MASSACHUSETTS

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Pharmacy Medical Policy

Asthma and Chronic Obstructive Pulmonary Disease Medication Management

Table of Contents

Policy Number: 011

BCBSA Reference Number: N/A

Related Policies

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

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**7/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers 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 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** 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 **Policy does NOT apply to**: • Medicare Advantage			

Summary

Asthma and chronic obstructive pulmonary disease (COPD) are both common inflammatory airway diseases. Even though distinct disorders, about 20 percent of patients with obstructive lung disease have features of both. When this overlap is suspected, diagnosis is based on symptoms and assessment of lung function and airway inflammation.

Asthma is commonly diagnosed in childhood when symptoms such chest tightness, cough, wheezing, and breathlessness are present typically with variability from day to day but worse at night and early morning.

Other allergic conditions such as rhinitis and eczema may be present. COPD is however typically diagnosed in middle to older aged adults and is characterized by dyspnea that worsens with exercise or exertion and progresses over time. A history of recurrent infections, intermittent cough with our without sputum production and wheezing may also be present.

The following is a comprehensive policy covering prior authorization and quantity limit requirements for inhaled medications used for the treatment of Asthma and/or chronic obstructive pulmonary disease (COPD).

Policy

No Requirements

BCBSMA formulary coverage options for inhalers, include, but may not be limited to:

- Albuterol HFA (Proair and Proventil generics)
- Anoro Ellipta
- Arnuity Ellipta
- fluticasone propionate
- Perforomist
- Proair
- Pulmicort
- Qvar
- Serevent
- Spiriva

Prior Authorization Criteria

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorizations requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Formulary status/requirements of the medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Anoro Ellipta	Covered	Covered with no PA requirements
Albuterol HFA (Proair and Proventil generics)	Covered, QCD	
Arnuity Ellipta		
Breyna		
budesonide / formoterol		
Fluticasone Diskus or HFA		
Perforomist		
Proair		
Pulmicort		
Qvar		
Serevent		
Spiriva		
Advair Diskus ® (Fluticasone/Salmeterol)	Covered, PA, QCD	PA required. See below for criteria.
Advair ® HFA (Fluticasone/Salmeterol)		
Breztri ™ (budesonide/glycopyrrolate/formoterol)		
Dulera ® (mometasone/formoterol)		
Fluticasone/Salmeterol		
Incruse ™ Ellipta ® (umeclidinium)		
Trelegy Ellipta ® (fluticasone/umeclidinium/vilanterol)		

Wixela Inhub ® (Fluticasone/Salmeterol)	Covered, PA, QCD - Continued	PA required. See below for criteria.
AirDuo ™ (Fluticasone/Salmeterol)	NFNC, PA, QCD	
Breo Ellipta ® (fluticasone /vilanterol)		
Fluticasone /Vilanterol Inhaler (Breo Ellipta ® Authorized Generic [AG])		
Symbicort ® (Budesonide/Formoterol)		

PA – Prior Authorization; QCD – Quality Care Dosing (refer to policy #621b); NFNC – Non-formulary, non-covered

Dulera

Dulera ® may be considered **MEDICALLY NECESSARY** and covered when ONE (1) of the following criteria is met:

1. A documented diagnosis of Asthma, **OR**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications:
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product
    - Dulera
    - Breyna
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub)

Fluticasone/Salmeterol (all generics) and Wixela Inhub®

Fluticasone/Salmeterol and **Wixela Inhub** may be considered **MEDICALLY NECESSARY** and covered when ONE (1) of the following criteria is met:

1. A documented diagnosis of Asthma or COPD, **OR**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications:
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product.
    - Dulera
    - Breyna
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub)

Advair ® HFA or AirDuo™

Advair HFA, or AirDuo may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of ASTHMA**, AND**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications,
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product, **AND**
3. Claim history or prescriber documentation of previous use of TWO (2) of the following medications:
    - Dulera (mometasone/formoterol)
    - Breyna (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub)

Advair Diskus ® Symbicort ®

Advair Diskus, Symbicort (Budesonide/Formoterol) may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of Asthma or COPD**, AND**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications:
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product, **AND**
3. Claim history, or prescriber documentation of previous use of, TWO (2) of the following medications:
    - Breyna (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub)

