Clinical Policy: Umeclidinium/Vilanterol (Anoro Ellipta)
Reference Number: HIM.PA.106
Effective Date: 09.01.18
Last Review Date: 08.19
Line of Business: HIM

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 (LAMA) and a long-acting beta-2 agonist (LABA).

FDA Approved Indication(s)
Anoro Ellipta is indicated for the maintenance treatment of 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 ≥ 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 LABA (e.g., Serevent®) in combination with one formulary LAMA (e.g., Incruse® Ellipta®, Spiriva® Handihaler®/Respimat®, Tudorza® Pressair®);
         b. One formulary inhaled corticosteroid (ICS) in combination with a formulary LABA (e.g., Advair® Diskus®, Breo® Ellipta®, Symbicort®);
      4. Dose does not exceed 1 inhalation per day (1 inhaler per 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): HIM.PHAR.21 for health insurance marketplace.
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 per day (1 inhaler per 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.
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): HIM.PHAR.21 for health insurance marketplace.

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 – HIM.PHAR.21 for health insurance marketplace 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
GOLD: Global Initiative for Chronic Obstructive Lung Disease
ICS: inhaled corticosteroid
LABA: long-acting beta2 adrenergic agonist
LAMA: long-acting anticholinergic

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>Serevent® (salmeterol)</td>
<td>1 inhalation (50 mcg) BID</td>
<td>100 mcg/day</td>
</tr>
<tr>
<td>Incruse Ellipta® (umeclidinium)</td>
<td>1 inhalation (62.5 mcg) QD</td>
<td>62.5 mcg/day</td>
</tr>
<tr>
<td>Spiriva® Handihaler/ Respimat (tiotropium)</td>
<td>Handihaler: 2 inhalations (total 18 mcg) QD</td>
<td>Handihaler: 18 mcg/day</td>
</tr>
<tr>
<td></td>
<td>Respimat: 2 inhalations (total 5 mcg) QD</td>
<td>Respimat: 5 mcg/day</td>
</tr>
<tr>
<td>Tudorza Pressair® (aclidinium)</td>
<td>1 inhalation (400 mcg) BID</td>
<td>800 mcg/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<tr>
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</tr>
<tr>
<td>Advair Diskus® (fluticasone/salmeterol)</td>
<td>1 inhalation (250/50 mcg) BID</td>
<td>500/100 mcg/day</td>
</tr>
<tr>
<td>Breo Ellipta® (fluticasone/vilanterol)</td>
<td>1 inhalation (100/25 mcg) QD</td>
<td>100/25 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>
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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.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): severe hypersensitivity to milk proteins
- Boxed warning(s): none reported

Appendix D: General Information
- Per the 2019 GOLD COPD guidelines, combination therapy (LAMA + LABA, ICS + LABA, or ICS + LAMA + LABA) is recommended for Group D patients (i.e., those who are very symptomatic and are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
  - For those with more severe symptoms, LAMA + LABA may be used.
  - For those with a history of asthma or blood eosinophil counts at least 300 cells/uL, LABA + ICS may be used.
  - For those who are inadequately controlled by dual therapy, triple therapy with ICS + LAMA + LABA may be used.

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>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>05.21.18</td>
<td>08.18</td>
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3Q 2018 annual review: policy split from HIM.PA.74 Inhaled Long-Acting Beta₂ Agonists and Combination Products into individual Anoro Ellipta policy; redirection modified from short-acting bronchodilator to LABA in combination with LAA or ICS; age added; references reviewed and updated.

3Q 2019 annual review: no significant changes; modified FDA approved indication section to align with updated labeling language; references reviewed and updated.

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.

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Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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