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

Reference Number: IL.PMN.31
Effective Date: 1.1.20
Last Review Date: 6.30.21
Line of Business: 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 Centene Corporation® 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. Meet one of the either a or b:
   a. If request is for Diskus: age 4 years and older
   b. If request is for HFA: age 12 years and older
3. Failure of Wixela® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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 (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid 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; August 2020. Available at http://www.advair.com. Accessed June 30, 2021.
2. Advair HFA Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2020. Available at http://www.advair.com. Accessed June 30, 2021.
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 October 29, 2020
4. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: www.ginasthma.org. Accessed October 29, 2020.
5. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published November 2019. Available at: http://www.goldcopd.org. Accessed October 29, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted from CP.PMN.31 Fluticasone/Salmeterol (Advair Diskus, Advair HFA) policy.	11.21.19	1.7.20
2Q 2021 Annual review: added age requirement for Asthma. Diskus: age 4 years and older and HFA: age 12 years and older; reviewed and updated references	6.30.21	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.