AvMed

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 1-305-671-0200**. 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) **Injection (Pharmacy)**
{Severe Eosinophilic Asthma (SEA)}

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **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 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**

***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

- ❑ 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 AvMed 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 **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within a year of request:
  - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** 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 **ONE** 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 **AND** 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: _____ **Date:** _____

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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 has experienced a sustained positive clinical response to Nucala® therapy as demonstrated by at least **ONE** of the following **(check all that apply; chart notes must be submitted)**:
  - ❑ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - ❑ 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 **ONE** 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) **AND** 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 – Proprium Rx

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:** ~~3/17/2016;~~ 3/17/2022
REVISED/UPDATED/REFORMATTED: ~~5/6/2016; 9/28/2016; 12/11/2016; 4/1/2017; 8/6/2017; 6/19/18; 7/13/2018; 3/212019; 7/7/2019; 9/18/2019; 4/27/2022; 6/16/2022;7/13/2022; 10/27/2023;~~ **2/22/2024**