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: Nucala®SQ (mepolizumab) **(Pharmacy)**
{Eosinophilic Granulomatosis Polyangiitis (EGPA)}

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:** _____

Recommended Dosage: 300 mg/mL SubQ once every 4 weeks administered as 3 separate 100-mg injections; single-dose prefilled auto-injector/single-dose prefilled syringe

***The Health Plan considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, Tezspire® 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®, Tezspire® or Xolair® authorization on file, all subsequent requests for Nucala® 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.

Initial Authorization: 12 months

- ❑ Medication must be prescribed by an allergist, immunologist, or pulmonologist

(Continued on next page)

- ❑ Member must be 18 years of age or older
- ❑ Member must have diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) > 6 months based on the history or presence of asthma
- ❑ Lab documentation must show an eosinophil count of ≥150 cells/microliter at baseline
- ❑ Member must have documentation of **TWO** of the following:
  - ❑ A biopsy showing evidence of EGPA
  - ❑ Mono-or polyneuropathy
  - ❑ Pulmonary infiltrates, non-fixed on chest x-rays
  - ❑ Sino-nasal abnormality
  - ❑ Magnetic Resonance Imaging or Echocardiography of cardiomyopathy
  - ❑ Glomerulonephritis
  - ❑ Alveolar hemorrhage (by bronchoalveloar lavage)
  - ❑ Palpable purpura
  - ❑ Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
- ❑ Member must have a history of relapsing **OR** refractory disease defined as **(select one of the following)**:
  - ❑ **Relapsing disease:**
    - ❑ Must have a history of at least **ONE** confirmed EGPA relapse requiring:
      - ❑ An increase in oral corticosteroids (OCS) dose
      - ❑ Initiation or increased dose of immunosuppressive therapy **(e.g., azathioprine, cyclophosphamide, methotrexate, or mycophenolate mofetil)**
      - ❑ Hospitalization
    - ❑ Must have occurred > 12 weeks but < 2 years prior to initiation while receiving a dose of prednisone (or equivalent) of >7.5 milligram per day (mg/day) for **at least 90 consecutive days**
  - ❑ **Refractory disease:**
    - ❑ Refractory disease must meet **ONE** of the following:
      - ❑ Failure to attain remission (Birmingham Vasculitis Activity Score (BVAS) =0) and OCS dose <7.5 mg/day prednisone or equivalent) for **at least 90 consecutive days** within the last 6 months following induction treatment with a standard regimen **(e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, or high-dose corticosteroids (> 15 mg/day prednisone)**, administered for at least 3 months
      - ❑ Within 6 months prior to initiation, recurrence of symptoms of EGPA while tapering oral corticosteroids (OCS), occurring at any dose level ≥7.5 mg/day prednisone or equivalent taken for **at least 90 consecutive days**

(Continued on next page)

Exclusion Criteria – Therapy will NOT be approved if member has history of any of the following:

- Organ/life threatening EGPA within 3 months prior to initiation
- Malignancy: current malignancy or previous history of cancer in remission for < 12 months
- Unstable cardiovascular disease: Ejection fraction < 20%, New York Heart Association Class III/IV failure, acute myocardial infarction diagnosed less than 3 months
- Unstable liver disease: Presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, cirrhosis, and known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones
- Rituximab within the past year; IVIg within the past 6 months; omalizumab within the past 4 months
- Pregnancy, breast-feeding, absence of contraception if female of child-bearing age

Reauthorization: 12 months. 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 must meet **ONE** of the following:
  - ❑ Documentation of remission or improvement in the Birmingham Vasculitis Activity Score (BVAS) or prednisone/prednisolone daily dose of ≤ 7.5mg
  - ❑ Documentation of decrease in maintenance dose of systemic corticosteroids, improvement in asthma symptoms or asthma exacerbations
  - ❑ Documentation of disease flares with tapering of corticosteroid therapy or immunotherapy

Medication being provided by a 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.

***Approved by Pharmacy and Therapeutics Committee:** ~~6/29/2018;~~ 8/16/2018
REVISED/UPDATED/REFORMATTED: ~~12/30/2018;3/18/2019; 5/5/2019; 7/7/2019;9/18/2019; 10/27/2023~~, **2/21/2024**