Clinical Policy: Umeclidinium/Vilanterol (Anoro Ellipta)
Reference Number: CP.PMN.149
Effective Date: 09.01.18
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
Umeclidinium/vilanterol (Anoro® Ellipta®) is a combination product containing a long-acting anticholinergic and a long-acting beta-2 agonist.

FDA Approved Indication(s)
Anoro Ellipta is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation(s) of use: Anoro Ellipta is not indicated for relief of acute bronchospasm or for the treatment of asthma.

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 Anoro Ellipta is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Chronic Obstructive Pulmonary Disease (must meet all):
      1. Diagnosis of COPD;
      2. Age $\geq$ 18 years;
      3. Failure of one of the following (a or b) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
         a. One formulary long-acting beta-2 agonist (e.g., Serevent®) in combination with one formulary long-acting anticholinergic (e.g., Tudorza® Pressair®, Incruse® Ellipta®);
         b. One formulary inhaled corticosteroid in combination with a formulary long-acting beta-2 agonist (e.g., Symbicort®);
      4. Dose does not exceed 1 inhalation/day (1 inhaler/30 days).
   Approval duration: 12 months

   B. 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. Chronic Obstructive Pulmonary Disease (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 1 inhalation/day (1 inhaler/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. Asthma.

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>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incruse Ellipta (umeclidinium)</td>
<td>1 inhalation (62.5 mcg) QD</td>
<td>62.5 mcg/day</td>
</tr>
<tr>
<td>Symbicort (budesonide/formoterol)</td>
<td>2 inhalations of 80/4.5 mcg BID</td>
<td>2 inhalations of 80/4.5 mcg BID</td>
</tr>
<tr>
<td>Serevent (salmeterol)</td>
<td>1 inhalation (50 mcg) BID</td>
<td>100 mcg/day</td>
</tr>
<tr>
<td>Tudorza Pressair (aclidinium)</td>
<td>1 inhalation (400 mcg) BID</td>
<td>800 mcg/day</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/Boxed Warnings
   - Contraindications: Severe hypersensitivity to milk proteins.
• Boxed Warnings: Long-acting beta-2 agonists, such as vilanterol, increase the risk of asthma-related death. A placebo-controlled study with another long-acting beta-2 agonist (salmeterol) showed an increase in asthma-related deaths in patients receiving salmeterol. This finding of an increased risk of asthma-related death with salmeterol is considered a class effect of all long-acting beta-2 agonists.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD</td>
<td>One inhalation by mouth QD</td>
<td>1 inhalation/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Inhalation powder: Inhaler containing 2 foil blister strips of powder formulation for oral inhalation. One strip contains umeclidinium 62.5 mcg per blister and the other contains vilanterol 25 mcg per blister

VII. References


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>3Q 2018 annual review: policy split from CP.PMN.69 Inhaled combination LAA-LABA into individual Anoro Ellipta policy; no significant changes; age added; requirement for one agent to have been used in the last 60 days removed; references reviewed and updated.</td>
<td>05.17.18</td>
<td>08.18</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.
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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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