UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for ICS.LABA Combination Products

Program	Prior Authorization
Medication	Dulera (mometasone/formoterol), Breo Ellipta (fluticasone/vilanterol), Advair Diskus (fluticasone/salmeterol), Advair HFA (fluticasone/salmeterol), Symbicort (budesonide/formoterol), fluticasone/salmeterol (authorized generic of AirDuo), Airduo (fluticasone/salmeterol)
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Formulary Status

Preferred Products	**Non-preferred Products**
Breo Ellipta (fluticasone/vilanterol)* fluticasone/salmeterol (authorized generic of AirDuo)	Advair Diskus (fluticasone/salmeterol) Advair HFA (fluticasone/salmeterol) Symbicort (budesonide/formoterol) AirDuo (fluticasone/salmeterol) Dulera (mometasone/formoterol)

*Breo Ellipta is available with a step through an inhaled corticosteroid

FDA Approved Indications

1. **Asthma**

   Advair, Dulera, Symbicort, Breo Ellipta, AirDuo, fluticasone/salmeterol (authorized generic of AirDuo)

2. **Chronic Obstructive Pulmonary Disease (COPD)**

   Advair, Symbicort, Breo Ellipta

NOTE: This policy does not apply to Washington, please refer to global criteria.

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2. Coverage Criteria:

A. <u>Authorization Criteria</u>

1. <u>Asthma</u>

a. **Breo Ellipta** will be approved for patients based on the following criteria:

(1) Diagnosis of severe persistent asthma

-OR-

(2) **<u>Both</u>** of the following:

i. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an inhaled corticosteroid (e.g. Arnuity Ellipta, Flovent, Qvar, Asmanex, Pulmicort)

-AND-

ii. Diagnosis of asthma

2. <u>COPD</u>

a. **Breo Ellipta** will be approved for patients based on the following criteria:

(1) Diagnosis of COPD

-AND-

(2) **<u>One</u>** of the following:

i. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of a long-acting beta-agonist (e.g. Foradil, Serevent, Striverdi, Arcapta).

-OR-

ii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza, Incruse Ellipta).

-OR-

iii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/ long-acting beta-agonist combination agent (e.g. Anoro Ellipta, Stiolto Respimat).

Authorization will issued for 12 months.

B. Non-Preferred Agents: Advair

a. **Advair** will be approved for patients based one of the following:

(1) **All** of the following:

(a) Diagnosis of **asthma**

-AND-

(b) History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an inhaled corticosteroid (e.g. Arnuity Ellipta, Flovent, Qvar, Asmanex, Pulmicort)

-AND-

(c) History of failure, contraindication, or intolerance to treatment with **both** of the following preferred products:

- Breo Ellipta
- Fluticasone/salmeterol (authorized generic of AirDuo)

-OR-

(2) **All** of the following:

(a) Diagnosis of **COPD**

-AND-

(b) **One** of the following:

i. History of failure, contraindication, or intolerance to treatment with at least a 30 daytrial of a long-acting beta-agonist (e.g. Foradil, Serevent, Striverdi, Arcapta).

-OR-

ii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza, Incruse Ellipta).

-OR-

iii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/ long-acting beta-agonist combination agent (e.g. Anoro Ellipta, Stiolto Respimat).

-AND-

(c) History of failure, contraindication, or intolerance to treatment with the following preferred product:

- Breo Ellipta

Authorization will issued for 12 months.

C. Non-Preferred Agents: Symbicort

1. **One** of the following:

a. The patient is **12 years of age and older** based on the following criteria:

(1) All of the following:

(a) Diagnosis of **asthma**

-AND-

(b) History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an inhaled corticosteroid (e.g. Arnuity Ellipta, Flovent, Qvar, Asmanex, Pulmicort)

-AND-

(c) History of failure, contraindication, or intolerance to treatment with **both** of the following preferred products:

- Breo Ellipta
- Fluticasone/salmeterol (authorized generic of AirDuo)

-OR-

(2) All of the following:

(a) Diagnosis of **COPD**

-AND-

(b) **One** of the following:

i. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of a long-acting beta-agonist (e.g. Foradil, Serevent, Striverdi, Arcapta).

-OR-

ii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent (e.g. Spiriva, Atrovent, Combivent, Tudorza, Incruse Ellipta).

-OR-

iii. History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an orally inhaled anticholinergic agent/ long-acting beta-agonist combination agent (e.g. Anoro Ellipta, Stiolto Respimat).

