Reference number(s)
6573-A

Standard Medicare Part B Management 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
Ohtuvayre	ensifentrine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Authorization of 12 months may be granted for treatment of chronic obstructive pulmonary disease (COPD) in an adult patient when one of the following criteria are met:

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- The patient has experienced an inadequate treatment response to dual therapy (long-acting muscarinic antagonist [LAMA] and long-acting beta-2 agonist [LABA]), or triple therapy (LAMA, LABA, and ICS)
- The patient has experienced an intolerance to dual therapy (LAMA and LABA), or triple therapy (LAMA, LABA, and inhaled corticosteroid [ICS])
- The patient has a contraindication that would prohibit a trial of dual therapy (LAMA and LABA), or triple therapy (LAMA, LABA and ICS)

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Ohtuvayre
- Ohtuvayre is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - Positive clinical response to therapy (e.g., improvement in FEV1, dyspnea, and/or exacerbations), or
    - Maintenance of symptoms (e.g., FEV1, dyspnea, exacerbations)

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Ohtuvayre
- The available compendium
    - Micromedex DrugDex
    - Lexi-Drugs
- Global Initiative for Chronic Obstructive Lung Disease 2024 Report

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Ohtuvayre to treat chronic obstructive lung disease (COPD) can be found in the Global Initiative for Chronic Obstructive Lung Disease 2024 Report. Treatment for COPD should be initiated with a long-acting beta agonist and a long-acting muscarinic antagonist (LABA+LAMA). LABA+LAMA is superior to treatment with only a LAMA with regard to several endpoints. Therefore, LABA+LAMA is the recommended initial pharmacological choice. If LABA+LAMA combination is not considered appropriate,

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there is no evidence to recommend one class of long-acting bronchodilators over another (LABA or LAMA) for initial relief or symptoms. A LABA+LAMA combination was the highest ranked treatment group to reduce COPD exacerbations. The use of LABA + an inhaled corticosteroid (ICS) in COPD is not encouraged. If there is an indication for an ICS, then LABA+LAMA+ICS has been shown to be superior to LABA+ICS and is therefore the preferred choice.[4]

References

1. Ohtuvayre [package insert]. Raleigh, North Carolina: 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 31, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/31/2024).
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2024 report. 2024

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