



## PHARMACY POLICY STATEMENT

### HAP CareSource™ Marketplace

DRUG NAME	Ohtuvayre (ensifentrine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ohtuvayre, approved by the FDA in 2024, is a phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

Ohtuvayre (ensifentrine) will be considered for coverage when the following criteria are met:

#### Chronic Obstructive Pulmonary Disease (COPD)

For **initial** authorization:

1. Member is at least 18 of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has a diagnosis of COPD confirmed by spirometry demonstrating FEV1/FVC ratio <0.7 post-bronchodilation; AND
4. Chart notes include baseline FEV1; AND
5. Member has experienced a COPD exacerbation (ex. hospitalization, steroid use, increased use of short-acting beta agonists etc.) while on standard of care such as dual LAMA and LABA therapy AND
6. Member has had a 3-month trial of a long-acting muscarinic antagonists (LAMA) combined with a long-acting beta agonist (LABA); AND
7. Provider attests that member will continue maintenance therapy; AND
8. Provider attests that member does **NOT** have a primary asthma diagnosis.
9. **Dosage allowed/Quantity limit:** 3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece. Quantity limit: 1 carton (60 ampules) per 30 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as improvement in FEV1 from baseline, decreased exacerbations, decreased shortness of breath, decreased cough etc.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**HAP CareSource considers Ohtuvayre (ensifentrine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**



**HAP CareSource™**

DATE	ACTION/DESCRIPTION
08/08/2024	New policy for Ohtuvayre (ensifentrine) created.

References:

1. Ohtuvayre [package insert]. Verona Pharma, Inc; 2024.
2. Venkatesan P. GOLD COPD report: 2024 update. *Lancet Respir Med*. 2024;12(1):15-16. doi:10.1016/S2213-2600(23)00461-7
3. Nici L, Mammen MJ, Charbek E, et al. Pharmacologic Management of Chronic Obstructive Pulmonary Disease. An Official American Thoracic Society Clinical Practice Guideline [published correction appears in *Am J Respir Crit Care Med*. 2020 Sep 15;202(6):910. doi: 10.1164/rccm.v202erratum5]. *Am J Respir Crit Care Med*. 2020;201(9):e56-e69. doi:10.1164/rccm.202003-0625ST
4. Lin G, Whittington MD, Wright A, McKenna A, Richardson M, Rind DM. Ensifentrine for the Treatment of Chronic Obstructive Pulmonary Disease: Effectiveness and Value. Institute for Clinical and Economic Review, July 16, 2024. <https://icer.org/assessment/copd-2024/>
5. Anzueto A, Barjaktarevic IZ, Siler TM, et al. Ensifentrine, a Novel Phosphodiesterase 3 and 4 Inhibitor for the Treatment of Chronic Obstructive Pulmonary Disease: Randomized, Double-Blind, Placebo-controlled, Multicenter Phase III Trials (the ENHANCE Trials). *Am J Respir Crit Care Med*. 2023;208(4):406-416. doi:10.1164/rccm.202306-0944OC

Effective date: 01/01/2025

Revised date: 08/08/2024