Oscar Clinical Guideline: Ohtuvayre (ensifentrine) (PG237, Ver. 2)

Ohtuvayre (ensifentrine)

Summary

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterized by persistent respiratory symptoms and airflow limitation. The main risk factor for COPD is tobacco smoking, but other environmental exposures such as fuel exposure and air pollution may contribute. Aside from exposures, individual factors, such as history of infections (e.g. childhood pneumonia, tuberculosis, human immunodeficiency virus [HIV]) genetic abnormalities, abnormal lung development, and sex (female sex provides a higher risk of COPD), predispose individuals to develop COPD as well. COPD is associated with significant concomitant chronic diseases, which increase its morbidity and mortality. Emphysema and chronic bronchitis are the two most common conditions that contribute to COPD. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions. Although COPD is a progressive disease that gets worse over time, it is treatable. With proper management, most people with COPD can achieve good symptom control and quality of life, as well as reduced risk of other associated conditions.

According to the 2025 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for COPD, long-acting beta-2 agonists (LABAs) may be used as initial monotherapy in patients in Groups A, B, and E. In both group B and E, long-acting muscarinic antagonists (LAMAs) can be added to LABAs therapy. It is noted in the guidelines that single inhalers are preferred over multiple inhalers as they are

more effective and improve adherence. It may also be considered to initiate a combined LAMA/LABA and Inhaled corticosteroid (ICS) if one's blood eosinophil count is greater than or equal to (≥) 300. Add-on options for select patients include roflumilast, azithromycin, or theophylline.

Ohtuvayre (ensifentrine) is a nebulized phosphodiesterase-3 and -4 inhibitor indicated as add-on therapy for the maintenance treatment of COPD in adults.

Definitions

"COPD" refers to chronic obstructive pulmonary disease, a lung disease characterized by chronic obstruction of lung airflow that interferes with normal breathing

"COPD exacerbation" is defined as an acute worsening of respiratory symptoms that results in additional therapy.

"FEV1" is forced expiratory volume in 1 second, a measure of lung function

"ICS" is inhaled corticosteroid, an anti-inflammatory medication

"LABA" is long-acting beta2-agonist, a bronchodilator medication

"LAMA" is long-acting muscarinic antagonist, an anticholinergic bronchodilator medication

Medical Necessity Criteria for Initial Authorization

The Plan considers Ohtuvayre (ensifentrine) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has a diagnosis of chronic obstructive pulmonary disease (COPD), confirmed by spirometry; *AND*
3. The member has persistent symptoms (e.g., dyspnea, cough, sputum production) and/or a history of exacerbations despite adherent use for at least 3 months of ONE (1) of the following:
    a. Inhaled triple therapy with an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA); *or*
    b. Dual bronchodilator therapy with a LAMA and a LABA, AND if the member has severe COPD, chronic bronchitis, and a history of exacerbations, they have also tried roflumilast; *AND*
4. Ohtuvayre (ensifentrine) will be used as an add-on to (i.e., not a replacement for) the member's existing maintenance therapy regimen (i.e., either triple therapy with ICS/LABA/LAMA or dual therapy with LAMA/LABA); *AND*
5. Ohtuvayre (ensifentrine) will not be used:

   a. Concomitantly with other phosphodiesterase inhibitors (e.g. roflumilast); *or*
   b. To treat acute symptoms of bronchospasm; *AND*
6. The prescribed dose does not exceed 3 mg twice daily.

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has clinical chart documentation demonstrating beneficial response with Ohtuvayre (ensifentrine) therapy as demonstrated by ONE (1) of the following:

1. Reduction in COPD exacerbations compared to pre-treatment baseline; *OR*
2. Improvement in lung function (e.g., increase in FEV1); *OR*
3. Improvement in respiratory symptoms (e.g., dyspnea).

<u>If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.</u>

Experimental or Investigational / Not Medically Necessary

Ohtuvayre (ensifentrine) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- In combination with other PDE4 inhibitors, such as roflumilast. Ohtuvayre (ensifentrine) should not be used in combination with other PDE4 inhibitors and has not been studied in this manner.
- For treatment of asthma or other respiratory conditions besides COPD. Ohtuvayre (ensifentrine) has only been studied and approved for the maintenance treatment of COPD.
- Via any route of administration other than oral inhalation with a standard jet nebulizer. Ohtuvayre (ensifentrine) has not been studied for administration by any other method or route.

References

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Clinical Guideline Revision / History Information

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