Adbry (tralokinumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial approval duration: 6 months Continuation approval duration: 12 months

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

* 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.

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 weighs100 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).

APPROVAL CRITERIA

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 0.015% Cream; **OR**
   E. Vtama; **OR**
   F. Phototherapy (UVB or PUVA); **OR**
   G. Non-corticosteroid systemic immunosuppressants (including cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
   H. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Zoryve 0.015% Cream AND Vtama AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use phototherapy;

AND

IV. Documentation is provided that individual has been receiving and is maintained on a stable dose of the Adbry;

OR

V. Documentation is provided that individual has had a trial of and inadequate response or intolerance to Dupixent (dupilumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.

Continuation requests for Adbry (tralokinumab) for atopic dermatitis 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 (including cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil); **OR**
IV. When the above criteria are not met and for all other indications.

Key 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.