Breo Ellipta ® or fluticasone /vilanterol Inhaler (Authorized Generic)

Breo Ellipta or **fluticasone /vilanterol Inhaler** (Authorized Generic) may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of Asthma or COPD**, AND**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications**:**
    - Inhaled corticosteroid
    - Inhaled beta2 agonist

- Inhaled mast cell stabilizer
- Inhaled anticholinergic
- Oral albuterol product
- Oral theophylline containing product, **AND**

3. For diagnosis of Asthma, claim history or prescriber documentation of previous use of TWO (2) of the following medications.
    - Dulera (mometasone/formoterol)
    - Breyna (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub), **OR**
4. For diagnosis of COPD, claim history or prescriber documentation of previous use of ONE (1) of the following:
    - Breyna (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Fluticasone/Salmeterol (Most generics, including Wixela Inhub, but excluding AirDuo generics)

Breztri ™

Breztri may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of COPD; **AND**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications**:**
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product.
    - Inhaled Corticosteroid /Long-acting Beta agonist
    - Long-acting muscarinic antagonist -containing product.
    - Long-acting Beta agonist -containing product, **AND**
3. Claim history or prescriber documentation of previous use of ONE (1) of the following medications:
    - Breyna (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Anoro Ellipta (umeclidinium bromide and vilanterol trifenatate)
    - Stiolto (tiotropium bromide and olodaterol
    - Fluticasone/Salmeterol (Most generics, including Wixela Inhub, but excluding AirDuo generics)

Incruse ™ Ellipta ®

Incruse Ellipta may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of COPD**, AND**
2. Claim history or prescriber documentation of previous use of Spiriva (tiotropium bromide).

Trelegy Ellipta ®

Trelegy Ellipta may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. A documented diagnosis of Asthma **OR** COPD, **AND**
2. Claim history or prescriber documentation of previous use of ONE (1) of the following medications:
    - Inhaled corticosteroid
    - Inhaled beta2 agonist
    - Inhaled mast cell stabilizer
    - Inhaled anticholinergic
    - Oral albuterol product
    - Oral theophylline containing product.
    - Inhaled Corticosteroid /Long-acting Beta agonist
    - Long-acting muscarinic antagonist -containing product.
    - Long-acting Beta agonist -containing product,

    AND
3. Claim history or prescriber documentation of previous use of ONE (1) of the following medications :
    - Breyna ™ (Budesonide/Formoterol)
    - Budesonide / Formoterol
    - Dulera ® (mometasone/formoterol)
    - Fluticasone/Salmeterol (all generics, including Wixela Inhub ®)
    - Anoro Ellipta (umeclidinium bromide and vilanterol Trifenatate
    - Stiolto (tiotropium bromide and olodaterol)

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications, history of adverse effects, expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements,
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable,
- Clinical literature from reputable peer reviewed journals,
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®, and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

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

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
7/2024	Update to remove Prior authorization of Breyna and other generics of Budesonide / Formoterol.
4/2024	Require Diagnosis for Trelegy and Breztri to align with rest of the Policy.
2/2024	Updated to add Fluticasone/Salmeterol to COPD part of Breo Ellipta's Criteria and to other drugs where it was missing.
1/2024	Updated to move Symbicort to Non-formulary Non-Covered in the policy.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A. Updated to include summary of COPD, Asthma, and drugs with no coverage requirements. Added Breyna to the policy with UM criteria like Symbicort.
7/2023	Updated to move Wixela with the other Advair Generics.
4/2023	Updated to add generic Advair AG to same criteria as AirDuo Generic.
8/2022	Updated to add fluticasone /vilanterol Inhaler (Breo Ellipta ®** Authorized Generic [AG]) to the policy.
7/2022	Clarified coding for non-preferred medications for Asthma vs COPD.
2/2022	Updated to add an additional option in criteria and add additional options to allow approval for the triple inhalers at the request of P & T.
1/2022	Updated to add Trelegy Ellipta® & Breztri™ to the policy.
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.

Forms

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

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. McDonald VM, Gibson PG. "To define is to limit": perspectives on Asthma-COPD overlap syndrome and personalized medicine. *Eur Respir J* 2017,49:1700336
2. Gibson PG, McDonald VM. Asthma-COPD overlap 2015: now we are six. *Thorax* 2015,70:683-91

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

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