Pharmacy Medical Policy
Asthma and Chronic Obstructive Pulmonary Disease Medication Management

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Policy History
- Information Pertaining to All Policies
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Policy Number: 011
BCBSA Reference Number: None

Related Policies
- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.
Prior Authorization Information

☒ Prior Authorization
☐ Step Therapy
☒ Quality Care Dosing

Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Policy last updated 7/1/2023

Pharmacy (Rx) or Medical (MED) benefit coverage
☒ Rx
☐ MED

To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

Policy applies to Commercial Members:
- Managed Care (HMO and POS),
- PPO and Indemnity
- MEDEX with Rx plan
- Managed Major Medical with Custom BCBSMA Formulary
- Comprehensive Managed Major Medical with Custom BCBSMA Formulary
- Managed Blue for Seniors with Custom BCBSMA Formulary

Please refer to the chart below for the formulary status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advair Diskus</strong> (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Advair</strong> HFA (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>AirDuo</strong> (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Breo Ellipta</strong> (fluticasone/vilanterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Breztri</strong> (budesonide/glycopyrrolate/formoterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Budesonide / Formoterol**</td>
<td>PA Required</td>
</tr>
<tr>
<td>Dulera® (mometasone/formoterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Fluticasone/Salmeterol (AirDuo™ Generic)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Fluticasone/Salmeterol (Advair Diskus® Authorized Generic [AG])</td>
<td>PA Required</td>
</tr>
<tr>
<td>Fluticasone/Vilanterol Inhaler (Breo Ellipta® Authorized Generic [AG])</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Incruse™ Ellipta</strong> (umeclidinium)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Symbicort® (Budesonide/Formoterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Trelegy Ellipta</strong> (fluticasone/umeclidinium/vilanterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Wixela Inhub (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
</tbody>
</table>

**Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations.

Dulera® *% (mometasone/formoterol) may be covered when the following criteria are met:
- The patient has a physician documented diagnosis of asthma

OR
• There is a paid claim with any ONE of the following within the previous 130 days:
  o One inhaled corticosteroid
  o One inhaled beta2 agonist
  o One inhaled mast cell stabilizer
  o One inhaled anticholinergic
  o One oral albuterol product
  o One oral theophylline containing product
  o Dulera
  o Symbicort
  o Fluticasone/Salmeterol

*Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Symbicort ® % (Budesonide/Formoterol) is covered when the following criteria are met:
• The patient has a physician documented diagnosis of asthma or COPD.
OR
• There is a paid claim with any ONE of the following within the previous 130 days:
  o One inhaled corticosteroid
  o One inhaled beta2 agonist
  o One inhaled mast cell stabilizer
  o One inhaled anticholinergic
  o One oral albuterol product
  o One oral theophylline containing product
  o Symbicort
  o Dulera
  o Fluticasone/Salmeterol

*Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Fluticasone/Salmeterol ™% (All Generics including Wixela Inhub ®) are covered when the following criteria are met:
• The patient has a physician documented diagnosis of asthma.
OR
• There is a paid claim with any ONE of the following within the previous 130 days:
  o One inhaled corticosteroid
  o One inhaled beta2 agonist
  o One inhaled mast cell stabilizer
  o One inhaled anticholinergic
  o One oral albuterol product
  o One oral theophylline containing product
  o Dulera
  o Symbicort
  o Fluticasone/Salmeterol

*Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Advair ® HFA ™% (Fluticasone/Salmeterol) OR AirDuo™ ™% ™ (Fluticasone/Salmeterol) are covered when the following criteria are met:
• The patient has a physician documented diagnosis of asthma
• There must be evidence of a paid claim or physician documented use with any ONE of the following:
  o One inhaled corticosteroid
  o One inhaled beta2 agonist
One inhaled anticholinergic
One inhaled mast cell stabilizer
One oral albuterol product
One oral theophylline containing product

AND
- There is previous treatment or a BCBSMA paid Claim(s) for TWO of the following: [Dulera ® (mometasone/formoterol), OR Symbicort ® (Budesonide/Formoterol), OR Fluticasone/Salmeterol (All Generics including Wixela Inhub ®)]

