# Clinical Policy: Revefenacin (Yupelri)

Reference Number: PA.CP.PMN.195
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

**Description**
Revefenacin (Yupelri™) is a long-acting muscarinic antagonist (LAMA).

**FDA Approved Indication(s)**
Yupelri is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with PA Health & Wellness® that Yupelri is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Chronic Obstructive Pulmonary Disease** (must meet all)**:**

1. Diagnosis of COPD;
2. Age ≥ 18 years;
3. Dose does not exceed 175 mcg (1 vial) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to PA.CP.PMN.53

**II. Continued Therapy**

**A. Chronic Obstructive Pulmonary Disease** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 175 mcg (1 vial) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 12 months (whichever is less)**; or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – refer to PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
LAMA: long-acting muscarinic antagonist

*Appendix B: Therapeutic Alternatives*
Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): hypersensitivity to revefenacin or any component of this product
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| COPD | One 175 mcg vial (3 mL) inhaled QD with a standard jet nebulizer with a mouthpiece connected to an air compressor | 175 mcg/day |

## VI. Product Availability

Inhalation solution in a unit-dose vial for nebulization: 175 mcg/3 mL

## VII. References

1. Yupelri Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; November 2018. Available at: www.yupelri.com. Accessed November 20, 2018.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2019 report). Available from: www.goldcopd.org. Accessed November 20, 2018.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 04.17.19 | |