Ohtuvayre (ensifentrine) Inhalation Suspension 3 mg/2.5 mL

Prior Authorization Checklist

This form highlights information typically required for a prior authorization (PA) for **Ohtuvayre™** for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. This is for reference only and does not guarantee PA approval. Requirements may vary by plan, so please consult individual payer policies to verify clinical guidelines.

Patient name: _____ Date of birth: __/__/____

Prescription and Diagnosis

- ☐ **Ohtuvayre™** (ensifentrine), NDC 83034-003-60, quantity requested: 60 ampules per 30 days
- ☐ ICD-10-CM diagnosis code for COPD: _____
  - Generally, COPD ICD-10-CM codes range from J41 to J44.9; other codes may be appropriate. Only a patient's healthcare provider may determine the appropriate diagnosis and ICD-10-CM code. For a full list of codes, please consult the most recent version of the ICD-10-CM manual
- ☐ **Ohtuvayre** was prescribed by, or in consultation with, a pulmonologist

Patient History

- ☐ Patient is 18 years of age or older
- ☐ Patient's inspiratory flow rate is too low to utilize inhalers
- ☐ Patient experiences persistent symptoms or exacerbations despite current treatment
- ☐ Patient has current and past medications for COPD maintenance **OR** ☐ Patient has never been prescribed COPD maintenance treatments

Include drug name(s), duration of treatment, reasons for discontinuation, and any contraindications to any treatment

- Medication: _____ Start date - End date: __/__/____ - __/__/____
  Additional notes: _____
- Medication: _____ Start date - End date: __/__/____ - __/__/____
  Additional notes: _____
- Medication: _____ Start date - End date: __/__/____ - __/__/____
  Additional notes: _____

If the policy requires step through of a medication you do not believe is clinically appropriate for your patient, provide the clinical rationale for an exception

_____

Additional documentation: Include recent clinical notes on patient symptoms, spirometry, and diagnostic tests. Providing additional support can help decrease the likelihood of denials and avoid unnecessary treatment delays

Additional Information for PA Renewals

- Provide the most recent **Ohtuvayre** PA approval documentation or approval number
- Documentation of clinical response to treatment with **Ohtuvayre**

Contact your Verona Pharma Field Reimbursement Manager for additional questions or support with the PA process

INDICATION

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

IMPORTANT SAFETY INFORMATION

Contraindication: Ohtuvayre is contraindicated in patients with hypersensitivity to ensifentrine or any component of this product.

Please see additional Important Safety Information on next page and the Full Prescribing Information for Ohtuvayre, also available at Ohtuvayrehcp.com.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

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IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions:

Acute Episodes of Bronchospasm Ohtuvayre should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting bronchodilator.

Paradoxical Bronchospasm As with other inhaled medicines, Ohtuvayre may produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with Ohtuvayre, it should be treated immediately with an inhaled, short-acting bronchodilator. Ohtuvayre should be discontinued immediately and alternative therapy should be instituted.

Psychiatric Events Including Suicidality Before initiating treatment with Ohtuvayre, healthcare providers should carefully weigh the risk and benefits of treatment with Ohtuvayre in patients with a history of depression and/or suicidal thoughts or behavior. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts, or other mood changes, and if such changes occur to contact their healthcare provider. Healthcare providers should carefully evaluate the risks and benefits of continuing treatment with Ohtuvayre if such events occur.

Treatment with Ohtuvayre is associated with an increase in psychiatric adverse reactions. Psychiatric events including suicide-related adverse reactions were reported in clinical studies in patients who received Ohtuvayre (1 suicide attempt and 1 suicide). Additionally, the most commonly reported psychiatric adverse reactions in the pooled 24-week safety population were insomnia (6 patients [0.6%] OHTUVAYRE 3 mg; 2 patients [0.3%] placebo), and anxiety (2 patients [0.2%] Ohtuvayre 3 mg; 1 patient [0.2%] placebo). Depression-related reactions including depression, major depression, and adjustment disorder with depressed mood occurred in 4 patients [0.4%] receiving Ohtuvayre and no patients receiving placebo.

Adverse Reactions: The most common adverse reactions ≥1% in Ohtuvayre and greater than placebo in the pooled population were back pain 1.8%, hypertension 1.7%, urinary tract infection 1.3%, and diarrhea 1.0%.

These are not all of the possible risks associated with Ohtuvayre. **Please see Full Prescribing Information, including Instructions for Use, for Ohtuvayre.**

To report suspected adverse reactions, contact Verona Pharma, Inc. at 1-888-672-0371 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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