Pharmacy Medical Policy
Asthma and Chronic Obstructive Pulmonary Disease Medication Management

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Policy Number: 011
BCBSA Reference Number: None

Related Policies
None

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. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com. Patients must have pharmacy benefits under their subscriber certificates.

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>Fluticasone/Salmeterol</strong></td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Advair Diskus®)</em> (Fluticasone/Salmeterol)</td>
<td></td>
</tr>
<tr>
<td><em>(Advair® HFA)</em> (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Airduo™)</em> (Fluticasone/Salmeterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Breo Ellipta®)</em> (Fluticasone/vilanterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Dulera®)</em> (mometasone/formoterol)</td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Fluticasone/Salmeterol)</em> (Airduo™ Generic)</td>
<td>PA Required</td>
</tr>
<tr>
<td><em>(Incruse™ Ellipta®)</em> (umeclidinium)</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:
    - One inhaled corticosteroid
    - One inhaled beta2 agonist
    - One inhaled mast cell stabilizer
    - One oral albuterol product
    - One oral theophylline containing product
    - Dulera
    - Symbicort
    - 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:
    - One inhaled corticosteroid
    - One inhaled beta2 agonist
    - One inhaled mast cell stabilizer
    - One oral albuterol product
    - One oral theophylline containing product
    - Symbicort
    - Dulera
    - 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 (Airduo™ Generic) is 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:
    - One inhaled corticosteroid
    - One inhaled beta2 agonist
    - One inhaled mast cell stabilizer
    - One oral albuterol product
    - One oral theophylline containing product
    - Dulera
    - Symbicort
    - 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 Diskus® (Fluticasone/Salmeterol), Advair® HFA (Fluticasone/Salmeterol), Fluticasone/Salmeterol (Advair Diskus® Authorized Generic [AG]), Wixela Inhub (Fluticasone/Salmeterol -Advair Diskus® Generic) or Airduo™ (Fluticasone/Salmeterol) are covered when the following criteria are met:

- The patient has a physician documented diagnosis of asthma (Advair, AirDuo, Advair Diskus® Authorized Generic [AG], Wixela Inhub [Fluticasone/Salmeterol -Advair Diskus® Generic]) or COPD*# (Advair, Advair Diskus® Authorized Generic [AG], Wixela Inhub [Fluticasone/Salmeterol -Advair Diskus® Generic])
- 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 mast cell stabilizer
  - One oral albuterol product
  - One oral theophylline containing product

AND
- There is a BCBSMA paid claim(s) for Dulera® (mometasone/formoterol) AND Symbicort® (Budesonide/Formoterol)

*# COPD Diagnosis does NOT need to try both Dulera® (mometasone/formoterol) AND Symbicort® (Budesonide/Formoterol) as Dulera® is not FDA approved for COPD.

Breo Ellipta® (fluticasone/vilanterol) 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 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) AND OR Symbicort® (Budesonide/Formoterol) AND OR Fluticasone/Salmeterol by the patient** ]

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

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)
  - Tudorza® (aclidinium bromide)

**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
Managed Care Authorization Instructions
- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale.
  Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com.

PPO and Indemnity Authorization Instructions
- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale.
  Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<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>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™, Stiolt® 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 Inruse™ Ellipta® to step 3.</td>
</tr>
<tr>
<td>8/2015</td>
<td>Added Stiolt® 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>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>
</tbody>
</table>
No changes to policy statements.

1/2010 Updated to change coverage criteria for Advair® Diskus and Advair® HFA.

9/2009 Policy updated to change 180 day look back period to 130 days, remove Medicare Part D criteria from Medical Policy and update sample language.


1/2008 Updated include prior authorization requirements for Advair Diskus®, Advair® HFA and Symbicort.


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: http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf