Clinical Policy Title:	revefenacin
Policy Number:	RxA.326
Drug(s) Applied:	Yupelri®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of COPD;
   a At least GOLD group B
2. Age ≥ 18 years;
3. Dose does not exceed 175 mcg (1 vial) per day.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

II. 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

III. 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 June 3, 2021.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2021 report). Available from: www.goldcopd.org. Accessed June 3, 2021.

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

Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A.1.a was updated to include “At least GOLD group B”. 3. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 4. References were reviewed and updated.	5/28/2021	09/14/2021