Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Tralokinumab-ldrm (Adbry®)	MP-RX-FP-149-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Tralokinumab-ldrm (Adbry®),* an interleukin-13 antagonist approved by the Food and Drug Administration (FDA) 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.

Background Information

Adbry is a is a human IgG4 monoclonal antibody that specifically binds to human interleukin13 (IL-13) and inhibits its interaction with the IL-13 receptor α1 and α2 subunits (IL-13Rα1 and IL13Rα2). IL-13 is a naturally occurring cytokine of the Type 2 immune response. Tralokinumab-ldrm inhibits the bioactivity of IL-13 by blocking IL-13 interaction with IL-13Rα1/IL-4Rα receptor complex. Tralokinumab-ldrm inhibits IL-13-induced responses including the release of proinflammatory cytokines, chemokines and IgE.

Per the American Academy of Dermatology (AAD 2014) AD, the most common form of eczema, affects approximately 2% to 3% of adults and 25% of children. AD is frequently associated with a personal or family history of allergies, allergic rhinitis and asthma. AD typically follows a relapsing/chronic course but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and crusting, or lichenification. While there is no accepted standardized method of classifying disease severity, categorization is usually based upon objective disease features, extent of skin involvement and possibly subjective disease features. Due to the impaired skin integrity, affected individuals are more susceptible to skin infections.

In 2023, the American Academy of Dermatology (AAD) published updated guidelines for the treatment of atopic dermatitis with topical therapies. The guidelines state that “Despite advances in systemic therapy for AD, topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile.” Topical calcineurin inhibitors (TCIs), topical corticosteroids (TCS), crisaborole (Eucrisa), and ruxolitinib (Opzelura) are currently supported as acceptable treatments for AD. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. The academy recommended the use of dupilumab (Dupixent), tralokinumab (Adbry), baricitinib (Olumiant), abrocitinib (Cibinqo), and upadacitinib (Rinvoq). There are also recommendations for phototherapy, cyclosporine, methotrexate, azathioprine, and mycophenolate. Systemic corticosteroids are not recommended.

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Approved Indications

A. Treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis in 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.

Other Uses

i. None.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3490	Unclassified drugs (when specified as [Adbry] (tralokinumab)
J3590	Unclassified biologics (when specified as [Adbry] (tralokinumab)
C9399	Unclassified drugs or biologicals (when specified as Adbry] (tralokinumab)

ICD-10	Description
L20	Atopic dermatitis
L20.9	Atopic dermatitis, unspecified

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Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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

Tralokinumab-ldrm (Adbry®)

A. Criteria For Initial Approval *Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual is 12 years of age or older; **AND**
ii. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
iii. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
    A. Topical calcineurin inhibitors; **OR**
    B. Eucrisa; **OR**
    C. Phototherapy (UVB or PUVA); **OR**
    D. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
    E. Individual has contraindications to topical calcineurin inhibitors *AND* Eucrisa *AND* Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) *AND* unable to use phototherapy.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Tralokinumab-ldrm (Adbry®) therapy medically necessary in members requesting reauthorization after 6 months if the following criterion is met:
    A. Treatment with Adbry (tralokinumab) has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

C. Authorization Duration

i. Initial Approval Duration: 12 months
ii. Reauthorization Approval Duration: 12 months

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D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Adbry (tralokinumab) may not be approved for the following:

i. In combination with oral or topical JAK inhibitors; **OR**
ii. In combination with biologic immunomodulators; **OR**
iii. In combination with other immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
iv. When the above criteria (section A: Criteria for Initial Approval) are not met and for all other indications

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosage	Limit
Adbry (tralokinumab) 150 mg/ml prefilled syringe	• Initial loading dose: 600 mg sc once (four 150 mg injections) • Subsequent Dosage: 300 mg sc every other week (two 150mg injections)	• 2 syringes per 28 days
Adbry (tralokinumab) 300 mg/2 ml autoinjector	• Initial loading dose: 600 mg sc once (two 300 mg injections) • Subsequent Dosage: 300 mg sc every other week (one 150mg injection)	• 1 autoinjector per 28 days

Exceptions

For Adbry Initiation of therapy in adult patients: May approve six (6) -150 mg syringes or three (3) – 300 mg autoinjectors in the first month of therapy for initiation dose and first maintenance dose, then four (4) -150 mg syringes or two (2) – 300 mg autoinjectors for the following five months of maintenance therapy for a total of twenty-six (26) - 150 mg syringes or thirteen (13) – 300 mg autoinjectors in the first six months of therapy.

For Adbry Maintenance therapy:

I. Continue authorization for one year with four (4)- 150 mg syringes or two (2) – 300 mg autoinjectors per 28 days if the following are met:
   A. Individual weighs 100 kg or more;
   OR
   B. Individual weighs less than 100 kg; **AND**
      1. One of the following is met:
         a. Individual has not achieved clear to almost clear skin in the last 6 months; **OR**
         b. Provider submits documentation providing rationale for the four (4) -150 mg syringes or two (2) – 300 mg autoinjectors per 28 days dosing (i.e. patient did not achieve or maintain clear or almost clear skin); **OR**

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c. Provider submits supporting documentation that the member has tried two (2) - 150mg syringes or one (1) – 300 mg autoinjector per 28 days dosing and did not achieve or maintain clear or almost clear skin.

Reference Information

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 21, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Atopic Dermatitis Clinical Guideline. Guidelines of care for the management of atopic dermatitis. Journal of the American Academy of Dermatology. 2014. Available at https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis. Accessed on June 21, 2022.
6. Sidbury, Robert et al. "Guidelines of care for the management of atopic dermatitis in adults with topical therapies." Journal of the American Academy of Dermatology vol. 89,1 (2023): e1-e20. doi:10.1016/j.jaad.2022.12.029

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 11/17/2025	Removed from tried and fail criteria: Opzelura and Zoryve cream as they are not part of our Part D formulary. Minimal Changes; Coding reviewed: No changes.	12/3/2025	12/11/2025
Annual Review 12/18/2024	Update Adbry criteria for age limit from 18 to 12 years of age, update trial agents for atopic dermatitis criteria. Add Adbry 300mg autoinjector, add Zoryve 0.15% cream trial to criteria. Modify quantity limit table to add autoinjector and quantity limits. Wording and formatting changes. Coding Reviewed: No changes.	3/20/2025	4/2/2025
Policy Inception 01/25/2024	Elevance Health's Medical Policy Adoption	N/A	6/28/2024