Select Inhaled Respiratory Agents

Policy # 00526
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Inhaled Corticosteroid Products
Based on review of available data, the Company may consider the inhaled corticosteroid products Aerospan® (flunisolide), Alvesco® (ciclesonide), Asmanex® Twishtaler® (mometasone furoate), Asmanex® HFA (mometasone furoate), and Pulmicort Flexhaler® (budesonide) to be eligible for coverage when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Aerospan (flunisolide), Alvesco (ciclesonide), Asmanex Twishtaler (mometasone furoate), Asmanex HFA (mometasone furoate), or Pulmicort Flexhaler (budesonide) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Arnuity™ Ellipta® (fluticasone furoate), Flovent® Diskus® (fluticasone propionate), Flovent® HFA (fluticasone propionate), or QVAR® (beclomethasone dipropionate) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Aerospan (flunisolide), Alvesco (ciclesonide), Asmanex Twishtaler (mometasone furoate), Asmanex HFA (mometasone furoate), or Pulmicort Flexhaler (budesonide) WITHOUT clinical evidence or patient history that suggests the use of Arnuity Ellipta (fluticasone furoate), Flovent Diskus (fluticasone propionate), Flovent HFA (fluticasone propionate), or QVAR (beclomethasone propionate) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary. **

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Inhaled Long Acting Beta Agonists (LABAs)
Based on review of available data, the Company may consider the inhaled long acting beta agonists Arcapta™ Neohaler™ (indacaterol) and Foradil® Aerolizer® (formoterol fumarate) to be eligible for coverage when the below patient selection criterion is met:
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Patient Selection Criteria
Coverage eligibility will be considered for Arcapta Neohaler (indacaterol) or Foradil Aerolizer (formoterol fumarate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Striverdi® Respimat® (olodaterol) or Serevent® Diskus (salmeterol xinafoate) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Arcapta Neohaler (indacaterol) or Foradil Aerolizer (formoterol fumarate) WITHOUT clinical evidence or patient history that suggests the use of Striverdi Respimat (olodaterol) or Serevent Diskus (salmeterol xinafoate) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Nebulized Long Acting Beta Agonists (LABAs)
Based on review of available data, the Company may consider the nebulized long acting beta agonists Brovana® (arformoterol tartrate) and Perforomist® (formoterol fumarate) to be eligible for coverage when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Brovana (arformoterol tartrate) or Perforomist (formoterol fumarate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of TWO of the following preferred bronchodilating agents for COPD (chronic obstructive pulmonary disease): Serevent Diskus (salmeterol xinafoate), Spiriva® Respimat® (tiotropium bromide), Spiriva HandiHaler® (tiotropium bromide), Anoro® Ellipta (umeclidinium/vilanterol), Striverdi Respimat (olodaterol), or Incruse® Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Brovana (arformoterol tartrate) or Perforomist (formoterol fumarate) WITHOUT clinical evidence or patient history that suggests the use of TWO of the following preferred bronchodilating agents for COPD (chronic obstructive pulmonary disease): Serevent Diskus (salmeterol xinafoate), Spiriva Respimat (tiotropium bromide), Spiriva HandiHaler (tiotropium bromide), Anoro Ellipta (umeclidinium/vilanterol), Striverdi Respimat (olodaterol), or Incruse Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**
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When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Inhaled Corticosteroid/Long Acting Beta Agonist Combination Products (ICS/LABAs)
Based on review of available data, the Company may consider the inhaled corticosteroid/long acting beta agonist combination product Dulera (mometasone furoate/formoterol furoate) to be eligible for coverage when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Dulera (mometasone furoate/formoterol furoate) when the following criterion is met:
- There is clinical evidence or patient history that suggests the use of Advair Diskus (fluticasone propionate/salmeterol), Advair HFA (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), or Symbicort (budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Dulera (mometasone furoate/formoterol furoate) WITHOUT clinical evidence or patient history that suggests the use of Advair Diskus (fluticasone propionate/salmeterol), Advair HFA (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), or Symbicort (budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Inhaled Long Acting Antimuscarinic Agents (LAMAs)
Based on review of available data, the Company may consider the inhaled long acting antimuscarinic agents Tudorza Pressair (aclidinium bromide) and Seebri Neohaler (glycopyrrolate) to be eligible for coverage when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Tudorza Pressair (aclidinium bromide) or Seebri Neohaler (glycopyrrolate) when the following criterion is met:
- There is clinical evidence or patient history that suggests the use of Spiriva Respimat (tiotropium bromide), Spiriva HandiHale (tiotropium bromide), or Incruse Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient.
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When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Tudorza Pressair (acldinium bromide) or Seebri Neohaler (glycopyrrolate) WITHOUT clinical evidence or patient history that suggests the use of Spiriva Respimat (tiotropium bromide), Spiriva HandiHaler (tiotropium bromide), or Incruse Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Inhaled Long Acting Antimuscarinic Agent/Long Acting Beta Agonist Combination Products (LAMA/LABAs)
Based on review of available data, the Company may consider the inhaled long acting antimuscarinic agent/long acting beta agonist combination products Stiolto® Respimat (tiotropium bromide/olodaterol), Bevespi Aerosphere™ (glycopyrrolate/formoterol fumarate), and Utibron™ Neohaler (indacaterol/glycopyrrolate) to be eligible for coverage when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Stiolto Respimat (tiotropium bromide/olodaterol), Bevespi Aerosphere (glycopyrrolate/formoterol fumarate), or Utibron Neohaler (indacaterol/glycopyrrolate) when the following criterion is met:
- There is clinical evidence or patient history that suggests the use of Anoro Ellipta (umeclidinium/vilanterol) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of Stiolto Respimat (tiotropium bromide/olodaterol), Bevespi Aerosphere (glycopyrrolate/formoterol fumarate), or Utibron Neohaler (indacaterol/glycopyrrolate) WITHOUT clinical evidence or patient history that suggests the use of Anoro Ellipta (umeclidinium/vilanterol) will be/was ineffective or will/did cause an adverse reaction to the patient to be not medically necessary.**

