SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Nucala® SQ (mepolizumab) **(J2182) (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:** _____

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:** _____

- ❑ 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

***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.**

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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 pharmacy 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 a Specialty Pharmacy – Proprium Rx

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