Ohtuvayre *(ensifentrine)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Ohtuvayre is a nebulized phosphodiesterase inhibitor (PDE3/PDE4) indicated for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD).
Exclusion Criteria	Must not be used in combination with roflumilast.
Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. For initial requests, medical records supporting the request must be provided and include the following: 1. Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% . 2. Trial and failure of dual or triple therapy in the past six months that included a LABA/LAMA therapy (e.g., Trelegy Ellipta, Anoro Ellipta, Stiolto Respimat). Failure is defined as no improvement, worsening of the condition, or an intolerance after trying the required therapy at the maximum dosages for at least 4 weeks consistently.
Age Restriction	Patient is at least 18 years of age.
Prescriber Restrictions	Prescriber is or has consulted a pulmonologist.
Coverage Duration	Initial: one year. Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. For reauthorization, documentation supporting a decrease in symptoms, improvement in lung function, and/or reduced COPD exacerbations with Ohtuvayre compared to baseline must be provided.
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

HCPCS	Description	Billing Units/How Supplied
J7601	Ohtuvayre (ensifentrine)	**Billing unit: 3 mg** 3 mg/2.5mL ampule

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025