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.
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**Inhaled Short Acting Beta Agonists (SABAs)**
Based on review of available data, the Company may consider the short acting beta agonists Proventil HFA (albuterol sulfate) and Xopenex HFA (levalbuterol tartrate) to be **eligible for coverage** when the below patient selection criterion is met:

**Patient Selection Criteria**
Coverage eligibility will be considered for Proventil HFA (albuterol sulfate) or Xopenex HFA (levalbuterol tartrate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), ProAir HFA (albuterol sulfate) or Ventolin HFA (albuterol sulfate) will be/was ineffective or will/did cause an adverse reaction to the patient.

**When Services Are Considered Not Medically Necessary**
Based on review of available data, the Company considers the use of Proventil HFA (albuterol sulfate) or Xopenex HFA (levalbuterol tartrate) **WITHOUT** clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), ProAir HFA (albuterol sulfate), or Ventolin HFA (albuterol sulfate) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.**

### Schematic

<table>
<thead>
<tr>
<th>Class</th>
<th>Non-Preferred Products</th>
<th>Preferred Products</th>
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<td></td>
<td>Aerospan</td>
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<td>Inhaled Long Acting Beta Agonists (LABAs)</td>
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<td></td>
<td>Foradil Aerolizer</td>
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<td>Nebulized Long Acting Beta Agonists (LABAs)</td>
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<td>Perforomist</td>
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<td>Anoro Ellipta</td>
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<td>Seebri Neohaler</td>
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<td>Utibron Neohaler</td>
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<td></td>
<td>Bevespi Aerosphere</td>
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<tr>
<th>(LAMA/LABA)</th>
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<th>Proventil HFA</th>
<th>Xopenex HFA</th>
<th>ProAir RespiClick</th>
<th>ProAir HFA</th>
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**Background/Overview**

The various products mentioned in this policy are approved for use in COPD and/or asthma patients, depending on the particular product.

**Rationale/Source**

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the preferred products listed in this policy will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using the non-preferred agents mentioned in this policy over the preferred agents mentioned in this policy.

**References**

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**Policy History**

Original Effective Date: 01/01/2017
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09/08/2016 Medical Policy Committee review
09/21/2016 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 09/2017

**Medically Necessary (or “Medical Necessity”) -** Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient’s illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.