BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
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STRIVERDI RESPIMAT® (olodaterol hcl) aerosol

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.**

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

Description:

Striverdi Respimat (olodaterol HCl) is a selective long-acting beta-2 agonist (LABA) indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Striverdi Respimat (olodaterol) exerts its pharmacological effects by binding and activating beta-2 adrenoceptors. Activation of these receptors in the airways results in a stimulation of intracellular adenyl cyclase, an enzyme that mediates the synthesis of cyclic-3', 5' adenosine monophosphate (cAMP). Elevated levels of cAMP causes bronchodilation by relaxing airway smooth muscle cells.

Beta-adrenoceptors are divided into three subtypes: beta-1 adrenoceptors are predominantly expressed on cardiac smooth muscle, beta-2 adrenoceptors are predominantly expressed on airway smooth muscle, and beta-3 adrenoceptors are predominantly expressed on adipose tissue. Beta-2 agonists cause bronchodilation.

Although the beta-2 adrenoceptor is the predominant adrenergic receptor in the airway smooth muscle, they are also present on the surface of a variety of other cells, including lung epithelial and endothelial cells and in the heart. The precise function of beta-2 receptors in the heart is not known, but their presence raises the possibility that even highly selective beta-2 agonists may have cardiac effects.

Chronic obstructive pulmonary disease (COPD)

- COPD is a common, preventable, and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities
- Characteristics of 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
- Chronic bronchitis is defined as a chronic productive cough for three months in each of two successive years in a patient in whom other causes of chronic cough have been excluded
- Emphysema is a pathological term that describes some of the structural changes sometimes associated with COPD
    - These changes include abnormal and permanent enlargement of the airspaces distal to the terminal bronchioles that is accompanied by destruction of the airspace walls, without obvious fibrosis
- Asthma is a chronic inflammatory disorder of the airways
- Significant overlap exists between COPD and other disorders that cause airflow limitation: emphysema, chronic bronchitis, asthma, bronchiectasis, and bronchiolitis
- The most important risk factor for COPD is cigarette smoking and all patients should be encouraged and helped in quitting through use of behavior modification and medications aimed at smoking cessation

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

- The three cardinal symptoms of COPD are dyspnea, chronic cough, and sputum production and the most common early symptom is exertional dyspnea. Less common symptoms include wheezing and chest tightness

- No single COPD product adds superior clinical value over alternatives within any pharmacologic class
    - Guidelines recommend COPD medications by class, not by specific medication, and the drugs within each class are not separated for safety or efficacy superiority

- Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines suggests using an assessment of airflow limitation with an assessment of an individual's symptoms and exacerbation history to guide therapy
    - The severity of lung function impairment is stratified based on the post-bronchodilator FEV_1, using the GOLD classification
    - Symptom severity is assessed using the COPD Assessment Test (CAT) or modified Medical Research Council (mMRC) dyspnea scale
    - Lung function in addition to the number of exacerbations and hospitalizations for exacerbations in the previous 12 months can be used to predict future risk
        - No or one exacerbation in the past 12 months and GOLD 1 or 2 level suggests a low future risk of exacerbations
        - Two or more exacerbations or a hospitalized exacerbation or GOLD 3 or 4 level suggest a high future risk
    - Components are combined into four groups: A, B, C, & D

- 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
    - A step-wise approach to treatment is used to minimize symptoms and reduce frequency and severity of exacerbations
    - As of yet, no medication modifies long-term decline in lung function
    - An inhaled corticosteroid (ICS) can be used for those patients who are at high risk for exacerbations

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

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

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

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

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

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:** 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

