AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Adbry™ (tralokinumab)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limits: 4 mL (4 prefilled syringes) per 28 days

Recommended Dosage: 600 mg (given as four 150 mg injections) once, followed by 300 mg (given as two 150 mg injections) once every other week. In members with body weight <100 kg who achieve clear or almost clear skin after 16 weeks of therapy, may reduce dosage to 300 mg every 4 weeks.

***AvMed considers the use of concomitant therapy with Adbry™, Cinqair®, Dupixent®, Fasenra®, Nucala®, and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Fasenra®, Nucala®, and Xolair® authorization on file, all subsequent requests for Adbry™ will NOT be approved.**

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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❑ Diagnosis: Moderate-to-Severe Atopic Dermatitis

Initial Authorization: 4 months

- ❑ Member has a diagnosis of **moderate to severe atopic dermatitis** with disease activity confirmed by **ONE** of the following **(chart notes documenting disease severity and BSA involvement must be included):**
  - ❑ Body Surface Area (BSA) involvement >10%
  - ❑ Eczema Area and Severity Index (EASI) score ≥ 16
  - ❑ Investigator's Global Assessment (IGA) score ≥ 3
  - ❑ Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- ❑ Prescribed by or in consultation with an **Allergist, Dermatologist** or **Immunologist**
- ❑ Member is 18 years of age or older
- ❑ Member has tried and failed, has a contraindication, or intolerance to **ALL** four of the following therapies **(chart notes documenting contraindication(s) or intolerance must be attached; trials will be verified using pharmacy claims and/or submitted chart notes)**:
  - ❑ 30 days (14 days for very high potency) of therapy with **ONE** medium to very-high potency topical corticosteroid in the past 180 days
  - ❑ 30 days of therapy with **ONE** of the following topical calcineurin inhibitors in the past 180 days:
    - ❑ tacrolimus 0.03 % or 0.1% ointment
    - ❑ pimecrolimus 1% cream **(requires prior authorization)**
  - ❑ 90 days of phototherapy (e.g., NB UV-B, PUVA) unless the member is not a candidate and/or has an intolerance or contraindication to therapy
  - ❑ 90 days of therapy with **ONE** of the following oral immunosuppressants in the past 180 days:
    - ❑ azathioprine
    - ❑ cyclosporine
    - ❑ methotrexate
    - ❑ mycophenolate

❑ Diagnosis: Moderate-to-Severe Atopic Dermatitis

Reauthorization: 12 months. Check below all that apply. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has experienced a positive clinical response to Adbry™ therapy (e.g., reduced BSA involvement, decrease in severity based on physician assessment) **(chart notes must be submitted)**

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- Provider submits clinical documentation to support **ONE** of the following:
  - Maintenance dosage has been decreased to 300 mg every 4 weeks
  - Member has tried and failed 180 days of therapy at maintenance dosage of 300 mg every 4 weeks and is no longer experiencing a positive clinical response to Adbry therapy™ (e.g., increased BSA involvement, increase in severity based on physician assessment) **(verified by paid claims; chart notes must be submitted)**

Medication being provided by Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** 3/17/2022
REVISED/UPDATED/REFORMATTED: ~~3/8/2022; 5/2/2022; 6/15/2022;06/16/2022;~~ **10/25/2023**