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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

Quantity Limits:

- 150 mg/mL solution in a single-dose prefilled syringe with needle guard: 4 mL (4 prefilled syringes) per 28 days
- Injection: 300 mg/2 mL solution in a single-dose auto-injector: 4 mL (2 auto-injectors) per 28 days

Recommended Dosage:

Adults

Formulation	Initial Loading Dose	Subsequent Dosage
Prefilled syringe	600 mg (four 150 mg injections)	300 mg (two 150 mg injections) every other week
Auto-injector	600 mg (two 300 mg injections)	300 mg (one 300 mg injection) every other week
NOTE: After 16 weeks of treatment, for adult patients with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered.		

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Pediatric Patients 12 years of age and older

Formulation	Initial Loading Dose	Subsequent Dosage
Prefilled syringe	300 mg (two 150 mg injections)	150 mg (one 150 mg injection) every other week

NOTE: The Health Plan 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.

- Will the member be discontinuing a previously prescribed biologic if approved for requested medication?
  ❑ Yes **OR** ❑ No
- If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

  Medication to be discontinued: _____ **Effective date:** _____

  Medication to be initiated: _____ **Effective date:** _____

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.

❑ 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 12 years of age or older

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- ❑ 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

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)**
- ❑ 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 – Proprium Rx

*****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.****