AvMed

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) **Injection (J2182) (Medical)**
{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:** _____

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:

- **Pediatric Patients aged 6 – 11 years: 40 mg prefilled syringe, every 4 weeks, under the guidance of a healthcare provider or administered at home by a caregiver once trained by a healthcare provider**
- **Adults and adolescents aged 12 years and older: 100 mg lyophilized powder in single-dose vial or solution in prefilled syringe/auto-injector every 4 weeks**

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***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.**

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 pharmacy 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

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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:** ~~3/17/2016~~; **3/17/2022**
REVISED/UPDATED: ~~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~~; ~~9/15/2019~~; ~~4/27/2022~~; ~~6/16/2022~~; 7/13/2022**; 2/22/2024**.