Mass General Brigham
Health Plan

Ohtuvayre (ensifentrine)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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

Coverage Guidelines
Authorization may be granted for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:
1. Member has a diagnosis of chronic obstructive pulmonary disease (COPD)
2. Member has had an inadequate response or adverse reaction with one of the following maintenance regimens:
    a. **LABA/LABA:** Combination of long-acting beta-agonist (LABA) and long-acting muscarinic antagonist (LAMA)
    b. **LABA/LAMA/ICS:** Combination of long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), and inhaled corticosteroid (ICS)

Continuation of Therapy
Requests for reauthorization will be approved when the following criteria are met:
1. Member has had a positive clinical response to therapy

Limitations
1. Initial and reauthorization requests will be approved for 12 months
2. The following quantity limitations apply:

Drug Name	Quantity Limitations

Ohtuvayre ampules	2 ampules per day

References

1. 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(4):406-416. doi: 10.1164/rccm.202306-0944OC.
2. Ferguson GT, Kerwin EM, Rheault T, Bengtsson T, Rickard K. A dose-ranging study of the novel inhaled dual PDE 3 and 4 inhibitor ensifentrine in patients with COPD receiving maintenance tiotropium therapy. *Int J Chron Obstruct Pulmon Dis*. 2021;16:1137-1148. doi: 10.2147/COPD.S307160.
3. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2024. https://goldcopd.org/2024-gold-report/. Accessed July 15, 2024.
4. Leidy NK, Bushnell DM, Thach C, Hache C, Gutzwiller FS. Interpreting Evaluating Respiratory Symptoms™ in COPD diary scores in clinical trials: Terminology, methods, and recommendations. *Chronic Obstr Pulm Dis*. 2022;9(4):576-590. doi: 10.15326/jcopdf.2022.0307.
5. Lin G, Whittington MD, Wright A, McKenna A, Richardson M, Rind DM. Ensifentrine for the treatment of chronic obstructive pulmonary disease: Effectiveness and value. Institute for Clinical and Economic Review, July 16, 2024. https://icer.org/assessment/copd-2024/.
6. Lipson DA, Barnhart F, Brealey N, et al. Once-daily single-inhaler triple versus dual therapy in patients with COPD. *N Engl J Med*. 2018;378(18):1671-1680.
7. Liu Y, Carlson SA, Watson KB, Xu F, Greenlund KJ. Trends in the prevalence of chronic obstructive pulmonary disease among adults aged ≥ 18 years - United States, 2011–2021. *MMWR Morb Mortal Wkly Rep*. 2023;72:1250-256. doi: http://dx.doi.org/10.15585/mmwr.mm7246a1.
8. Ohtuvayre (ensifentrine) [prescribing information]. Verona Pharma: Raleigh, NC; June 2024.
9. Singh D, Martinez FJ, Watz H, Bengtsson T, Maurer BT. A dose-ranging study of the inhaled dual phosphodiesterase 3 and 4 inhibitor ensifentrine in COPD. *Respir Res*. 2020;21(1):47. doi: 10.1186/s12931-020-1307-4.

Review History

12/11/2024 – Created and reviewed at December P&T. Effective 3/1/2025.