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 1-877-535-1391**. 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® (mepolizumab) **(J2182) (Medical)**
Chronic Obstructive Pulmonary Disease (COPD)

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.

Quantity Limit: 100 mg per 28 days

***The Health Plan considers the use of concomitant therapy with Cinqair®, Nucala®, Dupixent®, Fasenra®, 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®, and/or Xolair® authorization on file, any 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.

❑ **DIAGNOSIS: Chronic Obstructive Pulmonary Disease**

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist or pulmonologist
- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of moderate to severe Chronic Obstructive Pulmonary Disease (COPD) confirmed with spirometry demonstrating **ONE** of the following:
  - ❑ FEV1/FVC ratio <0.7 post-bronchodilation
  - ❑ Post-bronchodilator FEV1 % predicted of ≥ 30% and ≤ 80%
- ❑ Member has experienced **ONE** of the following:
  - ❑ At least two (2) exacerbations treated with short-acting bronchodilators and oral corticosteroids, with or without antibiotics in the past 12 months
  - ❑ At least one (1) exacerbation requiring hospitalization in the past 12 months
- ❑ Provider must submit a member blood eosinophil count level greater than or equal to 300 cells per microliter following at least 90 days of therapy of dual or triple-maintenance therapies
- ❑ 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 year of the request **(verified by pharmacy paid claims)**:
  - ❑ Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat®), long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera®) alone if inhaled corticosteroid (ICS) is contraindicated
- ❑ Member is requesting Nucala® (mepolizumab) as add-on maintenance therapy to dual or triple therapy **(verified by pharmacy paid claims)**

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)**:
  - ❑ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - ❑ Reduction in exacerbations (e.g., decrease oral corticosteroids) or fewer hospitalizations
  - ❑ Reduction in dyspnea symptoms such as chest tightness, shortness of breath

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- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications **(verified by pharmacy paid claims)**:
  - ❑ Triple therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat®), long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera®), and an inhaled corticosteroid (ICS) (e.g., fluticasone propionate)
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera®) alone if inhaled corticosteroid (ICS) is contraindicated
- ❑ Member continues to use Nucala® (mepolizumab) as add-on maintenance therapy to dual or triple therapy **(verified by pharmacy paid claims)**

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

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.****