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

Reference Number: IL.ERX.PMN.31
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

FDA Approved Indication(s)
Advair Diskus/HFA is indicated:

- For the twice-daily 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 (COPD) (Diskus only)

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

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions 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. Failure of Wixela® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed:
   a. Advair Diskus: 2 inhalations per day (60 blisters every 30 days);
   b. Advair HFA: 4 inhalations per day (1 inhaler every 30 days).

Approval duration: 12 months

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

1. Diagnosis of COPD;
2. Request is for Advair Diskus;
3. Failure of Wixela® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 2 inhalations per day (60 blisters every 30 days).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed:
   a. Advair Diskus: 2 inhalations per day (60 blisters every 30 days);
   b. Advair HFA: 4 inhalations per day (1 inhaler every 30 days).

Approval duration: 12 months

B. Other diagnoses/indications:

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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

Appendix B: Contraindications/Boxed Warnings

- Contraindication(s): primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures, hypersensitivity to milk proteins (Diskus only) or any ingredient
- Boxed warning(s): none reported

V. Dosage and Administration

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

VI. Product Availability

Drug Name	Availability
Fluticasone/salmeterol (Advair Diskus)	Inhalation powder containing fluticasone/salmeterol: 100/50 mcg, 250/50 mcg, 500/50 mcg
Fluticasone/salmeterol (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; January 2019. Available at http://www.advair.com. Accessed April 23, 2019.
2. Advair HFA Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2019. Available at http://www.advair.com. Accessed April 23, 2019.
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 April 22, 2019.
4. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2018 report). Available from: www.ginaasthma.org. Accessed April 22, 2019.

5. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2019 report). Published January 2019. Available at: http://www.goldcopd.org. Accessed April 22, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.