Prior Authorization Checklist

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

The items and information listed below may be requested by your patient's health plan or contracted entity to obtain a prior authorization decision. It is important to review the health plan's specific guidelines for obtaining a prior authorization because these guidelines can differ depending on the health plan, the medication being prescribed, and other factors.

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

OHTUVAYRE is contraindicated in patients with hypersensitivity to ensifentrine or any component of this product.

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. OHTUVAYRE has not been studied in the relief of acute symptoms and extra doses of OHTUVAYRE should not be used for that purpose. 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: 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.

Before initiating treatment with OHTUVAYRE, healthcare providers should carefully weigh the risks 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.

ADVERSE REACTIONS

The most common adverse reactions ≥1% in OHTUVAYRE and greater than placebo in the pooled population in the ENHANCE-1 and ENHANCE-2 clinical trials were back pain (1.8% vs 1.0%), hypertension (1.7% vs 0.9%), urinary tract infection (1.3% vs 1.0%), and diarrhea (1.0% vs 0.7%).

These are not all of the possible risks associated with OHTUVAYRE.

DOSAGE AND ADMINISTRATION

The recommended dosage of OHTUVAYRE is 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a standard jet nebulizer with a mouthpiece.

SPECIAL POPULATIONS

Pediatric Use: The safety and effectiveness of OHTUVAYRE have not been established in pediatric patients.

Lactation: There are no data on the presence of ensifentrine in human milk, the effects on the breastfed child, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OHTUVAYRE and any potential adverse effects on the breastfed child from OHTUVAYRE or from the underlying maternal condition.

Important Safety Information continued on next page.

Information that might be necessary to obtain a prior authorization from an insurer:

- ☐ Prescription: OHTUVAYRE, NDC 83034-003-60, quantity requested: 60 ampules per 30 days
- ☐ Diagnosis: ICD-10-CM diagnosis code for COPD
  - Generally, COPD ICD-10-CM codes range from J41 to J44.9; other codes may be appropriate.[1] 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
- ☐ Note if OHTUVAYRE was prescribed by, or in consultation with, a pulmonologist
- ☐ Patient's age (18 years of age or older)
- ☐ Document other patient information that supports the request:
  - Patient's inspiratory flow rate is too low to utilize inhalers
  - Patient experiences persistent symptoms or exacerbations despite current treatment
  - Current and past medications for COPD maintenance or if patient has never been prescribed COPD maintenance treatments
  - Include drug name(s), duration of treatment, reasons for discontinuation, and any contraindications to any treatment
- ☐ 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:** Consider including recent clinical notes on patient symptoms, spirometry, and diagnostic tests. Providing additional support may help decrease the likelihood of denials and avoid unnecessary treatment delays

Additional information for prior authorization renewals:

- Provide the most recent OHTUVAYRE prior authorization approval documentation or approval number
- Documentation of clinical response to treatment with OHTUVAYRE

Contact your Merck Field Access Manager (FAM) if you have additional questions about the prior authorization process.

IMPORTANT SAFETY INFORMATION (*continued*)

SPECIAL POPULATIONS (*continued*)

Geriatric Use: In clinical trials, patients aged 65 and older showed no overall differences in the safety or effectiveness of OHTUVAYRE compared with younger adults, but greater sensitivity in some older individuals cannot be ruled out.

Hepatic Impairment: Ensifentrine systemic exposure increased by 2.3-fold in subjects with moderate or severe hepatic impairment compared with healthy subjects. Use OHTUVAYRE with caution in patients with hepatic impairment.

Before prescribing OHTUVAYRE, please read the accompanying Prescribing Information. The Patient Information and Instructions for Use also are available.

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

Reference: 1. ICD-10-CM tabular list of diseases and injuries FY 2026. Centers for Medicare & Medicaid Services. Accessed March 24, 2026. https://www.cms.gov/files/zip/april-1-2026-code-tables-tabular-index.zip

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