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

Reference Number: CP.PMN.31
Effective Date: 08.01.16
Last Review Date: 08.20
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)
- 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. Age is one of the following (a or b):
   a. Advair Diskus: ≥ 4 years;
   b. Advair HFA: ≥ 12 years;
3. If request is for Advair HFA or brand Advair Diskus, medical justification supports inability to use generic Advair Diskus (e.g., contraindications to excipients);
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. Age ≥ 18 years;
3. Request is for Advair Diskus;

4. If request is for brand Advair Diskus, medical justification supports inability to use generic Advair Diskus (e.g., contraindications to excipients);
5. 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.

IV. Appendices/General Information

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

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Symbicort (budesonide/ formoterol)	Asthma: 2 inhalations BID (starting dosage is based on asthma severity) COPD: 2 inhalations of 80/4.5 mcg BID	Asthma: 2 inhalations of 160/4.5 mcg BID COPD: 2 inhalations of 80/4.5 mcg BID
Dulera (mometasone/ formoterol)	Asthma: 2 inhalations BID (starting dosage is based on asthma severity)	2 inhalations of 200/50 mcg BID

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: 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 15, 2020.
2. Advair HFA Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; February 2019. Available at http://www.advair.com. Accessed April 15, 2020.
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 13, 2020.
4. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: www.ginasthma.org. Accessed April 6, 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 April 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Guideline created.	06.16	08.16
Asthma/COPD: removed trial durations and instead required that preferred drugs be trialed at up to maximally indicated doses Asthma: updated preferencing criteria as one of the PDL products (Symbicort) is now FDA approved for ages 6 and up	03.17	08.17
3Q 2018 annual review: removed requirement for drug trials verifiable with claims data in the past 60 days; references reviewed and updated.	04.17.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.23.19	08.19
Per SDC CY2020 strategy: modified re-direction from Dulera and/or Symbicort to generic Advair Diskus. Other changes per current safety guidance: added age limit for COPD; removed "acute bronchospasm" from Section III diagnoses not covered.	12.10.19	
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.15.20	08.20

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.

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.