

## Clinical Policy: Fluticasone/Salmeterol (Advair Diskus, Advair HFA)

Reference Number: PA.CP.PMN.31

Effective Date: 01/18

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

### Description

Fluticasone/salmeterol (Advair Diskus<sup>®</sup>, Advair HFA<sup>®</sup>) is a combination product containing a corticosteroid and long acting beta-2 agonist.

### FDA approved indication

Advair Diskus/HFA is indicated:

- For the treatment of asthma in patients aged 4 years and older (Diskus) or 12 years and older (HFA)
- For the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (Diskus only)

Limitation of use: Advair Diskus/HFA is not indicated for relief of acute bronchospasm.

### Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> that Advair Diskus/HFA is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Asthma (must meet all):

1. Diagnosis of asthma;
2. Member meets one of the following (a, b, or c):
  - a. Age between 4 to 5 years, and request is for Advair Diskus;
  - b. Age between 6 to 11 years, and failure of Symbicort at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - c. Age  $\geq$  12 years, and failure of Dulera and Symbicort at up to maximally indicated doses with pharmacy claims record supporting the use of either agent in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed:
  - a. Advair Diskus: 2 inhalations/day (60 blisters every 30 days);
  - b. Advair HFA: 4 inhalations/day (1 inhaler every 30 days).

**Approval duration: 12 months**

##### B. Chronic Obstructive Pulmonary Disease (must meet all):

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1. Diagnosis of COPD;
2. Request is for Advair Diskus;
3. Failure of Symbicort at up to maximally indicated doses with pharmacy claims record supporting use in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 2 inhalations/day (60 blisters every 30 days).

**Approval duration: 12 months**

**C. Other diagnoses/indications**

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. All Indications** (must meet all):

1. Previously authorized (by prior authorization) to receive Advair Diskus/HFA via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; **or the Continuity of Care policy (PA.LTSS.PA.01) applies;**
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed:
  - a. Advair Diskus: 2 inhalations/day (60 blisters every 30 days);
  - b. Advair HFA: 4 inhalations/day (1 inhaler every 30 days).

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; **or the Continuity of Care policy (PA.LTSS.PA.01) applies.**

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

**B.** Acute bronchospasm

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

**V. Dosage and Administration**

Drug Name	Indication	Dosing Regimen	Maximum Dose
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Advair Diskus	Asthma	1 inhalation twice daily (starting dosage is based on asthma severity)	500/50 mcg twice daily
	COPD	1 inhalation of 250/50 mcg twice daily	250/50 mcg twice daily
Advair HFA	Asthma	2 inhalations twice daily (starting dosage is based on asthma severity)	2 inhalations of 230/21 mcg twice daily

**VI. Product Availability**

<b>Drug</b>	<b>Availability</b>
Advair Diskus	Inhalation powder containing fluticasone/salmeterol: 100/50 mcg, 250/50 mcg, 500/50 mcg
Advair HFA	Inhalation aerosol containing fluticasone/salmeterol: 45/21 mcg, 115/21 mcg, 230/21 mcg

**VII. References**

1. Advair Diskus Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2017. Available at <http://www.advair.com>. Accessed March 27, 2017.
2. Advair HFA Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2017. Available at <http://www.advair.com>. Accessed March 27, 2017.
3. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: <http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report/>. Accessed March 28, 2017.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, 2017 report. Published January 2017. Available from: <http://goldcopd.org/>. Accessed March 28, 2017.

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>	<b>P&amp;T Approval Date</b>