RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	revefenacin
Policy Number:	RxA.326
Drug(s) Applied:	Yupelri®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Revefenacin (Yupelri®) is a long-acting muscarinic antagonist (LAMA). It is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Revefenacin (Yupelri®)	chronic obstructive pulmonary disease	One 175 mcg vial (3 mL) inhaled once daily with a standard jet nebulizer with a mouthpiece connected to an air compressor	175 mcg/day

Dosage Forms

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

Clinical Policy

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

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

Commercial : 12 months
Medicaid: 12 months
HIM : 12 months

I. Continued Approval Criteria

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial : 12 months
Medicaid : 12 months
HIM : 12 months

II. Appendices

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

References

1. Yupelri Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; May 2019. Available at: www.yupelri.com. Accessed July 21,2020.
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 July 21,2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy description table was updated 2. Continuation therapy criteria II.A.1. was rephrased to"Member is currently receiving medication that has been authorized by RxAdvance…" 3. Initial therapy and continued therapy approval duration was updated 4. References were updated	07/21/2020	09/14/2020