CareSource Rxinnovations

PHARMACY POLICY STATEMENT
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.

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.

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

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