SENTARA COMMUNITY PLAN (MEDICAID)

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; <u>fax to 1-800-750-9692</u>. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. <u>If the information provided is not</u> complete, correct, or legible, the authorization process can be delayed.

<u>Drug Requested</u>: Nucala[®] SQ (mepolizumab) Injection (Pharmacy) {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: | |
| DEA OR NPI #: | |
| DRUG INFORMATION: Authorization may be delayed if incomplete. | |
| Drug Name/Form/Strength: | |
| Dosing Schedule: | Length of Therapy: |
| Diagnosis: | ICD Code, if applicable: |
| Weight: | Date: |

IF REQUIRED, TYPE RECOMMENDED DOSAGE AND/OR QUANTITY LIMITS

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 \geq 6 years to 11 years: 40 mg/mL SubQ, single-dose prefilled syringe, once every 4 weeks

*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 <u>NOT</u> been established and will <u>NOT</u> 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 <u>NOT</u> 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. (Trials will be verified using pharmacy claims and/or submitted chart notes.)

Initial Authorization: 12 months

- □ Prescribed by or in consultation with an allergist, immunologist or pulmonologist
- □ Member is 6 years of age or older
- □ Has the member been approved for Nucala[®] previously through the Health Plan medical department?

□ Yes □ No

- □ Member has been diagnosed with severe eosinophilic phenotype defined by a baseline (pre-Nucala[®] treatment) peripheral blood eosinophil level ≥ 150 cells/microliter
- Member is currently being treated with <u>ONE</u> of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy <u>for at least 90 consecutive days</u> within a year of request:
 - □ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) <u>AND</u> an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
 - One maximally dosed combination ICS/LABA product (e.g., Advair[®] (fluticasone propionate/salmeterol), Dulera[®] (mometasone/formoterol), Symbicort[®] (budesonide/formoterol))
- □ Member has experienced <u>ONE</u> of the following (check box that applies):
 - More than > 2 exacerbations requiring additional medical treatment (e.g., an increase in oral corticosteroid dose, emergency department, urgent care visits or hospitalizations) within the past 12 months
 - □ Any prior intubation for an asthma exacerbation
- □ Member has a baseline forced expiratory volume (FEV1) < 80% predicted normal (< 90% for members 6-17 years old) submitted within year of request
- Provider must submit member blood eosinophil count after a trial and failure of at least 90 consecutive days of therapy with high dose inhaled corticosteroids <u>AND</u> long-acting inhaled beta-2 agonist. A failure of these medications is defined as a blood count > 150 cells/microliter (submit labs collected within the past 12 months)

 Eosinophil count:

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<u>Reauthorization</u>: 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 has experienced a sustained positive clinical response to Nucala[®] therapy as demonstrated by at least <u>ONE</u> of the following (check all that apply; chart notes must be submitted):
 - □ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
 - **D** Reduction in the dose of inhaled corticosteroids required to control asthma
 - □ Reduction in the use of oral corticosteroids to treat/prevent exacerbation
 - Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath or nocturnal awakenings
- □ Member is currently being treated with <u>ONE</u> of the following unless there is a contraindication or intolerance to these medications:
 - □ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) <u>AND</u> an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
 - □ One maximally dosed combination ICS/LABA product (e.g., Advair[®] (fluticasone propionate/salmeterol), Dulera[®] (mometasone/formoterol), Symbicort[®] (budesonide/formoterol))

Medication being provided by a Specialty Pharmacy- PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria. *<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>*