UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2151-8
Program	Prior Authorization/Medical Necessity
Medication	Lonhala Magnair® (glycopyrrolate inhalation solution)*, Yupelri® (revefenacin inhalation solution)
P&T Approval Date	9/2018, 1/2019, 7/2019, 8/2020, 11/2020, 11/2021, 11/2022, 11/2023
Effective Date	2/1/2024

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]:

A. Initial Authorization

1. **Lonhala Magnair*** 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 **both** of the following:

         a) Spiriva® Handihaler® or Respimat® (tiotropium)
         b) Yupelri (revefenacin inhalation solution)

      - OR-

      2) **Both** of the following:

         a) Patient is unable to use a metered-dose, dry powder or slow mist inhaler (e.g. Spiriva Respimat) 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 Yupelri (revefenacin inhalation solution)

Authorization will be issued for 12 months

2. **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 Spiriva Handihaler or Respimat (tiotropium)

      - OR-

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

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

Authorization will be issued for 12 months

B. Reauthorization

1. **Lonhala Magnair* or Yupelri** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy

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.

***Lonhala Magnair is typically excluded from coverage**

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). 2023.
2. Lonhala Magnair [package insert]. Marlborough, MA: Sunovian Pharmaceuticals Inc. August 2020.

3. Yupelri [package insert]. Morgantown, WV: Mylan Specialty L.P.; May 2022.
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

Program	Prior Authorization/Medical Necessity – Lonhala Magnair, Yupelri
Change Control	
Date	Change
9/2018	New program
1/2019	Added Yupelri to the criteria.
7/2019	Removed ipratropium as a step 1 option, added Yupelri as step 1 option prior to Lonhala Magnair and noted that Lonhala Magnair is typically excluded from coverage.
8/2020	Annual review. Updated references and removed step through Seebri Neohaler due to removal from the market.
10/2020	Formatting update.
11/2021	Annual review. Updated references.
11/2022	Annual review. Removed Incruse Ellipta as a step first-line agent. Updated references.
11/2023	Annual review. Updated references.