Advairst Diskus ® % (Fluticasone/Salmeterol), OR Budesonide/ Formoterol % aerosol are covered when the following criteria are met:
- The patient has a physician documented diagnosis of Asthma OR COPD
- There must be evidence of a paid claim or physician documented use with any ONE of the following:
  - One inhaled corticosteroid
  - One inhaled beta2 agonist
  - One inhaled anticholinergic
  - One inhaled mast cell stabilizer
  - One oral albuterol product
  - One oral theophylline containing product

AND
- There is previous treatment or a BCBSMA paid Claim(s) for BOTH of the following: [Symbicort ® (Budesonide/Formoterol) AND Fluticasone/Salmeterol (All Generics including Wixela Inhub ®)] by the patient.

Breo Ellipta © % (fluticasone/ vilanterol) OR fluticasone/ vilanterol Inhaler (Breo Ellipta ® Authorized Generic [AG]) maybe covered when the following criteria are met:
- The patient has a physician documented diagnosis of asthma or COPD*$
- There must be evidence of a paid claim or physician documented use with any ONE of the following:
  - One inhaled corticosteroid
  - One inhaled beta2 agonist
  - One inhaled anticholinergic
  - One inhaled mast cell stabilizer
  - One oral albuterol product
  - One oral theophylline containing product

AND
- There is a BCBSMA paid Claim(s) for TWO of the following: [Dulera ® (mometasone/formoterol), Symbicort ® (Budesonide/Formoterol), OR Fluticasone/Salmeterol (All Generics including Wixela Inhub ®)] by the patient)

*$ COPD Diagnosis does NOT need to try two as Dulera ® (mometasone/formoterol) AND Fluticasone/Salmeterol (AirDuo™ Generic) are not FDA approved for COPD.

Breztri ™ % (budesonide/glycopyrrolate/formoterol) maybe covered when the following criteria are met:
- There is a paid claim with any ONE of the following within the previous 130 days:
  - One inhaled corticosteroid
  - One inhaled beta2 agonist
  - One inhaled mast cell stabilizer
  - One inhaled anticholinergic
  - One oral albuterol product
  - One oral theophylline containing product
  - One Inhaled Corticosteroid /Long-acting Beta agonist
  - One Long-acting muscarinic antagonist -containing product
  - One Long-acting Beta agonist -containing product

AND
- There is a BCBSMA paid Claim(s) for ONE of the following: Symbicort ® (Budesonide/Formoterol) OR Anoro Ellipta (umeclidinium bromide and vilanterol Trifenatate) OR Stiolto (tiotropium bromide and olodaterol) by the patient.
Incruse™ Ellipta®* (umeclidinium inhalation powder) is covered when the following criteria are met:

- The patient has a physician documented diagnosis COPD
- AND
- There must be evidence of a paid claim or physician documented use with any ONE of the following:
  - Spiriva® (tiotropium bromide)

Trelegy Ellipta®* (fluticasone/umeclidinium/vilanterol) maybe covered when the following criteria are met:

- There is a paid claim with any ONE of the following within the previous 130 days:
  - One inhaled corticosteroid
  - One inhaled beta2 agonist
  - One inhaled mast cell stabilizer
  - One inhaled anticholinergic
  - One oral albuterol product
  - One oral theophylline containing product
  - One Inhaled Corticosteroid /Long-acting Beta agonist
  - One Long-acting muscarinic antagonist -containing product
  - One Long-acting Beta agonist -containing product
- AND
- There is a BCBSMA paid Claim(s) for ONE the of the following: Symbicort® (Budesonide/Formoterol) OR Dulera® (mometasone/formoterol) OR Fluticasone/Salmeterol (All Generics including Wixela Inhub®) OR Anoro Ellipta (umeclidinium bromide and vilanterol Trifenatate) OR Stiolto (tiotropium bromide and olodaterol) by the patient.

*Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Individual Consideration
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Updated to move Wixela with the other Advair Generics.</td>
</tr>
<tr>
<td>4/2023</td>
<td>Updated to add generic Advair AG to same criteria as AirDuo Generic.</td>
</tr>
<tr>
<td>8/2022</td>
<td>Updated to add fluticasone/vilanterol Inhaler (Breo Ellipta® Authorized Generic [AG]) to the policy.</td>
</tr>
<tr>
<td>7/2022</td>
<td>Clarified coding for non-preferred medications for Asthma vs COPD.</td>
</tr>
<tr>
<td>2/2022</td>
<td>Updated to add an additional option in criteria and add additional options to allow approval for the triple inhalers at the request of P &amp; T.</td>
</tr>
<tr>
<td>1/2022</td>
<td>Updated to add Trelegy Ellipta® &amp; Breztri™ to the policy.</td>
</tr>
<tr>
<td>6/2020</td>
<td>Updated to add AG of Symbicort to the policy as non-covered.</td>
</tr>
<tr>
<td>1/2020</td>
<td>Updated criteria for Incruse™ Ellipta® and clarify criteria for non-preferred.</td>
</tr>
<tr>
<td>3/2019</td>
<td>Updated to include Wixela Inhub &amp; the AG to Advair Discus as Preferred and PA required.</td>
</tr>
<tr>
<td>1/2019</td>
<td>Updated to add Breo Ellipta™ back into the policy and it is still non covered medication.</td>
</tr>
<tr>
<td>Date</td>
<td>Update Description</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1/2018</td>
<td>Updated to include Fluticasone/Salmeterol, AirDuo™ and to modify Advair®/ AirDuo™ Criteria.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>9/2016</td>
<td>Updated to remove Step from policy. This resulted in the removal of Singulair®, Anoro™ Ellipta™, Stiolto™ Respimat® and Breo™ Ellipta™ from the policy.</td>
</tr>
<tr>
<td>6/2016</td>
<td>Updated to add Seebri™ Neohaler® and Utibron™ Neohaler® to step 3.</td>
</tr>
<tr>
<td>12/2015</td>
<td>Updated by adding Incruse™ Ellipta® to step 3.</td>
</tr>
<tr>
<td>8/2015</td>
<td>Added Stiolto™ Respimat® to step 3 &amp; removed Zyflo &amp; Accolate from policy.</td>
</tr>
<tr>
<td>7/2015</td>
<td>Added new indication for Breo™ Ellipta™</td>
</tr>
<tr>
<td>10/2014</td>
<td>Added Anoro™ Ellipta™ to the policy.</td>
</tr>
<tr>
<td>4/2014</td>
<td>Updated by moving montelukast &amp; zafirlukast to Step 1 and Advair to step 3.</td>
</tr>
<tr>
<td>3/2014</td>
<td>Added Breo™ Ellipta™ to the policy.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Updated ExpressPAth language and remove Blue Value.</td>
</tr>
<tr>
<td>8/2012</td>
<td>Updated to include coverage criteria for new generic montelukast.</td>
</tr>
<tr>
<td>11/2011-</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.</td>
</tr>
<tr>
<td>4/2012</td>
<td>No changes to policy statements.</td>
</tr>
<tr>
<td>1/1/2012</td>
<td>Updated to include coverage criteria for COPD diagnosis and to remove physician documented use criteria for requested medications.</td>
</tr>
<tr>
<td>1/2011</td>
<td>Updated to include coverage criteria for new generic zafirlukast.</td>
</tr>
<tr>
<td>1/1/2011</td>
<td>Updated coverage criteria to require previous use of one inhaled corticosteroid, one inhaled beta2 agonist, one inhaled mast cell stabilizer, one oral albuterol product or one oral theophylline containing product by the patient within the previous 130 days for a diagnosis of asthma.</td>
</tr>
<tr>
<td>11/2010</td>
<td>Updated to include coverage criteria of new FDA approved medication Dulera®.</td>
</tr>
<tr>
<td>1/2010</td>
<td>Updated to change coverage criteria for Advair® Diskus and Advair® HFA. No changes to policy statements.</td>
</tr>
<tr>
<td>9/2009</td>
<td>Policy updated to change 180 day look back period to 130 days, remove Medicare Part D criteria from Medical Policy and update sample language.</td>
</tr>
<tr>
<td>1/2008</td>
<td>Updated include prior authorization requirements for Advair Diskus®, Advair® HFA and Symbicort.</td>
</tr>
</tbody>
</table>

**References**


Endnotes
A.) Based upon the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 10/2002.
B.) Based upon the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 9/2007.
C.) Based upon the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 9/2009.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below: