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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

Description:

Striverdi (olodaterol) 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.

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

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. 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 LABA or long-acting antimuscarinic agent (LAMA). Use of an inhaled LABA and an inhaled LAMA relax bronchial smooth muscle. An inhaled corticosteroid (ICS) can be used for those patients who are at high risk for exacerbations. Other COPD medications include inhaled short-acting bronchodilators (beta-agonists (SABA) and antimuscarinic agents (SAMA)), methylxanthines, oral corticosteroids, and phosphodiesterase-4 (PDE-4) inhibitors.

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.

Striverdi (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.

Although the beta-2 adrenoceptor is the predominant adrenergic receptor in the airway smooth muscle, it is 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.

**Definitions:**

**Drug related events:**

Ineffective / failure

Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened

A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

Adverse Drug Event: Allergic reaction / Hypersensitivity / Intolerance

Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual’s outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals’ body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.
### STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

*Allergic reaction / hypersensitivity* – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline.

*Intolerance* – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record.

*Contraindication*

Use of a drug that is not recommended by the manufacturer or FDA labelling.

Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental.

*Non-adherence*

Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record.

### Precertification:

Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.

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](http://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.

### Criteria:

See “Resources” section for FDA-approved dosage.
STRIVERDI RESPIMAT® (olodaterol hcl) aerosol (cont.)

- Precertification for Striverdi (olodaterol hcl) requires completion of the specific request form in its entirety. 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 will be returned.

- FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Striverdi (olodaterol hcl) is considered medically necessary when ALL of the following criteria are met:
  1. Individual is 18 years of age or older
  2. Medical record documentation of a confirmed diagnosis of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema
  3. Medical record documentation that the individual is unable to use ALL of the following due to a failed response, significant adverse drug event or contraindication:
     - Arcapta Neohaler (indacaterol) inhalation capsules
     - Serevent Diskus (salmeterol) inhalation aerosol powder
     - Anoro Ellipta (umeclidinium-vilanterol) aerosol powder
     - Simultaneous use of Spiriva (tiotropium) with Severevent (salmeterol)
     - Simultaneous use of Spiriva (tiotropium) with Arcapta (indacaterol)
  4. Absence of ALL of the following contraindications:
     - Use in patients with asthma without use of a long-term asthma control medication
  5. Absence of ALL of the following exclusions:
     - Use for the treatment of asthma
     - Use in acutely deteriorating COPD patients
     - Use for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm
     - Simultaneous use with another long-acting beta-2 adrenergic agonist

- Striverdi (olodaterol hcl) for all other indications not previously listed is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

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


FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
</table>
| Striverdi Respimat Inhalation Spray is a long-acting beta-adrenergic agonist indicated for: The long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. | • For oral inhalation only
• Two inhalations of Striverdi Respimat once-daily at the same time of day |

Important limitations:

• Striverdi Respimat is NOT indicated to treat acute deterioration of COPD
• Striverdi Respimat is NOT indicated to treat asthma