


| | | | |
|---|---|---|---|
|  | | AETNA BETTER HEALTH® Coverage Policy/Guideline | |
| Name: | Ohtuvayre (ensifentrine) | Page: | 1 of 2 |
| Effective Date: | 2/13/2025 | Last Review Date: | 1/2025 |
| Applies to: | <input checked="" type="checkbox"/> Illinois <input type="checkbox"/> Florida Kids | <input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids | <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Virginia |

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ohtuvayre under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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

Applicable Drug List:

Ohtuvayre

Policy/Guideline:

Criteria for Initial Approval:

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)

Criteria for 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

| | |
|---|--------------------------|
|  | |
| AETNA BETTER HEALTH® Coverage Policy/Guideline | |
| Name: Ohtuvayre (ensifentrine) | Page: 2 of 2 |
| Effective Date: 2/13/2025 | Last Review Date: 1/2025 |
| Applies to: <div> <input checked="" type="checkbox"/> Illinois <input type="checkbox"/> Florida Kids <input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Virginia </div> | |

symptoms since the start of therapy (e.g., increased shortness of breath, coughing, wheezing/chest tightness, fatigue)

Approval Duration and Quantity Restrictions:

Approval Duration: 12 months

Quantity Level Limit: 60 ampu;es per 30 days

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.