

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	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
<u>For Asthma:</u> Breo Ellipta (fluticasone/vilanterol) fluticasone/salmeterol (generic AirDuo RespiClick) Wixela Inhub (fluticasone/salmeterol) Authorized Generic Advair Diskus (fluticasone/salmeterol)	Preferred	May be subject to quantity limit
<u>For COPD:</u> Breo Ellipta (fluticasone/vilanterol) 100 mcg/25 mcg Wixela Inhub (fluticasone/salmeterol) 250 mcg/50 mcg Authorized Generic Advair Diskus (fluticasone/salmeterol) 250 mcg/50 mcg	Preferred	
<u>For Asthma:</u> AirDuo RespiClick (fluticasone/salmeterol) Advair HFA (fluticasone/salmeterol) Dulera (mometasone/formoterol) Symbicort (budesonide/formoterol)	Non-Preferred	
<u>For COPD:</u> Symbicort (budesonide/formoterol) 160 mcg/4.5 mcg	Non-Preferred	

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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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);

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, fluticasone/salmeterol (generic AirDuo Respiclick), Wixela Inhub (fluticasone/salmeterol), Authorized Generic Advair Diskus (fluticasone/salmeterol)] indicated for asthma;

OR

B. A metered dose inhaler (MDI)[^], 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. 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 agents are Breo Ellipta 100mcg/25 mcg, Wixela Inhub (fluticasone/salmeterol) 250 mcg/50 mcg Authorized Generic Advair Diskus (fluticasone/salmeterol) 250 mcg/50 mcg);

OR

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

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OR

- C. The preferred agents, Breo Ellipta 100 mcg/25 mcg, Wixela Inhub (fluticasone/salmeterol) 250 mcg/50 mcg, Authorized Generic Advair Diskus (fluticasone/salmeterol) 250 mcg/50 mcg cannot be utilized because the individual has a known or suspected hypersensitivity to milk proteins*.

^Note: MDI ICS/LABA agents indicated for asthma: Advair HFA, Dulera, and Symbicort.
 DPI ICS/LABA agents indicated for asthma: Wixela Inhub, Authorized Generic 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: Wixela Inhub, Authorized Generic 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.

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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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