

# Rning,SENTARA COMMUNITY PLAN (MEDICAID)

## MEDICAL 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 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

**Drug Requested:** Nucala<sup>®</sup> SQ (mepolizumab) (C9166) (Medical)  
Eosinophilic Granulomatosis Polyangiitis (EGPA)\*

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

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ 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: \_\_\_\_\_

- 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.

**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

- Nucala<sup>®</sup> 100mg/ml single pre-filled syringe, auto-injector and vial= 100 billable units

**\*The Health Plan considers the use of concomitant therapy with Cinqair<sup>®</sup>, Dupixent<sup>®</sup>, Fasentra<sup>®</sup>, Tezspire<sup>®</sup> and Xolair<sup>®</sup> 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<sup>®</sup>, Dupixent<sup>®</sup>, Fasentra<sup>®</sup>, Tezspire<sup>®</sup> or Xolair<sup>®</sup> authorization on file, all subsequent requests for Nucala<sup>®</sup> will NOT be approved.**

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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 Authorization: 6 months**

1. Has the member been approved for Nucala<sup>®</sup> previously through the Sentara pharmacy department?  
 Yes    No
2. Is the member 18 years of age or older?  
 Yes    No
3. Does the member have a confirmed diagnosis of EGPA (aka Churg-Strauss Syndrome)?  
 Yes    No
4. Does the member have blood eosinophils  $\geq 150$  cells/ $\mu$ L within 6 weeks of dosing?  
 Yes    No
5. Has the member been on stable dose of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day)?  
 Yes    No
6. Has the physician assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)?  
 Yes    No

**Reauthorization: 12 months.** 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.

1. Has the member been assessed for toxicity?  
 Yes    No
2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
  - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of  $\leq 7.5$  mg]
  - Decrease in maintenance dose of systemic corticosteroids
  - Improvement in BVAS score compared to baseline
  - Improvement in asthma symptoms or asthma exacerbations
  - Improvement in duration of remission or decrease in the rate of relapses? Yes    No

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**\*Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all the following:**

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute count > 1000 cells/mm<sup>3</sup>
- Two or more of the following criteria:
  - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates
  - Sinonasal abnormalities
  - Cardiomyopathy
  - Glomerulonephritis
  - Alveolar hemorrhage
  - Palpable purpura
  - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

**Medication being provided by a Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.\****