UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2350-1
Program	Prior Authorization/Medical Necessity
Medication	Ohtuvayre™ (ensifentrine)
P&T Approval Date	9/2024
Effective Date	12/1/2024

1. Background:

Ohtuvayre™ (ensifentrine) is a phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Ohtuvayre** will be approved based on **all** of the following criteria:

   a. Diagnosis of chronic obstructive pulmonary disease

   -AND-

   b. Submission of medical records (e.g., chart notes) documenting **both** of the following

      1) Post-bronchodilator forced expiratory volume (FEV1) / forced vital capacity (FVC) ratio less than 0.7

      2) Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than 80%

   -AND-

   c. **One** of the following:

      1) **Both** of the following:

         a) Patient is on a stabilized dose and receiving concomitant therapy with **one** of the following (document name):

            i. a long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
            ii. a long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
            iii. a LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat)
            iv. an ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

- AND-

b) **<u>One</u>** of the following:

i. **<u>All</u>** of the following:

(1) FEV1 less than 50% of predicted
(2) History of chronic bronchitis
(3) History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)]

-OR-

ii. FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

- OR-

2**) Both of the following:**

a) Patient has a failure, contraindication, or intolerance to **<u>all</u>** of the following (document name and date tried):

i. a long-acting beta-agonist [LABA (e.g., Serevent Diskus)]
ii. a long-acting antimuscarinic agent [LAMA (e.g., Spiriva Respimat/HandiHaler)]
iii. a LABA/LAMA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat),
iv. an ISC/LABA/LAMA (i.e., Breztri Aerosphere, Trelegy Ellipta)

- AND-

b) **<u>One</u>** of the following:

i. **<u>All</u>** of the following:

(1) FEV1 less than 50% of predicted
(2) History of chronic bronchitis
(3) History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitor [i.e., roflumilast (Daliresp)]

-OR-

ii. FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

-OR-

3) **All** of the following:

a) Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Respimat) to control their COPD due to **one** of the following:

i) Cognitive or physical impairment limiting coordination of handheld devices (e.g., cognitive decline, arthritis in the hands) (Document impairment)
ii) Patient is unable to generate adequate inspiratory force (e.g., peak inspiratory flow rate (PIFR) resistance is <60 L/min)

-AND-

b) Patient requires the use of **both** of the following (document date)

i) a nebulized LABA [i.e., arformoterol (generic Brovana), formoterol (generic Perforomist)]
ii) a nebulized long-acting antimuscarinic agent [LAMA (i.e.,Yupelri)]

-AND-

c) **One** of the following:

i. **All** of the following:

(1) FEV1 less than 50% of predicted
(2) History of chronic bronchitis
(3) History of failure, contraindication, or intolerance to a selective phosphodiesterase 4 (PDE4) inhibitors [i.e., roflumilast (Daliresp)]

-OR-

ii. FEV1 is less than 80% of predicted but greater than or equal to 50% of predicted

-AND-

d. Patient experiences dyspnea during everyday activities (e.g., short of breath when walking up a slight hill)

-AND-

e. Prescribed by or in consultation with a Pulmonologist

Authorization will be issued for 12 months

B. Reauthorization

1. **Ohtuvayre** will be approved for based on the following criterion:

    a. Documentation of positive clinical response to **Ohtuvayre** therapy demonstrated by **both** of the following:

        1) Improved COPD symptoms (e.g., dyspnea)
        2) Improved FEV_1

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ohtuvayre [package insert]. Raleigh, NC: Verona Pharma; June 2024.
2. Global strategy for the diagnosis, management and prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2024.
3. Anzueto, A, Barjaktarevic, IZ, Siler, TM, et.al. Ensifentrine, a Novel Phosphodiesterase 3 and 4 Inhibitor for the Treatment of Chronic Obstructive Pulmonary Disease: Randomized, Double-Blind, Placebo-controlled, Multicenter Phase III Trials (the ENHANCE Trials. *Am J Respir Crit Care Med*. 2023; 208: 406-16.

Program	Prior Authorization/Medical Necessity – Ohtuvayre
Change Control	
Date	Change
9/2024	New program.