

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Non-Preferred Inhaled Corticosteroid (ICS)/Long-Acting Beta-2 Agonist (LABA) Combination Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medication	Comments	Quantity Limit
<b><u>For Asthma:</u></b> Breo Ellipta (fluticasone/vilanterol) fluticasone/salmeterol (generic AirDuo RespiClick)	Preferred	May be subject to quantity limit
<b><u>For COPD:</u></b> Breo Ellipta (fluticasone/vilanterol) 100 mcg/25 mcg	Preferred	
<b><u>For Asthma:</u></b> AirDuo RespiClick (fluticasone/salmeterol) Advair Diskus (fluticasone/salmeterol) Advair HFA (fluticasone/salmeterol) Dulera (mometasone/formoterol) Symbicort (budesonide/formoterol)	Non-Preferred	
<b><u>For COPD:</u></b> Advair Diskus (fluticasone/salmeterol) 250 mcg/50 mcg Symbicort (budesonide/formoterol) 160 mcg/4.5 mcg	Non-Preferred	

### **APPROVAL CRITERIA**

- I. Individual has been on the requested non-preferred agent in the past 180 days (medication samples/coupons/discount cards are excluded from consideration as a trial);

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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**OR**

II. Requests for an ICS/LABA combination agent for **asthma** may be approved if the following criteria are met:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one preferred ICS/LABA agent (preferred agents are Breo Ellipta and fluticasone/salmeterol) indicated for asthma;

**OR**

B. A metered dose inhaler (MDI)<sup>^</sup>, Advair HFA, Dulera, Symbicort, may be approved for individuals with a weak or ineffective inspiratory effort;

**OR**

C. A non-preferred agent may be approved if the preferred agent(s) are not acceptable due to concomitant clinical conditions, such as but not limited to the following:

1. If the preferred agent(s) are not indicated for the individual's age, may approve:
  - a. Advair Diskus for individuals age 4-17; **OR**
  - b. Symbicort for individuals age 6-17

**OR**

2. Individual has a known or suspected hypersensitivity to milk proteins\*.

III. Requests for a non-preferred ICS/LABA combination agent for **COPD** may be approved if the following criteria are met:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred ICS/LABA combination agent indicated for COPD: (preferred agent is Breo Ellipta 100mcg/25 mcg);

**OR**

B. Symbicort (metered dose inhaler [MDI]<sup>^</sup>) may be approved for individuals with a weak or ineffective inspiratory effort;

**OR**

C. The preferred agent, Breo Ellipta 100 mcg/25 mcg, cannot be utilized because the individual has a known or suspected hypersensitivity to milk proteins\*.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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**^Note:** MDI ICS/LABA agents indicated for asthma: Advair HFA, Dulera, and Symbicort.  
 DPI ICS/LABA agents indicated for asthma: Advair Diskus, AirDuo RespiClick, Breo Ellipta, and fluticasone/salmeterol.

**\*Note:** Agents inhaled utilizing a dry powder dose form (capsule, blister, inhaler) may contain lactose as an inactive ingredient. Individuals with a severe milk protein allergy should avoid use of these agents due to risk of anaphylactic reactions.

Lactose-containing ICS/LABA agents: Advair Diskus, Breo Ellipta, AirDuo RespiClick, fluticasone/salmeterol.

Lactose-free ICS/LABA agents: Advair HFA, Dulera, and Symbicort.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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