UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for ICS.LABA Combination Products -ARIZONA

Program	Prior Authorization
Medication	Dulera (mometasone/formoterol), Breo Ellipta (fluticasone/vilanterol), Advair Diskus (fluticasone/salmeterol), Advair HFA (fluticasone/salmeterol), Symbicort (budesonide/formoterol)
Markets in Scope	Arizona

1. Background:

Formulary Status

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

FDA Approved Indications

1. **Asthma**

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

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

Advair Diskus, Symbicort, Breo Ellipta

2. Coverage Criteria:

A. Authorization Criteria

1. **Asthma**

a. **Advair Diskus, Advair HFA, Dulera, or Symbicort** will be approved for patients based on the following criteria:

(1) Diagnosis of severe persistent asthma

-AND-

(2) The patient has a history of failure, contraindication, or intolerance to treatment with at least a 30 day trial of **one** of the following:

- Beclomethasone dipropionatte (Qvar)
- Budesonide (Pulmicort)
- Fluticasone propionate (Flovent HFA)

- Mometasone (Asmanex Twisthaler)

-AND-

(3) If the claim is for Advair HFA the patient must be 4 to 12 years of age.

2. COPD

a. **Advair Diskus or Symbicort** will be approved for patients based on the following criteria:

(1) Diagnosis of COPD

-AND-

(2) **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).

Authorization will issued for 12 months.

B. Non-Preferred Agents: Breo Ellipta

a. **Breo Ellipta** will be approved for patients when the following circumstances are met:

(1) All of the following:
i. Diagnosis of **asthma**

-AND-

ii. 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)

iii. The patient has a history of failure, contraindication, or intolerance to treatment with **all** of the following preferred products

- Advair Diskus or Advair HFA
- Dulera
- Symbicort

-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) The patient has a history of failure, contraindication, or intolerance to treatment with **both** of the following preferred products:

- Advair Diskus
- Symbicort

Authorization will issued for 12 months.

C. Non-Preferred Agents: Airduo, fluticasone/salmeterol (authorizaed generic of Airduo)

a. **AirDuo or fluticasone/salmeterol (authorized generic of Airduo)** 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 **three** of the following preferred products:

- Advair Diskus (fluticasone/salmeterol)/Advair HFA (fluticasone/salmeterol)
- Dulera (mometasone/formoterol)
- Symbicort (budesonide/formoterol)

Authorization will issued for 12 months.

3. References:

1. Advair Prescribing Information. GlaxoSmithKline, September 2011.
2. Dulera Prescribing Information. Merck & Co, March 2012.
3. Symbicort Prescribing Information. AstraZeneca, June 2010.
4. Breo Ellipta Prescribing Information. GlaxoSmithKline, May 2013.
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.

Change Control	
Date	Change
August 2017	New policy specific to Arizona. Different preferred products.
3/2018	Added prerequisite requirements into the non-preferred sections. Changed step therapy lookback to 30 days for all drugs.