Clinical Policy: Fluticasone/Umeclidinium/Vilanterol (Trelegy Ellipta)
Reference Number: CP.PMN.146
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Fluticasone/umeclidinium/vilanterol (Trelegy™ Ellipta®) is combination of an inhaled corticosteroid (ICS), long-acting anticholinergic (LAMA), and long-acting beta2-adrenergic agonist (LABA).

FDA Approved Indication(s)
Trelegy Ellipta is indicated for the maintenance treatment of:
- Patients with chronic obstructive pulmonary disease (COPD)
- Asthma in patients aged 18 years and older

Limitation(s) of use: Trelegy Ellipta 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 Trelegy 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 clinically significant adverse effects are experienced or all are contraindicated:
         a. One LABA (e.g., Serevent®, Striverdi Respimat®) in combination with one LAMA (e.g., Tudorza® Pressair®);
         b. One ICS in combination with a LABA (e.g., fluticasone/salmeterol [generic Advair® Diskus®], budesonide/formoterol [generic Symbicort®]);
      4. Dose does not exceed 1 inhalation (100/62.5/26 mcg) per day (60 blisters per 30 days).

      Approval duration: 12 months

   B. Asthma (must meet all):
      1. Diagnosis of asthma;
      2. Age ≥ 18 years;
3. Failure of one ICS in combination with a LABA (e.g., fluticasone/salmeterol [generic Advair® Diskus®], budesonide/formoterol [generic Symbicort®]);
4. Dose does not exceed 1 inhalation (200/62.5/26 mcg) per day (60 blisters per 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 1 inhalation (COPD: 100/62.5/26 mcg; asthma: 200/62.5/26 mcg) per day (60 blisters 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.

**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
GINA: Global Initiative for Asthma

GOLD: Global Initiative for Chronic Obstructive Lung Disease
ICS: inhaled corticosteroid
LABA: long-acting β2 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.*
**Appendix C: Contraindications/Boxed Warnings**
- Contraindication(s): severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients; primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required
- Boxed warning(s): none reported

**Appendix D: General Information**
- Per the 2020 Global Initiative for Chronic Obstructive Lung Disease (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.
- Per the 2020 Global Initiative for Asthma (GINA) guideline, the addition of tiotropium (a LAMA) to combination medium/high dose ICS + LABA can be considered as an alternative controller option at steps 4/5, following use of low/medium dose ICS + LABA.
- In Trelegy Ellipta’s pivotal trial for asthma, all patients enrolled were inadequately controlled on their current treatments of combination therapy (ICS + LABA).

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>COPD</td>
<td>1 inhalation (100/62.5/26 mcg) by mouth QD</td>
<td>1 inhalation/day</td>
</tr>
<tr>
<td>Asthma</td>
<td>1 inhalation (100/62.5/26 mcg or 200/62.5/26 mcg) by mouth QD</td>
<td>1 inhalation/day</td>
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</table>
VI. Product Availability
Inhalation powder: disposable inhaler containing 2 foil strips of 30 blisters each: one strip with fluticasone furoate (100 mcg or 200 mcg per blister), and the other strip with a blend of umeclidinium and vilanterol (62.5 mcg and 25 mcg per blister, respectively)

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created.</td>
<td>05.22.18</td>
<td>08.18</td>
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<td>3Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>04.23.19</td>
<td>08.19</td>
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<tr>
<td>3Q 2020 annual review: no significant changes; updated FDA approved indication language to reflect most recent labeling; modified preferred ICS/LABA to generic Symbicort and generic Advair Diskus per SDC meeting on 2/4/20; added Striverdi Respimat as a preferred LABA option and removed Incruse Ellipta as a preferred LAMA option per core Medicaid formulary status; references reviewed and updated.</td>
<td>04.15.20</td>
<td>08.20</td>
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<td>RT4: criteria added for new FDA approved indication: asthma; removed asthma from Section III diagnoses not covered; clarified max dosing for COPD; revised Appendix C per updated FDA contraindications; added new strength (200/62.5/26 mcg).</td>
<td>09.16.20</td>
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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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