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:** _____

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

- ❑ 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.

***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, or pulmonologist
- ❑ 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:**
    - ❑ 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 > 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

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- ❑ 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: 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

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.*

***Approved by Pharmacy and Therapeutics Committee:** ~~6/29/2018;~~ 8/16/2018
REVISED/UPDATED: ~~12/30/2018;~~ **(Reformatted)** ~~3/18/2019; 5/5/2019; 7/7/2019; 9/15/2019~~**, 2/22/2024**