Original Effective Date: 04/28/2022
Current Effective Date: 06/21/2023
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2024
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. 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 along with state and federal requirements, benefit being administered and formulary preferencing. 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.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
   AND
2. Prescriber attestation that member has completed or will complete all age-appropriate immunizations prior to initiation of Adbry
   AND
3. 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

4. (a) Member has atopic dermatitis involvement estimated to be ≥10% of the body surface area (BSA) according to the prescribing physician; AND meets all the following criteria:
    i. Member has used at least TWO of the following: a medium potency prescription topical corticosteroid, a medium-high potency prescription topical corticosteroid, a high potency prescription topical corticosteroid, OR a super high-potency prescription topical corticosteroid;
    AND
    ii. Each topical corticosteroid was applied daily for at least 14 consecutive days;
    AND
    iii. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescribing physician
    AND
    iv. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to ONE of the following: trial (6 weeks) of preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus) OR trial (4 weeks) of crisaborole (Eucrisa) OR trial (8 weeks) of Opzelura (ruxolitinib)

    OR

    (b) Member has atopic dermatitis involvement estimated to be <10 % of the BSA according to the prescribing physician and meets all of the following criteria:
    i. Member has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skin folds, and/or genitalia.
    AND
    ii. Documentation of inadequate response, serious side effects, contraindication or clinical rationale of inappropriateness to BOTH of the following: trial (6 weeks) of tacrolimus ointment (Protopic, generics) AND trial (8 weeks) of Opzelura (ruxolitinib)

    AND
5. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritis, BSA affected, topical requirement, etc.)
    AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance 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.

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

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:
18 years of age or older

QUANTITY:
Initial dose: 600 mg (four 150 mg injections)
Maintenance Dose: 300 mg (two 150 mg injections) every other week

Note: After 16 weeks of treatment, for 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.

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:
Adbry 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

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, use of live vaccines.

OTHER SPECIAL CONSIDERATIONS:
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, Abdry should be discontinued until the infection resolves.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Adbry SOSY 150MG/ML

REFERENCES

1. Adbry (tralokinumab-ldrm) injection [Prescribing Information], Madison, NJ: LEO Pharma Inc., November 2022
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

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q2 2023
New Criteria	Q2 2022