Clinical Policy: Fluticasone/Salmeterol (Advair Diskus, Advair HFA)
Reference Number: CP.PMN.31
Effective Date: 08.01.16
Last Review Date: 08.19
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 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 Symbicort 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: 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.
<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</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>(Advair Diskus)</td>
<td>COPD</td>
<td>1 inhalation of 250/50 mcg BID</td>
<td>250/50 mcg BID</td>
</tr>
<tr>
<td>Fluticasone/salmeterol</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>
<tr>
<td>(Advair HFA)</td>
<td>COPD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### VII. References


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**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

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**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>Symbicort (budesonide/formoterol)</td>
<td>Asthma</td>
<td>2 inhalations BID (starting dosage is based on asthma severity)</td>
<td>160/4.5 mcg BID</td>
</tr>
<tr>
<td></td>
<td>COPD</td>
<td>2 inhalations of 80/4.5 mcg BID</td>
<td>80/4.5 mcg BID</td>
</tr>
<tr>
<td>Dulera (mometasone/formoterol)</td>
<td>Asthma</td>
<td>2 inhalations BID (starting dosage is based on asthma severity)</td>
<td>200/50 mcg BID</td>
</tr>
<tr>
<td></td>
<td>COPD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**VI. Product Availability**

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

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**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.**

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline created.</td>
<td>06.16</td>
<td>08.16</td>
</tr>
<tr>
<td>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</td>
<td>03.17</td>
<td>08.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: removed requirement for drug trials verifiable with claims data in the past 60 days; references reviewed and updated.</td>
<td>04.17.18</td>
<td>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>04.23.19</td>
<td>08.19</td>
</tr>
</tbody>
</table>

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.

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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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