

Clinical Pharmacy Program Guidelines for Lonhala Magnair, Yupelri

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| Program | Prior Authorization |
| Medication | Lonhala Magnair (glycopyrrolate inhalation solution), Yupelri (revefenacin inhalation solution) |
| Markets in Scope | California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina |
| Issue Date | 9/2018 |
| Pharmacy and Therapeutics Approval Date | 8/2020 |
| Effective Date | 10/2020 |

1. Background:

Lonhala Magnair (glycopyrrolate inhalation solution) and Yupelri (revefenacin inhalation solution) are nebulized long acting antimuscarinic (anticholinergic) agents indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

2. Coverage Criteria:

A. Initial Authorization

1. **Lonhala Magnair and Yupelri** will be approved based on **all** of the following criteria:

a. Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD)

-AND-

b. **One** of the following:

1) History of failure, contraindication or intolerance to Incruse Ellipta (umeclidinium)

-OR-

2) **Both** of the following:

- a) Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Incruse Ellipta) to control his/her 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) History of failure, contraindication or intolerance to ipratropium nebulized solution (generic Atrovent)

Authorization will be issued for 12 months

B. Reauthorization

1. **Lonhala Magnair and Yupelri** will be approved based on the following criterion:
 - a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months

3. Additional Clinical Rules:

- 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. Global strategy for the diagnosis, management and prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2020.
2. Lonhala Magnair [package insert]. Marlborough, MA: Sunovian Pharmaceuticals Inc.; June 2019.
3. Yupelri [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2019.
4. Ferguson GT, Goodin T, Tosiello R, et al. Long-term safety of glycopyrrolate/eFlow CS in moderate-to-very severe COPD: results from the glycopyrrolate for obstructive lung disease via electronic nebulizer (GOLDEN) 5 randomized study. *Respiratory Medicine* 132; 2017:251-60.

5. Wise RA, Acevedo RA, Anzueto AR, et al. Guiding principles for the use of nebulized long-acting beta2-agonists in patients with COPD: An expert panel consensus. *Chronic Obstr Pulm Dis* 2017; 4(1): 7-20

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| Program | Prior Authorization – Lonhala Magnair, Yupelri |
| Change Control | |
| Date | Change |
| 9/2018 | New program |
| 1/2019 | Added Yupelri to the criteria. |
| 8/2020 | Annual review. Updated references and removed step through Seebri Neohaler due to removal from the market. |