Medical Drug Clinical Criteria

Subject:	Adbry (tralokinumab)		
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Overview

This document addresses the use of Adbry (tralokinumab), an injectable, selective interleukin (IL)-13 antagonist. Adbry is indicated for the treatment of moderate-to-severe atopic dermatitis (AD) 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.

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.

Clinical Criteria

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.

Adbry (tralokinumab)

Initial requests for Adbry (tralokinumab) for the treatment of atopic dermatitis may be approved if the following criteria are met:

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. Opzelura; **OR**
    D. Zoryve 0.15% Cream; **OR**
    E. Vtama; **OR**
    F. Phototherapy (UVB or PUVA); **OR**
    G. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**

H. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Vtama AND Zoryve 0.15% Cream AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use phototherapy.

Continuation requests for Adbry (tralokinumab) for atopic dermatitis after 6 months may be if approved if the following criterion is met:

I. 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).

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

I. In combination with oral or topical JAK inhibitors; **OR**
II. In combination with dupilumab, lebrikizumab-lbkz, or nemolizumab-ilto; **OR**
III. In combination with other immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
IV. When the above criteria are not met and for all other indications.

Initial approval duration: 6 months
Continuation approval duration: 12 months

Quantity Limits

Adbry (tralokinumab) Quantity Limits

Drug	Limit
Adbry (tralokinumab) 150 mg syringe*	2 syringes per 28 days
Adbry (tralokinumab) 300 mg autoinjector*	1 autoinjector per 28 days

* For Adbry Initiation of therapy: 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**
         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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

L20.0-L20.9	Atopic dermatitis

Document History

Revised: 02/21/2025
Document History:

- 02/21/2025 – Annual Review: add Vtama option, Update do not approve criteria. Coding Reviewed: Removed HCPCS NOC J3490 and all diagnoses pend. Added ICD-10-CM L20.0-L20.9.
- 08/16/2024 – Annual Review: Add Adbry 300mg autoinjector, add Zoryve 0.15% cream trial to criteria. Coding Reviewed: No changes.
- 03/11/2024 – Select Review: No change. Coding changes. No changes.
- 02/23/2024 – Select Review: update Adbry criteria for age limit from 18 to 12 years of age, update trial agents for atopic dermatitis criteria. Coding Reviewed: No changes.
- 08/18/2023 – No Changes. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Update do not approve criteria, update quantity limit override. Coding Reviewed: No changes.
- 06/13/2022 – Select Review: Update do not approve criteria, update quantity limit override criteria. Coding Reviewed: Added HCPCS C9399. Effective 8/1/2022 Added HCPCS J3590.
- 02/25/2022– Select Review: Clarify systemic therapy, modify do not approve criteria, wording and formatting changes. Coding Reviewed: No changes.
- 01/04/2022 – Select Review: Add new clinical criteria and quantity limit for Adbry. Coding Reviewed: Added HCPCS J3490. All diagnoses pend.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2025. 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: Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 202; Updated periodically.
5. 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. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102.
6. Eichenfield L. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. Journal of the American Academy of Dermatology. 2014-01;71:116.
7. 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.