Clinical Policy: Revefenacin (Yupelri)
Reference Number: ERX.NPA.116
Effective Date: 01.08.19
Last Review Date: 05.19

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Chronic Obstructive Pulmonary Disease (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
      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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.
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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>COPD</td>
<td>One 175 mcg vial (3 mL) inhaled QD with a standard jet nebulizer with a mouthpiece connected to an air compressor</td>
<td>175 mcg/day</td>
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VI. Product Availability
Inhalation solution in a unit-dose vial for nebulization: 175 mcg/3 mL

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>01.08.19</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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