Generic Name: Ensifentrine

Applicable Drugs: Ohtuvayre™

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of moderate-to-severe chronic obstructive pulmonary disease (COPD) diagnosis and meets criteria A and B:
   A. Spirometry test confirming COPD diagnosis, meeting criteria i and ii:
      i. Post-bronchodilator FEV1/FVC less than 0.7.
      ii. Post-bronchodilator FEV1 30 to 70% predicted normal.
   B. Blood eosinophil count of at least 100 cells/microliter at baseline.

II. 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 corticosteroids) therapy OR LAMA + LABA therapy if ICS is contraindicated.

III. Documentation that the patient's symptoms are poorly controlled despite therapy and meets criteria A AND B:
   A. Modified Medical Research Council (mMRC) dyspnea scale score of at least 2 OR COPD Assessment Test (CAT) score of at least 10.
   B. COPD exacerbation history in the past 12 months that meets criteria i or ii:
      i. Two or more COPD exacerbations requiring systemic corticosteroids and/or antibiotics.
         1. One of the exacerbations must require the use of systemic corticosteroids.
      ii. One or more COPD exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, emergency room visit).

IV. Ohtuvayre will be used in conjunction with LAMA + LABA + ICS or LAMA + LABA therapy as an add-on maintenance treatment.

V. Minimum age requirement: 18 years old

VI. Treatment must be prescribed by or in consultation with a pulmonologist.

VII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VIII. 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 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 October 15, 2024.
2. Global Initiative for Chronic Obstructive Lung Disease. 2024 REPORT Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2024. https://goldcopd.org/wp-content/uploads/2024/02/GOLD-2024_v1.2-11Jan24_WMV.pdf