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.

Guidelines from the AAD regarding the treatment of AD recommend non-pharmacologic therapy, pharmacologic therapy and phototherapy (AAD 2014). Non-pharmacologic therapy includes use of moisturizers (I, A) and use of wet wrap therapy with or without a topical corticosteroid for those with moderate to severe AD during flares (II, B). First line topical pharmacologic therapy are topical corticosteroids (I, A). Labeled dosage guidance from high dose topical steroids recommend limiting consecutive use to 2 weeks (Ultravate 2020, Diprolene 2019). Topical calcineurin inhibitors are recommended for use on actively affected areas as a steroid sparing agent (I, A). Labeled dosage guidance for Elidel and Protopic recommend re-evaluation if signs and symptoms persist beyond 6 weeks of use (Elidel 2017, Protopic 2019). Phototherapy is recommended as a second line treatment, after failure of first-line treatment (topical therapy) (II, B). In addition, phototherapy can be used as maintenance therapy in those with chronic disease. Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate) are indicated when individuals have disease symptoms not controlled by optimized topical regimens and/or phototherapy (I,II, B). The guidelines have not been updated to address the use of any biologic agent.

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Approved Indications

Adbry is approved by the Food and Drug Administration (FDA) for patients aged 12 years and older for the treatment of moderate-to-severe atopic dermatitis in whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Other Uses

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

i. Individual is 18 years of age or older; **AND**

ii. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**

iii. Individual meets one of the following (A or B):

A. Failure of topical pharmacological therapy as indicated by both (1 and 2) of the following:

1. Daily treatment of topical corticosteroids of medium to higher potency for at least fourteen (14) days has failed to achieve and maintain remission of low or mild disease activity state; **OR**

a. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (AAD 2014):

i. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**

ii. Individual has steroid-induced atrophy; **OR**

iii. History of long-term or uninterrupted topical steroid use;

AND

2. Documentation is provided that daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**

a. Documentation is provided that topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:

i. History of or active malignant or pre-malignant skin conditions; **OR**

ii. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**

iii. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis;

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OR

B. One of the following:
   1. Documentation is provided that phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated; **OR**
   2. Documentation is provided that non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) have failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

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

D. Conditions Not Covered

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

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.

Population	Initial Loading Dose	Subsequent Dosage
Adult 18 years and older	600 mg (four 150 mg injections)	300 mg (two 150 mg injections) every other week
Pediatric 12 to 17 years old	300 mg (two 150 mg injections)	150 mg (one 150 mg injection) every other week

Exceptions

<u>For Adbry Initiation of therapy in adult patients:</u> May approve six (6) -150 mg syringes in the first month of therapy for initiation dose and first maintenance dose, then four (4) -150 mg syringes for the following five months of maintenance therapy for a total of twenty-six (26) - 150 mg syringes in the first six months of therapy

<u>For Adbry maintenance therapy</u>:

I. Continue authorization for one year with four (4)- 150 mg syringes 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 per 28 days dosing (i.e. patient did not achieve or maintain clear or almost clear skin); **OR**
         c. Provider submits supporting documentation that the member has tried two (2) - 150mg syringes per 28 days dosing and did not achieve or maintain clear or almost clear skin.

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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
Policy Inception	Elevance Health's Medical Policy Adoption	N/A	6/28/2024

Revised: 01/25/2024