SENTARA HEALTH PLANS

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 1-800-750-9692**. 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 Sentara #: _____ **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:** _____

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.**

- 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:** _____

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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: 12 months

- ❑ Medication must be prescribed by an allergist, immunologist, pulmonologist, or rheumatologist
- ❑ Member must be 18 years of age or older
- ❑ Has the member been approved for Nucala® previously through the Health Plan medical department?
  - ❑ Yes ❑ No
- ❑ Member must have diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) based on the history or presence of asthma
- ❑ Member must have a blood eosinophil level >10% of total white blood cells or an absolute eosinophil count >1000 cells/mm^3 at baseline

  Eosinophil count: _____ **Date:** _____
- ❑ Member must have documentation of **TWO** of the following:
  - ❑ A biopsy showing histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - ❑ 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)
- ❑ Physician has 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, or rate of relapses, etc.)
- ❑ Member has active, non-severe disease defined as vasculitis without life- or organ-threatening manifestations. Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis

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- ❑ Member must have a history of **ONE** of the following:
  - ❑ **Relapsing disease:**
    - ❑ Member 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 within the past 2 years 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, high-dose corticosteroids, or rituximab 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**
- ❑ Member has been on a stable dose of oral corticosteroid therapy for at least 4 weeks prior to starting treatment (e.g., prednisone or equivalent of ≥ 7.5 mg/day)

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.

- ❑ Member must meet **ONE** of the following:
  - ❑ Documentation of remission or improvement in the Birmingham Vasculitis Activity Score (BVAS)=0 (no active vasculitis) plus prednisone/prednisolone daily dose of ≤ 7.5 mg/day or equivalent
  - ❑ Documentation of improvement in duration of remission or decrease frequency in the occurrence of relapses
  - ❑ Documentation of decrease in maintenance dose of systemic corticosteroids
  - ❑ Documentation of improvement on a disease activity scoring tool [e.g., Vasculitis Damage Index (VDI), Birmingham Vasculitis Activity Score (BVAS), Forced vital capacity (FVC), Forced Expiratory Volume during first second (FEV1), Asthma Control Questionnaire (6-item version) (ACQ-6), etc.]

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Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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;~~ **11/21/2024**
REVISED/UPDATED/REFORMATTED: ~~12/30/2018; 3/18/2019; 5/5/2019; 7/7/2019; 9/18/2019; 2/22/2024;~~**12/17/2024**