-AND-

(c) History of failure, contraindication, or intolerance to treatment with the following preferred product

- Breo Ellipta

-OR-

b. The patient is **less than 12 years of age** and meets **both** of the following:

(1) Diagnosis of **asthma**

-AND-

(2) History of failure, contraindication, or intolerance to at least a 30 day

trial of an inhaled corticosteroid (e.g. Arnuity Ellipta, Flovent, Qvar, Asmanex, Pulmicort).

Authorization will issued for 12 months.

D. Non-Preferred Agents: AirDuo and Dulera

a. **AirDuo or Dulera** will be approved for patients based on the following criteria:

(1) Diagnosis of **asthma**

-AND-

(2) History of failure, contraindication, or intolerance to treatment with at least a 30 day trial of an inhaled corticosteroid (e.g. Arnuity Ellipta, Flovent, Qvar, Asmanex, Pulmicort)

-AND-

(3) History of failure, contraindication, or intolerance to treatment with **both** of the following preferred products:

- Breo Ellipta
- fluticasone/salmeterol (authorized generic of AirDuo)

Authorization will issued for 12 months.

3. References:

1. Advair Prescribing Information. GlaxoSmithKline, February 2017.
2. Dulera Prescribing Information. Merck & Co, June 2017.
3. Symbicort Prescribing Information. AstraZeneca, January 2017.
4. Breo Ellipta Prescribing Information. GlaxoSmithKline, May 2017.
5. Snow V, Lascher S, Mottur-Pilson C. Evidence base for management of acute exacerbations of chronic obstructive pulmonary disease. *Ann Intern Med* 2001; 134(7):595-9.
6. National Heart, Lung, and Blood Institute (NHLBI). National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3: Guidelines for diagnosis and management of asthma. U.S Department of Health and Human Services. Full report August 28, 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asth.
7. Global Initiative for Asthma (GINA). National Heart, Lung, and Blood Institute (NHLBI). Global strategy for asthma management and prevention 2006.

8. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy For The Diagnosis, Management, And Prevention of Chronic Obstructive Pulmonary Disease (Updated 2014).
9. Veterans Health Administration, Department of Defense. Va/DoD Clinical Practice Guideline. The pharmacologic management of chronic obstructive pulmonary disease. Washington, DC: Veterans Health Administration, Department of Veterans Affairs 2002.
10. AirDuo Prescribing Information. Teva Respiratory, January 2017.

Program	Prior Authorization
Change Control	
Date	Change
6/2009	Criteria taken from previously approved Unison policy, RX12 Advair/Symbicort. Added prerequisite agents for COPD. Added diagnosis of severe persistent asthma to approval criteria. Policy reformatted.
9/2010	Symbicort removed from policy. Dulera added to criteria for asthma.
6/2011	Annual Review
6/2012	Symbicort added to policy for both Asthma and COPD.
12/2013	Breo Ellipta added to policy for COPD indication.
2/2013	Changed COPD criteria from requiring a trial of an anticholinergic and a long acting beta agonist to require a trial of an anticholinergic or a long acting beta agonist.
7/2015	Advair and Symbicort moved from preferred to non-preferred. Advair and Symbicort were removed from the automated step therapy criteria as they are now non-preferred. Automated COPD Criteria Section [III.A.2.a.(3)]: Added a third class of drugs (LAMA/LABA Combination) that the step therapy criteria will look for in the drug fill history. Non-Automated Criteria Section (III.B): Advair and Symbicort were removed from the criteria as they are now non-preferred. Non-Automated Criteria Section for Asthma (III.B.1): Combined requirements (2), (3), and (4) into a single requirement at (2). Non-Automated Criteria Section for COPD (III.B.2): Added a third class of drugs (LAMA/LABA Combination) that will

	qualify as prerequisite therapy. New Section Added: Section III.C for Non-Preferred drugs Advair and Symbicort. Examples of drugs in each class has been updated throughout the criteria.
11/2016	Updated policy template. Added authorization durations of 12 months to each section.
6/2017	Updated background. Added fluticasone/salmeterol (authorized generic of AirDuo) and AirDuo to the policy. Moved the automated step therapy section to the background section of the policy. Updated step therapy drugs for Advair and Symbicort based on the patient's diagnosis.
9/2017	Updated criteria to reflect that Dulera is being moved to a non-preferred status and fluticasone/salmeterol (authorized generic of AirDuo) is available without a step through an inhaled corticosteroid. Updated references.
10/2017	Added Symbicort as a preferred product for patients under the age of 12 years with asthma.
12/2017	Removed automated step therapy language from background.
3/2018	Added prerequisite requirements into the non-preferred sections. Changed step therapy lookback to 30 days for all drugs.