# 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:** 300mg/mL SubQ once every 4 weeks administered as 3 separate 100-mg injections; single-dose prefilled autoinjector/single-dose prefilled syringe

***AvMed considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, 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 Dupixent®, Fasenra®, Xolair® and Nucala® authorization on file, all subsequent requests will not be approved.**

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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**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 Approval Length: 12 months**

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

**AND**

- ❑ Member must be 18 years of age or older;

**AND**

- ❑ Member must have diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) > 6 months based on the history or presence of asthma;

**AND**

- ❑ Eosinophilia >10%;

**AND**

- ❑ 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)

**AND**

- ❑ History of relapsing **OR** refractory disease defined as **(must select one of the following)**:
  - ❑ **Relapsing disease:**
    - ❑ Must have a past 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., cyclophosphamide, methotrexate, azathioprine 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.**

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- **Refractory disease:**

  Either:

  - 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., cyclophosphamide, methotrexate, azathioprine, mycophenolate mofetil, or high-dose corticosteroids** (> 15 mg/day prednisone), administered for at least 3 months.

    **OR**

  - 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.**

**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 APPROVAL - 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.

- Documentation of remission or improvement in the Birmingham Vasculitis Activity Score (BVAS) or prednisone/prednisolone daily dose of ≤ 7.5mg

**OR**

- Documentation of decrease in maintenance dose of systemic corticosteroids, improvement in asthma symptoms or asthma exacerbations

**OR**

- Documentation of disease flares with tapering of corticosteroid therapy or immunotherapy

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## Medication being provided by a Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

***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**