Reference number(s)
6568-C

Initial Prior Authorization with Quantity Limit
Ohtuvayre

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Ohtuvayre	ensifentrine	all

Indications

FDA-approved Indications

Ohtuvayre is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Authorization may be granted when the requested drug is being prescribed for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in an adult patient when ALL of the following criteria are met:

- The requested drug is NOT being used for the relief of acute symptoms (i.e., as rescue therapy for the treatment of acute episodes of bronchospasm).
- The patient meets ONE of the following:
    - The patient is currently receiving treatment with dual therapy (long-acting muscarinic antagonist [LAMA] and long-acting beta agonist [LABA]) OR triple therapy (LAMA, LABA, and inhaled corticosteroid [ICS]).
    - The patient has experienced an inadequate treatment response to dual therapy (LAMA/LABA) OR triple therapy (LAMA/LABA/ICS).
    - The patient has experienced an intolerance to dual therapy (LAMA/LABA) OR triple therapy (LAMA/LABA/ICS).
    - The patient has a contraindication that would prohibit a trial of dual therapy (LAMA/LABA) OR triple therapy (LAMA/LABA/ICS).

Continuation of Therapy

Chronic Obstructive Pulmonary Disease (COPD)

Authorization may be granted when the requested drug is being prescribed for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in an adult patient when the following criteria is met:

- The patient has experienced a positive clinical response to therapy (e.g., improvement in forced expiratory volume in one second [FEV1], decrease in respiratory symptoms, fewer exacerbations) OR has not experienced worsening of symptoms since the start of therapy (e.g., increased shortness of breath, coughing, wheezing/chest tightness, fatigue).

Quantity Limits Apply

150 mL (60 ampules) per 25 days OR 450 mL (180 ampules) per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 6568-C: DOA: 12 months

Reference number(s)
6568-C

References

1. Ohtuvayre [package insert]. Raleigh, NC: Verona Pharma, Inc.; June 2024.
2. Lexicomp Online, Lexi Drugs. (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed July 15, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/23/2024).
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2024 Report). Available at: https://goldcopd.org/2024-gold-report/. Accessed July 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.