



# MASSACHUSETTS

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## 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.

| Drug   | Formulary Information |
|--|-----------------------|
|  | Standard              |
|  | Formulary Status      |
| <b>Advair Diskus®</b> (Fluticasone/Salmeterol)                         | PA Required           |
| <b>Advair® HFA</b> (Fluticasone/Salmeterol)                            | PA Required           |
| <b>Airduo™</b> (Fluticasone/Salmeterol)                                | PA Required           |
| <b>Breo Ellipta®**</b> (fluticasone /vilanterol)                       | PA Required           |
| <b>Dulera®</b> (mometasone/formoterol)                                 | PA Required           |
| <b>Fluticasone/Salmeterol</b> (Airduo™ Generic)                        | PA Required           |
| <b>Fluticasone/Salmeterol</b> (Advair Diskus® Authorized Generic [AG]) | PA Required           |
| <b>Incruse™ Ellipta®</b> (umeclidinium)                                | PA Required           |

|  |             |
|--|-------------|
| <b>Symbicort®</b> (Budesonide/Formoterol)    | PA Required |
| <b>Wixela Inhub</b> (Fluticasone/Salmeterol) | PA Required |

\*\*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 claims of **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

| Date           | Action  |
|----------------|---|
| 3/2019         | Updated to include Wixela Inhub & the AG to Advair Discus as Preferred and PA required.   |
| 1/2019         | Updated to add Breo Ellipta™ back into the policy and it is still non covered medication.   |
| 1/2018         | Updated to Include <b>Fluticasone/Salmeterol, AirDuo™</b> and to modify <b>Advair®/ AirDuo™</b> Criteria.   |
| 6/2017         | Updated address for Pharmacy Operations.  |
| 9/2016         | Updated to remove Step from policy. This resulted in the removal of Singulair®, Anoro™ Ellipta™, Stiolto™ Respimat® and Breo™ Ellipta™ from the policy.   |
| 6/2016         | Updated to add Seebri™ Neohaler® and Utibron™ Neohaler® to step 3.  |
| 12/2015        | Updated by adding Incruse™ Ellipta® to step 3.  |
| 8/2015         | Added Stiolto™ Respimat® to step 3 & removed Zylflo & Accolate from policy.   |
| 7/2015         | Added new indication for Breo™ Ellipta™   |
| 10/2014        | Added Anoro™ Ellipta™ to the policy.  |
| 4/2014         | Updated by moving montelukast & zafirlukast to Step 1 and Advair to step 3.   |
| 3/2014         | Added Breo™ Ellipta™ to the policy.   |
| 1/2014         | Updated ExpressPath language and remove Blue Value.   |
| 8/2012         | Updated to include coverage criteria for new generic montelukast.   |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates.<br>No changes to policy statements.  |
| 1/1/2012       | Updated to include coverage criteria for COPD diagnosis and to remove physician documented use criteria for requested medications.  |
| 5/2011         | Reviewed - Medical Policy Group - Pediatrics and Endocrinology.<br>No changes to policy statements.   |
| 3/2011         | Reviewed - Medical Policy Group - Allergy/Asthma/Immunology and ENT/Otolaryngology.<br>No changes to policy statements.   |
| 1/2011         | Updated to include coverage criteria for new generic zafirlukast.   |
| 1/1/2011       | Updated coverage criteria to require previous use of one inhaled corticosteroid, one inhaled beta <sub>2</sub> 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. |
| 11/2010        | Updated to include coverage criteria of new FDA approved medication Dulera®.  |
| 5/2010         | Reviewed - Medical Policy Group - Pediatrics.<br>No changes to policy statements.   |
| 3/2010         | Reviewed - Medical Policy Group - Pulmonology, Allergy and ENT/Otolaryngology.  |

|        |  |
|--------|--|
|        | 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. |
| 5/2008 | Reviewed - Medical Policy Group - Pediatrics.<br>No changes to policy statements.  |
| 3/2008 | Reviewed - Medical Policy Group - Pulmonology, Allergy and ENT/Otolaryngology.<br>No changes to policy statements.                             |
| 1/2008 | Updated include prior authorization requirements for Advair Diskus®, Advair® HFA and Symbicort.  |
| 5/2007 | Reviewed - Medical Policy Group - Pediatrics.<br>No changes to policy statements.  |
| 3/2007 | Reviewed - Medical Policy Group - Pulmonology, Allergy and ENT/Otolaryngology.<br>No changes to policy statements.                             |
| 2/2003 | New policy, effective 2/2003, describing covered and non-covered indications.  |

## References

- Palmer LJ, Silverman ES, Weiss ST, Drazen JM. Pharmacogenetics of asthma. *Am J Respir Crit Care Med* 2002; 165:861-866.
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- Drazen JM, Israel E, O'Byrne PM. Treatment of asthma with drugs modifying the leukotriene pathway. *N Engl J Med* 1999; 340:197-206.
- Curr Opin Allergy Clin Immunol* 2(5):395-401, 2002. © 2002 Lippincott Williams & Wilkins.
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- National Asthma Education and Prevention Program Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma 1997. Located at: <http://www.nhlbi.nih.gov/guidelines/asthma/index.htm>. Accessed on: 11/3/2005.
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- Breo™ Ellipta™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2013.
- Anoro™ Ellipta™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2014.
- Stiolto™ Respimat® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharm., Inc.; 2015.
- Incruse™ Ellipta® [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June 2014.
- Utibron™ Neohaler® [package insert]. East Hanover, NJ: Novartis; Jan 2016.
- Seebri™ Neohaler® [package insert]. East Hanover, NJ: Novartis; Jan 2016.
- AirDuo™ [package insert]. Jerusalem, Israel: Teva Respiratory, LLC; June 2017.
- Fluticasone/salmeterol [package insert]. Jerusalem, Israel: Teva Respiratory, LLC; June 2017.

## Endnotes

- Based upon the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 10/2002.
- Based upon the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 9/2007.
- 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](http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf)