Clinical Policy: Fluticasone/Salmeterol (Advair Diskus, Advair HFA)
Reference Number: CP.PMN.31
Effective Date: 08/16
Last Review Date: 08/17
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 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 (~~including~~ which may include office chart notes and lab results) 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. Member meets one of the following (a, b, or c)~~1 or 2~~:
   a. Age between 4 to~~-~~ ~~11~~ 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 in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
   ~~b.~~c. Age ≥ 12 years, and f~~F~~ailure of ~~PDL agents:~~ Dulera and Symbicort at up to maximally indicated doses~~, each trialed for ≥ 6 weeks,~~ 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. ~~Requested~~ D~~d~~ose does not exceed:
   a. Advair Diskus: 2 inhalations/day (60 blisters~~1 inhaler~~ every 30 days);
   ~~c.~~b. Advair HFA: 4 inhalations/day (1 inhaler every 30 days) ~~FDA approved maximum recommended dose and health plan approved daily quantity limit~~.

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Approval duration: 12 months

B. Chronic Obstructive Pulmonary Disease (must meet all)**:**
1. Diagnosis of COPD;
2. Request is for Advair Diskus;
2.3. Failure of ≥ 64 week trial of PDL agent: 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;
3.1. Request is for Advair Diskus;
4. Requested Ddose does not exceed 2 inhalations/day (60 blisters 1 inhaler every 30 days) FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to 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/Diskus via Centene benefit or member has previously met all initial approval criteria;
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 1 inhaler every 30 days);
   a.b. Advair HFA: 4 inhalations/day (1 inhaler every 30 days) FDA approved maximum recommended dose and health plan approved daily quantity limit.

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.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to 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 – CP.PMN.53 or evidence of coverage documents

A.B. Acute bronchospasm

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration

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V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
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

Drug	Availability
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. Workflow Document

CP.PMN.31
fluticasone-salmeter

VIII. References

1. Advair Diskus Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; ~~April 2016~~February 2017. Available at http://www.advair.com. Accessed ~~June 16, 2016~~March 27, 2017.
2. Advair HFA Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; ~~December 2014~~February 2017. Available at http://www.advair.com. Accessed ~~June 16, 2016~~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 ~~June 27, 2016~~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, ~~updated~~ 2017~~6~~ report. Published January 2017~~6~~. Available from: http://goldcopd.org/. Accessed ~~June 27, 2016~~March 28, 2017.

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Guideline created.	06/16	08/16
~~Clinical changes to criteria~~ Asthma/COPD: removed trial durations and instead required that preferred drugs be trialed at up to maximally indicated doses ~~Non-clinical change to criteria~~ Asthma: updated preferencing criteria as one of the PDL products (Symbicort) is now FDA approved for ages 6 and up	03/17	08/17

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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.

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.