BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 02/21/19
LAST REVIEW DATE: 02/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

YUPELRI™ (revefenacin) oral inhalation solution

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Yupelri (revefenacin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older
  2. A confirmed diagnosis of chronic obstructive pulmonary disease (COPD)
  3. Individual has failure, contraindication or intolerance to **two** trials of the following inhaled anticholinergic/anti-muscarinic with an inhaled long-acting beta-agonist with or without an inhaled corticosteroid:
     - Incruse ellipta (umeclidinium)
     - Seebri neohaler (glycopyrrlate)
     - Spiriva (tiotropium)
     - Tudorza (aclidinium)
  4. Individual has failure, contraindication or intolerance to ipratropium bromide solution for nebulization
  5. Individual does not have hepatic impairment
  6. Individual is a non-smoker or is quitting through use of behavior modification and/or medications aimed at smoking cessation
  7. There are **NO** contraindications
     - Contraindications include:
       - Hypersensitivity to revefenacin or any component of the product

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Yupelri (revefenacin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition has responded
     - Response is defined as BOTH of the following:
       - Improved FEV1 over baseline
       - Reduced number and frequency of exacerbations
  2. Individual has been adherent with the medication
  3. Individual is a non-smoker or is quitting through use of behavior modification and/or medications aimed at smoking cessation
  4. Individual does not have hepatic impairment

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5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Paradoxical bronchospasm

6. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Yupelri (revefenacin) inhalation solution is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Yupelri (revefenacin) is a long-acting muscarinic antagonist (LAMA). It has similar affinity to the subtypes of muscarinic receptors M1-M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation. The safety and efficacy of Yupelri (revefenacin) have been established in clinical trials when administered using the PARI LC® Sprint nebulizer with a mouthpiece and the PARI Trek® S compressor. The safety and efficacy delivered from non-compressor based nebulizer systems have not been established.

Characteristics COPD includes small airways disease (obstructive bronchiolitis) and parenchymal destruction (emphysema). The presence of chronic inflammation causes structural changes and narrowing of the small airways.

No one COPD product adds superior clinical value over alternatives within any pharmacologic class. Guidelines recommend COPD medications by class, not by specific medication. A step-wise approach is used to minimize symptoms and reduce frequency and severity of exacerbations. COPD evidence-based clinical practice guidelines recommend combining medications from various pharmacologic classes for long-term management of COPD in a step-wise fashion as symptoms progress. As of yet, no medication modifies long-term decline in lung function.

Initial management of COPD patients includes either an inhaled long-acting beta agonist (LABA) or a LAMA, both agents relax bronchial smooth muscle. An inhaled corticosteroid (ICS) is used for those patients who are at high risk for exacerbations. Other COPD medications include inhaled short-acting bronchodilators (beta-agonists and antimuscarinic agents), methylxanthines, oral corticosteroids, and phosphodiesterase-4 (PDE-4) inhibitors.

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Definitions:

Global Initiative for Chronic Obstructive Lung Disease (GOLD) assessment

GOLD: severity of airflow limitation (based on postbronchodilator FEV1)		
Stage	**Severity**	**FEV1 (%predicted)**
In patients with FEV1 / FVC < 0.7		
GOLD 1	Mild	≥ 80
GOLD 2	Moderate	50-79
GOLD 3	Severe	30-49
GOLD 4	Very severe	< 30
GOLD: Assessment of symptoms and risk for exacerbations		
Exacerbations/Hospitalizations	**Symptom assessment**	
	mMRC 0-1; CAT < 10	**mMRC ≥ 2; CAT ≥ 10**
0-1 exacerbations without hospitalization	A	B
≥ 2 exacerbations or ≥ 1 hospitalization	C	D
A: Low risk, less symptoms B: Low risk, more symptoms C: High risk, less symptoms D: High risk, more symptoms CAT: COPD Assessment Test mMRC: modified Medical research Council dyspnea scale		

Modified Medical Research Council Dyspnea Scale

Grade	Description of breathlessness
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness or have to stop for breath when walking at my own pace
3	I stop for breath after walking about 100 yards of after a few minutes on level ground
4	I am too breathless to leave the house or I am breathless when dressing

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COPD Assessment Test

	Circle the number that best describes you	
I never cough	1 2 3 4 5	I cough all the time
I have no phlegm in my chest at all	1 2 3 4 5	My chest is completely full of phlegm
My chest does not feel tight at all	1 2 3 4 5	My chest feels very tight
When I walk up a hill or one flight of stairs I am not breathless	1 2 3 4 5	When I walk up a hill or one flight of stairs I am very breathless
I am not limited doing any activities at home	1 2 3 4 5	I am very limited doing activities at home
I am confident leaving my home despite my lung condition	1 2 3 4 5	I am not at all confident leaving my home because of my lung condition
I sleep soundly	1 2 3 4 5	I don't sleep soundly because of my lung condition
I have lots of energy	1 2 3 4 5	I have no energy at all

Management of Stable COPD based on GOLD ABCD assessment of symptoms and risk of exacerbation

Category	Symptoms	Risk	Suggested treatment
A	Less symptomatic: Mild or infrequent symptoms (breathless with strenuous exercise or when hurrying on level ground or walking up a slight hill) or CAT <10	Low: 0 or 1 exacerbations in the past year without associated hospitalization	**Recommendation:** Short-acting bronchodilator or combination of short-acting beta-agonist and anticholinergic (antimuscarinic), as needed. **Alternative:** Long-acting bronchodilator if beneficial.
B	More symptomatic: Moderate to severe symptoms (patient has to walk more slowly than others of same age due to breathlessness, has to stop to catch breath when walking on level ground at own pace, or has more severe breathlessness) or CAT ≥10	Low: 0 or 1 exacerbations in the past year without associated hospitalization	**First choice:** Regular treatment with a long-acting bronchodilator, either LAMA or LABA, based on symptom relief. Short-acting bronchodilator available for symptom control as needed. **For persistent symptoms:** Regular treatment with a combination of LAMA and LABA.
C	Less symptomatic: Mild or infrequent symptoms (breathless with strenuous exercise or when hurrying on level ground or walking up a slight hill) or CAT <10[Δ]	High risk: ≥ 2 exacerbations per year with one or more leading to hospitalization	**First choice:** Regular treatment with a LAMA; SABA available for symptom control as needed. **For further exacerbations:**

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			Regular treatment with a LAMA plus LABA or (less preferred) LABA plus ICS
D	More symptomatic: Moderate to severe symptoms (patient has to walk slower than others of same age due to breathlessness, has to stop to catch breath when walking on level ground at own pace, or has more severe breathlessness)¶ or CAT ≥10	High risk: ≥ 2 exacerbations per year with one or more leading to hospitalization	**First choice:** Regular treatment with combination LABA plus LAMA. LABA plus ICS may be preferred, if features of asthma/COPD overlap. SABA available for symptom control as needed. LAMA alone, if LABA contraindicated. **For further exacerbations:** Regular treatment with combination of LAMA plus LABA plus ICS or (less preferred in absence of asthma overlap) switch to LABA plus ICS. If exacerbations continue despite triple therapy, additional options for selected patients include roflumilast (if chronic bronchitis and FEV_1 <50% predicted), theophylline, chronic therapy with a macrolide, and stopping ICS

Resources:

Yupelri product information accessed 02-13-19 at DailyMed:
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6

Global Initiative for Chronic Obstructive Lung Disease: Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2017 Report.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.