Pharmacy Medical Necessity Guidelines:
Ohtuvayre (ensifentrine)

Effective: January 13, 2025

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATION

Ohtuvayre (ensifentrine) is a PDE3 inhibitor and PDE4 inhibitor indicated for the maintenance treatment of COPD in adult patients.

COVERAGE GUIDELINES

The plan may authorize coverage of Ohtuvayre (ensifentrine) for Members when the following criteria are met:

1. Documented diagnosis of Chronic obstructive pulmonary disease (COPD)

   AND

2. The patient tried and failed therapy with one recommended initial COPD maintenance medication combination:
   a. Inhaled bronchodilators:
      i. Long-acting beta-2 agonists (LABAs) and Long-acting muscarinic antagonists (LAMAs) combination therapy

      OR

   b. Inhaled anti-inflammatory agents
      i. Inhaled corticosteroids (ICS) and LABA/LAMA combination therapy

      AND

3. Prescribed by or in consultation with a pulmonologist

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

October 2024: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 13, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services