MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

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. 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
Advair Diskus® (Fluticasone/Salmeterol)	PA Required
Advair® HFA (Fluticasone/Salmeterol)	PA Required
Airduo™ (Fluticasone/Salmeterol)	PA Required
Breo Ellipta®** (fluticasone /vilanterol)	PA Required
Budesonide / Formoterol**	PA Required
Dulera® (mometasone/formoterol)	PA Required
Fluticasone/Salmeterol (AirDuo™ Generic)	PA Required
Fluticasone/Salmeterol (Advair Diskus® Authorized Generic [AG])	PA Required
Incruse™ Ellipta® (umeclidinium)	PA Required

Symbicort® (Budesonide/Formoterol)	PA Required
Wixela Inhub (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)**, AirDuo™** (Fluticasone/Salmeterol) **OR Budesonide / Formoterol**** aerosol 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], **Budesonide / Formoterol****) or COPD*# (Advair, Advair Diskus® Authorized Generic [AG], Wixela Inhub [Fluticasone/Salmeterol **-**Advair Diskus® Generic], **Budesonide / Formoterol****)
- 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),**OR Symbicort®** (Budesonide/Formoterol), **OR Fluticasone/Salmeterol (**AirDuo™ Generic)) by the patient**]

*# 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), **Symbicort®** (Budesonide/Formoterol), **OR Fluticasone/Salmeterol (**AirDuo™ Generic) 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)

**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:

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.

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.

Policy History

Date	Action
6/2020	Updated to add AG of Symbicort to the policy as non-covered.
1/2020	Updated criteria for Incruse™ Ellipta® and clarify criteria for non-preferred.
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 **Fluticasone/Salmeterol**, **AirDuo™** and to modify **Advair®/ AirDuo™** 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 Zyflo & 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. 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. No changes to policy statements.
3/2011	Reviewed - Medical Policy Group - Allergy/Asthma/Immunology and ENT/Otolaryngology. 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$_2$ 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. 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. No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Pulmonology, Allergy and ENT/Otolaryngology. 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. No changes to policy statements.
3/2007	Reviewed - Medical Policy Group - Pulmonology, Allergy and ENT/Otolaryngology. No changes to policy statements.
2/2003	New policy, effective 2/2003, describing covered and non-covered indications.

References

1. Palmer LJ, Silverman ES, Weiss ST, Drazen JM. Pharmacogenetics of asthma. Am J Respir Crit Care Med 2002; 165:861-866.
2. Krawiec, ME., Jarjour,NJ, Leukotriene Receptor Antagonists 95(7):775-779, 2002. © 2002 Southern Medical Association.
3. Drazen JM, Israel E, O'Byrne PM. Treatment of asthma with drugs modifying the leukotriene pathway. N Engl J Med 1999; 340:197-206.
4. Curr Opin Allergy Clin Immunol 2(5):395-401, 2002. © 2002 Lippincott Williams & Wilkins.
5. Semin Respir Crit Care Med 23(4):399-410, 2002. © 2002 Thieme Medical Publishers.
6. 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.
7. National Asthma Education and Prevention Program Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma—Update on Selected Topics 2002. Located at: http://www.nhlbi.nih.gov/guidelines/asthma/index.htm. Accessed on: 11/3/2005.
8. Breo™ Ellipta™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2013.
9. Anoro™ Ellipta™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2014.
10. Stiolto™ Respimat® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharm., Inc.; 2015.
11. Incruse™ Ellipta® [package insert]. Research Triangle Park, NC: GlaxoSmithKline; June 2014.
12. Utibron™ Neohaler® [package insert]. East Hanover, NJ: Novartis; Jan 2016.
13. Seebri™ Neohaler® [package insert]. East Hanover, NJ: Novartis; Jan 2016.
14. AirDuo™ [package insert]. Jerusalem, Israel: Teva Respiratory, LLC; June 2017.
15. Fluticasone/salmeterol [package insert]. Jerusalem, Israel: Teva Respiratory, LLC; June 2017.

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.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf