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), Wixela Inhub (generic for Advair Diskus), fluticasone propionate/salmeterol diskus (generic for Advair Diskus), budesonide/formoterol (authorized generic of Symbicort)
Markets in Scope	Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Formulary Status

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

FDA Approved Indications

A. Asthma

Advair HFA/Diskus, Dulera, Symbicort, Breo Ellipta, AirDuo, fluticasone/salmeterol (authorized generic of AirDuo), fluticasone/salmeterol (generic for Advair Diskus), Wixela Inhub, budesonide/formoterol (authorized generic of Symbicort)

B. Chronic Obstructive Pulmonary Disease (COPD)

Advair Diskus, Symbicort, Breo Ellipta, fluticasone/salmeterol (generic for Advair Diskus), Wixela Inhub, budesonide/formoterol (authorized generic of Symbicort)

2. Coverage Criteria:

A. <u>Preferred Agents: fluticasone propionate/salmeterol diskus (generic for Advair Diskus) and Wixela Inhub (generic for Advair Diskus)</u>

a. **fluticasone propionate/salmeterol diskus (generic for Advair Diskus) and Wixela Inhub (generic for Advair Diskus)** will be approved for patients based on **<u>one</u>** of the following:

(1) Diagnosis of COPD

-OR-

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

(a) Diagnosis of asthma

-AND-

(b) History of failure, contraindication, or intolerance to treatment with fluticasone/salmeterol (authorized generic of AirDuo)

Authorization will be issued for 12 months.

B. <u>Non-Preferred Agents: Advair HFA, Dulera, and AirDuo (BRAND NECESSARY REQUESTS)</u>

a. **Advair HFA, Dulera, or AirDuo (BRAND NECESSARY)** will be approved for patients based on the following:

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

(a) Diagnosis of asthma

-AND-

(b) **<u>Both</u>** of the following:
(i) History of failure, contraindication, or intolerance to

fluticasone/salmeterol (authorized generic of AirDuo)

-AND-

(ii) History of failure, contraindication, or intolerance to **one** of the following:
- fluticasone propionate/salmeterol diskus (generic for Advair Diskus)
- Wixela Inhub (generic for Advair Diskus)

Authorization will be issued for 12 months.

C. Non-Preferred Agents: Symbicort, budesonide/formoterol (authorized generic of Symbicort), and Advair Diskus (BRAND NECESSARY)

1. **One** of the following:

a. **All** of the following:

(1) Diagnosis of asthma

-AND-

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

(a) Patient is less than 12 years of age

-OR-

(b) **Both** of the following:
(i) History of failure, contraindication, or intolerance to fluticasone/salmeterol (authorized generic of AirDuo)

-AND-

(ii) History of failure, contraindication or intolerance to **one** of the following:
- fluticasone propionate/salmeterol diskus (generic for Advair Diskus)
- Wixela Inhub (generic for Advair Diskus)

-AND-

(3) If the request is for Symbicort (BRAND NECESSARY), history of

failure, contraindication or intolerance to budesonide/formoterol (authorized generic of Symbicort)

-OR-

b. **All** of the following:

(1) Diagnosis of COPD

-AND-

(2) History of failure, contraindication or intolerance to **one** of the following:
- fluticasone propionate/salmeterol diskus (generic for Advair Diskus)
- Wixela Inhub (generic for Advair Diskus)

-AND-

(3) If the request is for Symbicort (BRAND NECESSARY), history of failure, contraindication or intolerance to budesonide/formoterol (authorized generic of Symbicort)

Authorization will be issued for 12 months.

D. Non-Preferred Agents: Breo Ellipta

1. **One** of the following:

a. **All** of the following:

(1) Diagnosis of asthma

-AND-

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

(a) History of failure, contraindication, or intolerance to fluticasone/salmeterol (authorized generic of AirDuo)
NOTE: Previous authorization on file does not guarantee continued coverage. Documentation of failure, contraindication, or intolerance to preferred alternatives is required.

-AND-

(b) History of failure, contraindication or intolerance to **one** of the following:

- fluticasone propionate/salmeterol diskus (generic for Advair Diskus)
- Wixela Inhub (generic for Advair Diskus)

NOTE: Previous authorization on file does not guarantee continued coverage. Documentation of failure, contraindication, or intolerance to preferred alternatives is required.

-OR-

b. **Both** of the following:

(1) Diagnosis of COPD

-AND-

(2) History of failure, contraindication or intolerance to **one** of the following:

- fluticasone propionate/salmeterol diskus (generic for Advair Diskus)
- Wixela Inhub (generic for Advair Diskus)

NOTE: Previous authorization on file does not guarantee continued coverage. Documentation of failure, contraindication, or intolerance to preferred alternatives is required.

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Advair Diskus [package insert]. Research Triange Park, NC: GlaxoSmithKline; January 2019.
2. Advair HFA [package insert]. Research Triange Park, NC: GlaxoSmithKline; February 2019.

3. Dulera [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; August 2019.
4. Symbicort [package insert]. Wilmington, DE: AstraZeneca; July 2019.
5. Breo Ellipta [package insert]. Research Triange Park, NC: GlaxoSmithKline; January 2019.
6. AirDuo [package insert]. Parsippany, NJ: Teva Respiratory; February 2020.
7. Wixela Inhub [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2019.
8. Fluticasone propionate and salmeterol inhalation powder [package insert]. Parsippany, NJ: Teva Respiratory. February 2020.
9. Budesonide and formoterol fumarate dihydrate [package insert]. Wilmington, DE: AstraZeneca; July 2019.

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.
5/2018	Created a Symbicort/Advair Diskus section and an Advair HFA/AirDuo/Dulera section and broke each of these sections into indication then age(s). Updated step therapy language for Breo to allow for continuation of ongoing ICS/LABA therapy.
10/2018	Moved Breo Ellipta to a non-preferred status for 1/1/19.
7/2019	Added coverage for authorized generic Advair and Wixela Inhub. Updated references.
9/2019	Removed prerequisite criteria for treatment of asthma and COPD. Updated step therapy criteria for non-preferred drugs.

11/2019	Added an operational note to Breo section regarding continuation of ongoing therapy.
4/2020	Updated criteria to reflect that brand Symbicort requires a step through the authorized generic. Updated references.
6/2020	Updated criteria to remove step through authorized generic of AirDuo for COPD.