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: Ohtuvayre™ (ensifentrine)

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:** _____

Recommended Dosage: 3 mg (one unit-dose ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece

Quantity Limit: One 60-ampule carton (150 mL total) per 30 days

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

- ❑ Member must be 18 years of age or older
- ❑ Medication must be prescribed by or in consultation with a pulmonologist

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- ❑ 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 is symptomatic confirmed by **ONE** of the clinical assessments:
  - ❑ Modified Medical Research Council (mMRC) dyspnea grade ≥ 2
  - ❑ COPD Assessment Test (CAT) score ≥ 10
- ❑ Member has experienced **ONE** of the following **(must submit chart notes)**:
  - ❑ 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
- ❑ Member has tried and failed at least **ONE** of the following dual or triple-maintenance therapies, unless there is a contraindication or intolerance to these medications, and must have been compliant with therapy **for at least 90 consecutive days** within year of the request **(verified by pharmacy paid claims and/or chart notes)**:
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
  - ❑ 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)
- ❑ 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 through paid claims or chart notes)**:
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
  - ❑ 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)
- ❑ Member must have trial and failure to roflumilast (Daliresp®) for at least 30 days within year of request **(verified by pharmacy paid claims and/or chart notes; inadequate response is defined by insufficient improvement in symptoms, lung function and quality of life, continued high exacerbation rates at recommended maintenance dose)**
- ❑ Member must continue to remain on dual or triple maintenance therapy while using Ohtuvayre™ **(verified by pharmacy paid claims and/or chart notes)**
- ❑ Medication will **NOT** be used in combination with an oral phosphodiesterase-4 (PDE4) inhibitor Daliresp® (roflumilast)

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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 Ohtuvayre® 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 exacerbations (e.g., decrease oral corticosteroids) or fewer hospitalizations
  - ❑ Reduction in dyspnea symptoms such as chest tightness, shortness of breath
- ❑ 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 and/or chart notes)**:
  - ❑ Dual therapy with a long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Respimat ®) and long-acting beta agonist (LABA) (e.g., Advair HFA, Dulera ®)
  - ❑ 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)

Medication being provided by 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.****