

Clinical Policy Title:	revefenacin
Policy Number:	RxA.326
Drug(s) Applied:	Yupelri <sup>®</sup>
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):
  - Diagnosis of COPD;
    - a At least GOLD group B
  - 2. Age  $\geq$  18 years;
  - 3. Dose does not exceed 175 mcg (1 vial) per day.

Approval duration: Commercial: 12 months Medicaid: 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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## 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):
  - o Hypersensitivity to revefenacin or any component of this product
- Boxed warning(s):
  - o None

#### References

- 1. Yupelri® Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; May 2019. Available at: <a href="https://www.yupelri.com">www.yupelri.com</a>. 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: <a href="www.goldcopd.org">www.goldcopd.org</a>. 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

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Policy was reviewed:  1. Statement about provider sample "The provision of provider samples does not guarantee coverage" was added to Clinical Policy.		
<ol><li>Initial Approval Criteria I.A.1.a was updated to include "At least GOLD group</li></ol>	5/28/2021	09/14/2021
B".	5/26/2021	03/14/2021
3. Initial Approval Criteria and Continued		
Therapy Approval Criteria were updated to remove HIM approval duration.		
4. References were reviewed and updated.		

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