

**Applicable Drugs:** Ohtuvayre (ensifentrine)

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 11/18/2024

**Date Last Reviewed / Revised:** 5/10/2026

## **PRIOR AUTHORIZATION CRITERIA**

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of chronic obstructive pulmonary disease (COPD) AND meets all the following criteria:
  - A. Documented spirometry testing meeting both of the following criteria:
    - i. Post-bronchodilator FEV1/FVC less than 0.7.
    - ii. Post-bronchodilator FEV1 between 30% to 70% predicted normal.
  - B. Documentation that the patient has been on a minimum of a six-month trial on LAMA + LABA + ICS (long-acting muscarinic antagonist + long-acting beta agonist + inhaled corticosteroid) therapy OR LAMA + LABA therapy if ICS is contraindicated.
  - C. Documentation that the patient's symptoms are poorly controlled despite therapy AND meets both of the following criteria:
    - i. Modified Medical Research Council (mMRC) dyspnea scale score of at least 2 OR Chronic Airways Assessment Test (CAAT) score of at least 10.
    - ii. COPD exacerbation history in the past 12 months that meets one of the following criteria (1 or 2):
      1. Two or more COPD exacerbations requiring systemic corticosteroids and/or antibiotics. One of the exacerbations must require the use of systemic corticosteroids.
      2. One or more COPD exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, or emergency room visit).
  - D. Documentation that Ohtuvayre will be used in conjunction with LAMA + LABA + ICS or LAMA + LABA therapy as an add-on maintenance treatment.
- II. Minimum age requirement: 18 years old
- III. Treatment must be prescribed by or in consultation with a pulmonologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

#### EXCLUSION CRITERIA

- Treatment of acute bronchospasm.
- Known diagnosis of alpha-1 antitrypsin deficiency
- Concurrent use with other anti-COPD agents (ie, Dupixent [dupilumab], Nucala [mepolizumab], and systemic roflumilast).

#### OTHER CRITERIA

- N/A

#### QUANTITY / DAYS SUPPLY RESTRICTIONS

- Sixty 3 mg (2.5 mL) ampules per 30 days

#### APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months. An updated letter of medical necessity or progress notes showing sustained clinical benefits from the drug treatment (ie, decreased use of beta agonists, decreased use of systemic corticosteroids, decreased emergency department visits, decreased hospital admissions, and preservation of pulmonary function).

#### APPENDIX

- N/A

#### REFERENCES

1. Ohtuvayre. Prescribing Information. Verona Pharma; 2024. Accessed May 10, 2026.
2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2026.  
[https://goldcopd.org/wp-content/uploads/2026/01/GOLD-REPORT-2026-v1.3-8Dec2025\\_WMV2.pdf](https://goldcopd.org/wp-content/uploads/2026/01/GOLD-REPORT-2026-v1.3-8Dec2025_WMV2.pdf)

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.