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® SQ (mepolizumab) Injection (J2182) (Medical)
Severe Eosinophilic Asthma* (SEA)

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 for Severe Asthma*:

- Adults and adolescents ≥ 12 years: 100 mg/mL SubQ, single-dose prefilled auto-injector or single dose prefilled syringe, once every 4 weeks
- Children ≥ 6 years to 11 years: 40 mg/mL SubQ, single-dose prefilled syringe, once every 4 weeks

Quantity Limit: 100 mg per 28 days

- Nucala® 100mg/ml single pre-filled syringe, auto-injector and vial= 100 billable units
- Nucala® 40mg/0.4ml prefilled syringe= 40 billable units

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***The Health Plan considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, 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.**

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® previously through the Sentara pharmacy department?
   ❑ Yes ❑ No
2. Is the member 6 years of age or older?
   ❑ Yes ❑ No
3. Does the member have a diagnosis of severe* asthma?
   ❑ Yes ❑ No
4. Does the member have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL?
   ❑ Yes ❑ No
5. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)?
   ❑ Yes ❑ No
5. Will this this be used for add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
   - Medium- to high-dose inhaled corticosteroids; **AND**
   - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers)?

   ❑ Yes ❑ No
6. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) **or** one exacerbation resulting in a hospitalization?
   ❑ Yes ❑ No
7. Does the member have at least one of the following for assessment of clinical status:
   - Use of systemic corticosteroids
   - Use of inhaled corticosteroids
   - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
   - Forced expiratory volume in 1 second (FEV_1)?

   ❑ Yes ❑ No

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8. Has the member tried and failed an adequate trial of the 2 different **preferred products (Fasenra® and Xolair®)?**
   ❑ 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. Has member had improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in **ONE or more** of the following **(check all that apply; chart notes must be submitted):**
   - Use of systemic corticosteroids
   - Hospitalizations
   - ER visits
   - Unscheduled visits to healthcare provider
   - Improvement from baseline in forced expiratory volume in 1 second (FEV1)?

   ❑ Yes ❑ No

***Components of severity for classifying asthma as *severe* may include any of the following (not all inclusive):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times per week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma.

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **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.****