Clinical Policy: Fluticasone/Salmeterol (Advair Diskus, Advair HFA)
Reference Number: CP.PMN.31
Effective Date: 08.01.16
Last Review Date: 08.18
Line of Business: Medicaid

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. 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 both (i and ii):
            i. Request is for Advair Diskus;
            ii. Failure of Symbicort® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
         c. Age ≥ 12 years, and failure of both Dulera® and Symbicort 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/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):
   1. Diagnosis of COPD;
   2. Request is for Advair Diskus;
   3. Failure of Symbicort at up to maximally indicated doses, 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 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/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 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: 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.
**CLINICAL POLICY**

Fluticasone/Salmeterol

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

*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**

- Primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures.

**V. Dosage and Administration**

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

**VI. Product Availability**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluticasone/salmeterol (Advair Diskus)</td>
<td>Inhalation powder containing fluticasone/salmeterol: 100/50 mcg, 250/50 mcg, 500/50 mcg</td>
</tr>
<tr>
<td>Fluticasone/salmeterol (Advair HFA)</td>
<td>Inhalation aerosol containing fluticasone/salmeterol: 45/21 mcg, 115/21 mcg, 230/21 mcg</td>
</tr>
</tbody>
</table>

**VII. References**

4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2018...
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.

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**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.

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