Clinical Policy: Fluticasone/Salmeterol (Advair Diskus, Advair HFA)
Reference Number: CP.PM.N.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)
- 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)  | Asthma: 2 inhalations of 160/4.5 mcg BID  
 | COPD: 2 inhalations of 80/4.5 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

<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


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</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>
<tr>
<td>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.</td>
<td>12.10.19</td>
<td></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.
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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.

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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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