Clinical Policy Title:	tralokinumab-ldrm
Policy Number:	RxA.722
Drug(s) Applied:	Adbry®
Original Policy Date:	04/18/2022
Last Review Date:	2/1/2024
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. Prescribed by or in consultation with a dermatologist, allergist, or immunologist;
3. Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25;
4. Trial and failure, unless contraindicated or clinically significant adverse effects are experienced, to one of the following (a, b, or c):
   a. medium to high potency topical corticosteroid;
   b. pimecrolimus cream or tacrolimus topical ointment
   c. crisaborole (Eucrisa®) ointment;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. J Am Acad Dermatol. 2014 February; 70(2): 338–351. Available at: https://www.jaad.org/article/S0190-9622(13)01095-5/fulltext. Accessed May 30, 2023.

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	06/29/2022	07/18/2022

diagnostic criteria from Documentation of involvement of at least 10% of body surface area to Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25. 2. Initial Approval Criteria, I.A.6: Updated to include new trial and failure criteria Member meets (a and b): 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 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. 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.6.a: Updated from trial and failure of any two of agents to any one agent. 2. References were reviewed and updated.	11/17/2022	11/21/2022
Policy was reviewed: 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". 2. Initial Approval Criteria I.A.7: Updated to remove combination therapy criteria "Adbry® should not be used (a, b and c); a. In combination with another biologic medication indicated for AD; b. In combination with JAK inhibitors indicated for AD; c. Other interleukin-receptor antagonists" 3. References were reviewed and updated.	05/30/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023

Updated trial and failure, removed dose and age criteria	2/1/2024	2/1/2024