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

Background

Adbry™ is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry™ can be used with or without topical corticosteroids.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tralokinumab-ldrm (Adbry™)	Treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies.	Administered as an initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment.	600 mg subcutaneously initially, then 300 mg subcutaneously every other week.

Dosage Forms

- Injection: 150 mg/mL solution in a single-dose prefilled syringe with needle guard.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of moderate to severe atopic dermatitis;
2. Age ≥18 years of age;
3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist;
4. Member has an Investigator's Global Assessment (IGA) score of 3 or 4;

5. Documentation of involvement of at least 10% of body surface area;
6. Failure of all of the following (a, b, c and d), unless contraindicated or clinically significant adverse effects are experienced:
   a. One formulary medium to very high potency topical corticosteroids, each used for ≥ 2 weeks;
   b. One non-steroidal topical therapy*: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment and pimecrolimus 1% cream) or Eucrisa®, each used for ≥ 4 weeks;
      * These agents may require prior authorization
   c. One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
7. 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;
8. Dose does not exceed the following:
   a. Initial (one-time) dose: 600 mg;
   b. Maintenance dose: 300 mg every other week.

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 medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. If clear or almost clear skin is achieved in the initial authorization periods and the dose is not reduced to every-4-week injections, clinical rationale supporting continuation of 300 mg every 2-week injections;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
IGA: Investigator's Global Assessment
AD: Atopic dermatitis
JAK: Janus kinase

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dupilumab (Dupixent®)	600 mg subcutaneously initially (administered as two 300 mg injections), followed by 300 mg subcutaneously every other week.	600 mg subcutaneously initially, then 300 mg subcutaneously every other week.

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand,

Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to tralokinumab-ldrm or any excipients in Adbry™.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received Adbry™.
- May alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with Adbry™.

References

1. Adbry™ Prescribing Information. Madison, NJ: LEO Pharma Inc; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d8020b69-3001-44e2-9b5d-5f93d9aaf6e1&type=display. Accessed February 2, 2022.
2. IPD Analytics Rx Insights_New Drug Review_ Adbry™ 01.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Adbry. Accessed February 2, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	2/2/2022	04/18/2022