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; <u>fax to 1-305-671-0200</u>. 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 #:	
Prescriber Name:	
Prescriber Signature:	Date:
Office Contact Name:	
Phone Number:	Fax Number:
DEA OR NPI #:	
DRUG INFORMATION: Authorization	n may be delayed if incomplete.
Drug Name/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.

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 <u>NOT</u> been established and will <u>NOT</u> 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 <u>NOT</u> 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.

Diagnosis: Moderate-to-Severe Atopic Dermatitis

Initial Authorization: 4 months

- Member has a diagnosis of <u>moderate to severe atopic dermatitis</u> with disease activity confirmed by <u>ONE</u> 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 \geq 3
 - □ Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- **D** Prescribed by or in consultation with an Allergist, Dermatologist or Immunologist
- □ Member is 12 years of age or older
- Member has tried and failed, has a contraindication, or intolerance to <u>ALL</u> 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 <u>ONE</u> medium to very-high potency topical corticosteroid in the past 180 days
 - □ 30 days of therapy with <u>ONE</u> 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 <u>ONE</u> of the following oral immunosuppressants in the past 180 days:
 - □ azathioprine
 - □ cyclosporine
 - □ methotrexate
 - □ mycophenolate

<u>Reauthorization</u>: 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 <u>ONE</u> 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)

(Continued on next page)

Medication being provided by Specialty Pharmacy – Proprium Rx

**Use of samples to initiate therapy does not meet step edit/ preauthorization criteria. ** *<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>*