

Clinical Policy Title:	tralokinumab-ldrm
Policy Number:	RxA.722
Drug(s) Applied:	Adbry®
Original Policy Date:	04/18/2022
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Moderate to severe atopic dermatitis (must meet all):

1. Diagnosis of moderate to severe atopic dermatitis;
2. Member meets one of the following (a or b):
 - a. $\geq 10\%$ of the body surface area involvement;
 - b. Baseline scoring atopic dermatitis (SCORAD) ≥ 25 ;
3. Trial and failure, unless contraindicated or clinically significant adverse effects are experienced, to one of the following (a or b):
 - a. Crisaborole (Eucrisa®) ointment;
 - b. Medium to high potency topical corticosteroid, pimecrolimus cream, or tacrolimus topical ointment.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Moderate to severe atopic dermatitis (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dermatitis. J Am Acad Dermatol. 2014 February; 70(2): 338–351. Available at: [https://www.jaad.org/article/S0190-9622\(13\)01095-5/fulltext](https://www.jaad.org/article/S0190-9622(13)01095-5/fulltext). Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/02/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated diagnostic criteria from Documentation of involvement of at least 10% of body surface	06/29/2022	07/18/2022

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>area to Member has atopic dermatitis involvement estimated to be $\geq 10\%$ of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25.</p> <p>2. Initial Approval Criteria, I.A.6: Updated to include new trial and failure criteria Member meets (a and b):</p> <p>a. Trial and failure of any two of medium to high potency topical corticosteroid, pimecrolimus cream, tacrolimus topical ointment, or Eucrisa (crisaborole) ointment at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced</p> <p>b. Trial and failure of at least one (1) systemic agent (e.g. corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, Dupixent, Adbry) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced.</p> <p>3. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria I.A.6.a: Updated from trial and failure of any two of agents to any one agent.</p> <p>2. References were reviewed and updated.</p>	11/17/2022	11/21/2022
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria I.A.4: Updated to remove IGA criteria “Member has an Investigator’s Global Assessment (IGA) score of 3 or 4”.</p> <p>2. Initial Approval Criteria I.A.7: Updated to remove combination therapy criteria “Adbry® should not be used (a, b and c);</p> <p>a. In combination with another biologic medication indicated for AD;</p> <p>b. In combination with JAK inhibitors indicated for AD;</p> <p>c. Other interleukin-receptor antagonists”</p> <p>3. References were reviewed and updated.</p>	05/30/2023	07/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023

Updated trial and failure, removed dose and age criteria	2/1/2024	2/1/2024
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prescriber criteria. 2. Updated approval duration verbiage. 3. Updated continuation of therapy language. 	03/24/2025	04/10/2025
Policy was reviewed: <ol style="list-style-type: none"> 1. Added to trial and failure (a <u>or</u> b): <ol style="list-style-type: none"> a. Medium to high potency topical corticosteroid <u>or</u> Pimecrolimus cream or tacrolimus topical ointment b. Crisaborole (Eucrisa®) ointment. 	6/19/2025	6/19/2025
Policy reviewed.	12/11/2025	12/11/2025