermatitis - Monoclonal Antibodies

FDA-APPROVED USES:
Indicated for the treatment of moderate-to-severe atopic dermatitis in in adults and pediatric patients 12 years of age 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria*.

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 200/65) Sec. 65. Length of prior authorization approval for treatment for chronic or long-term conditions. If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)"

Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request

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shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Atopic dermatitis (AD) is a chronic, inflammatory skin condition. Symptoms of AD include itch and recurrent eczematous skin lesions. Adbry (tralokinumab-ldrm) is a biologic agent which directly inhibits interleukin (IL)-13 for the treatment of moderate to severe atopic dermatitis (AD) in adults. IL-13 has been identified as a key driver for inflammation in AD. IL-13 may be responsible for skin inflammation and disruption, epidermal hyperplasia, itch and increased infection risk that are seen in AD. Safety and efficacy of Abdry (tralokinumab-ldrm) were established in 3 randomized, placebo-controlled trials: ECZTRA 1, ECZTRA 2, and ECZTRA 3. Adults with moderate-to-severe atopic dermatitis were randomized to Adbry (tralokinumab-ldrm) or placebo. Efficacy was assessed using the Investigator's Global Assessment (IGA) score and the Eczema Area and Severity Index (EASI) score on a scale of 0 to 72. Clinical response defined as achieving an IGA of 0 or 1 or EASI- 75, an improvement of at least 75% in EASI score from baseline. In all 3 trials, Adbry (tralokinumab- ldrm) met the primary endpoints.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Adbry (tralokinumab-ldrm) injection are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Adbry (tralokinumab-ldrm) include: known hypersensitivity to tralokinumab-ldrm or any excipients in Adbry, avoid use of live vaccines.

Exclusions/Discontinuation:

Members with pre-existing helminth infections should be treated prior to initiating treatment with Adbry. If member becomes infected while receiving treatment with Adbry and does not respond to anti-helminth treatment, Adbry should be discontinued until the infection resolves.

OTHER SPECIAL CONSIDERATIONS:

Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with Adbry.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

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HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Adbry SOSY 150MG/ML single-dose prefilled syringe
Adbry SOAJ 300MG/2ML single-dose auto-injector

REFERENCES

1. Adbry (tralokinumab-ldrm) injection, for subcutaneous use [prescribing information], Madison, NJ: LEO Pharma Inc., December 2025.
2. Wollenberg, A., Blauvelt, A., Guttman-Yassky, E., Worm, M., Lynde, C., Lacour, J. P., Spelman, L., Katoh, N., Saeki, H., Poulin, Y., Lesiak, A., Kircik, L., Cho, S. H., Herranz, P., Cork, M. J., Peris, K., Steffensen, L. A., Bang, B., Kuznetsova, A., Jensen, T. N., … ECZTRA 1 and ECZTRA 2 study investigators (2021). 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). *The British journal of dermatology*, *184*(3), 437–449. https://doi.org/10.1111/bjd.19574
3. Silverberg, J. I., Toth, D., Bieber, T., Alexis, A. F., Elewski, B. E., Pink, A. E., Hijnen, D., Jensen, T. N., Bang, B., Olsen, C. K., Kurbasic, A., Weidinger, S., & ECZTRA 3 study investigators (2021). 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. The British journal of dermatology, 184(3), 450–463. https://doi.org/10.1111/bjd.19573
4. Davis, D. M., Drucker, A. M., Alikhan, A., Bercovitch, L., Cohen, D., Darr, J. M., … Sidbury, R. (2023). Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Journal of the American Academy of Dermatology, 90(2). https://doi.org/10.1016/j.jaad.2023.08.102

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Duration of Approval FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation References	Q2 2026
REVISION-Notable revisions: Required Medical Information Quantity Other Special Considerations Available Dosage Forms References	Q2 2025
REVISION-Notable revisions: Required Medical Information Quantity Other Special Considerations Available Dosage Forms References	Q2 2025
REVISION-Notable revisions: Required Medical Information Age Restrictions	Q2 2024

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Quantity FDA-Approved Uses References	
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q2 2023
NEW CRITERIA CREATION	Q2 2022

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