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

Medications

Bronchodilators	
Short-acting antimuscarinics (SAMA)	ipratropium (Atrovent HFA)
Short-acting beta-agonists (SABA)	albuterol (ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA) levalbuterol (Xopenex HFA)
Long-acting antimuscarinics (LAMA)	aclidinium (Tudorza Pressair) glycopyrrolate (Seebri Neohaler) tiotropium (Spiriva, HandiHaler, Spiriva Respimat) umeclidinium (Incruse Ellipta)
Long-acting beta-agonists (LABA)	arformoterol (Brovana) – nebulized solution formoterol (Foradil aerolizer) formoterol (perforomist) – nebulized solution indacaterol (Arcapta Neohaler) olodaterol (Striverdi Respimat) salmeterol (Serevent Diskus)
Bronchodilator combination products	
SAMA / SABA	ipratropium / albuterol (Combivent Respimat)
LAMA / LABA	glycopyrrolate / formoterol (Bevespi Aerosphere) glycopyrrolate / indacaterol (Utibron) tiotropium / olodaterol (Stiolto Respimat) umeclidinium / vilanterol (Anoro Ellipta)
Corticosteroids	
Inhaled corticosteroids (ICS)	beclomethasone (Qvar) budesonide (Pulmicort Flexhaler) ciclesonide (Alvesco) flunisolide (Aerospan) fluticasone (Arnuity Ellipta, Flovent Diskus, Flovent HFA) mometasone (Asmanex, Asmanex HFA)
Corticosteroid-bronchodilator combination products	
ICS/LABA	budesonide / formoterol (Symbicort) fluticasone / salmeterol (Advair HFA, Advair Diskus) fluticasone / vilanterol (Breo Ellipta) mometasone / formoterol (Dulera)

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

Striverdi Respimat (olodaterol HCl)

Medication class:
Beta-2 adrenergic agonist, long acting

FDA-approved indication(s):
- Long-term once daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema

Recommended Dose:
- 2 inhalations once daily

Maximum dosage
- 2 inhalations once daily

Available Dosage Forms:
- One spray cartridge per carton, cartridge provides 60 metered actuations (2.5 mcg olodaterol/actuation) and one inhaler device per carton

Warnings and Precautions:
- It is not indicated to treat acutely deterioration of COPD
- It is not indicated to treat asthma
- Do not use for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm
- Do not exceed the recommended dose
- Discontinue if life-threatening paradoxical bronchospasm occur
- Discontinue if immediate hypersensitivity reactions, including angioedema, occurs
- Should not be used with another long-acting beta-2 adrenergic agonist
- Should not normally be used with a beta-blocker unless there are no suitable alternative to the beta-blocker, in this setting a cardioselective beta-blocker should be considered

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

Criteria:

- **Criteria for initial therapy:** Striverdi Respimat (olodaterol HCl) 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), including chronic bronchitis and/or emphysema

  3. Individual has failure, contraindication or intolerance such that the individual is unable to use **THREE** of the preferred step therapy products:
     - Preferred step therapy products include:
       - Arcapta Neohaler (indacaterol) inhalation capsules
       - Serevent Diskus (salmeterol) inhalation aerosol powder
       - Anoro Ellipta (umeclidinium-vilanterol) aerosol powder
       - Simultaneous use of Spiriva (tiotropium) with Serevent (salmeterol)
       - Simultaneous use of Spiriva (tiotropium) with Arcapta (indacaterol)

  4. Individual is a non-smoker or is quitting through use of behavior modification and medications aimed at smoking cessation

  5. There are **NO** of the following contraindications:
     - Contraindications include:
       - Use in patients with asthma without use of a long-term asthma control medication

  Initial approval duration: 12 months

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

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Less symptomatic over baseline
       - Fewer exacerbations or hospitalizations over baseline

  2. Individual has been adherent with the medication and does not smoke cigarettes

  3. 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

  4. There are no significant interacting drugs

  Renewal duration: 12 months

STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

Resources:

Striverdi. Package Insert. Revised by manufacturer 6/2016. Accessed 9/16/16.

Global Initiative for Chronic Obstructive Lung Disease: Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2016

UpToDate: Chronic obstructive pulmonary disease: Definitions, clinical presentations, diagnosis, and staging. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/chronic-obstructive-pulmonary-disease-definition-clinical-manifestations-diagnosis-and-staging?source=search_result&search=copd%20diagnosis&selectedTitle=1~150

UpToDate: Management of stable chronic obstructive pulmonary disease. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-of-stable-chronic-obstructive-pulmonary-disease?source=search_result&search=copd%20diagnosis&selectedTitle=3~150

UpToDate: Management of exacerbations of chronic obstructive pulmonary disease. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-of-exacerbations-of-chronic-obstructive-pulmonary-disease?source=search_result&search=copd%20diagnosis&selectedTitle=4~150

UpToDate: Management of refractory chronic obstructive pulmonary disease. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-of-refractory-chronic-obstructive-pulmonary-disease?source=search_result&search=copd%20diagnosis&selectedTitle=2~150

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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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Pharmacy Prior Authorization Request Form

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.