Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 1, 2025

Ohtuvayre™ (ensifentrine)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of chronic obstructive pulmonary disease (COPD); **AND**
- Patient has baseline pulmonary function tests (e.g., FEV1/FVC ratio, FEV1) performed within the past 30 days (*documentation required*); **AND**
- Patient has a history of moderate to severe COPD exacerbations and symptoms of chronic productive cough for at least 3 months, both within the past year while on maintenance triple therapy with an inhaled corticosteroid (ICS), a long-acting beta agonist (LABA), and a long-acting muscarinic antagonist (LAMA) (*documentation required*).

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response (e.g. improved lung function as demonstrated by a reduction in COPD exacerbations and significant improvement in pulmonary function tests compared to baseline); **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., psychiatric adverse reactions); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as inhalation suspension containing 3 mg/2.5 mL aqueous suspension in unit-dose ampules.