Clinical Policy: Fluticasone/Umeclidinium/Vilanterol (Trelegy Ellipta)

Reference Number: IL.PMN.146
Effective Date: 1.1.20
Last Review Date: 6.23.21
Line of Business: Medicaid

Revision Log

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 beta$_2$-adrenergic agonist (LABA).

FDA Approved Indication(s)

Trelegy Ellipta is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Trelegy Ellipta is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. Trelegy Ellipta is also indicated for maintenance treatment of 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 contraindicated or clinically significant adverse effects are experienced:
   a. One formulary LABA (e.g., Serevent®) in combination with Spiriva®
   b. One formulary inhaled corticosteroid (ICS) in combination with a formulary LABA (e.g., Symbicort® ,Wixela®)
4. Dose does not exceed 1 inhalation per day (60 blisters per 30 days).

Approval duration: 12 months

B. Asthma Maintenance (must meet all):

1. Diagnosis of asthma;
2. Age ≥ 18 years;
3. Failure of one ICS in combination with a LABA (e.g. Symbicort®, Wixela®, Dulera®);

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. Chronic Obstructive Pulmonary Disease and Asthma Maintenance (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
GOLD: Global Initiative for Chronic Obstructive Lung Disease
ICS: inhaled corticosteroid
LABA: long-acting beta$_2$ adrenergic agonist
LAMA: long-acting anticholinergic

Appendix B: 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 C: 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.

Trelegy Ellipta: In its pivotal trial for asthma, all patients enrolled were inadequately controlled on their current treatments of combination therapy (ICS + LABA). In addition, per the 2020 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	1 inhalation (100/62.5/26 mcg) by mouth QD	1 inhalation/day
Asthma	1 inhalation (100/62.5/26 mcg or 200/62.5/26 mcg) by mouth QD	1 inhalation/day

VI. Product Availability

Inhalation powder: disposable inhaler containing 2 foil strips of 30 blisters each: one strip with fluticasone furoate (100 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

1. Trelegy Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; 09/2020. Available at: www.trelegyellipta.com. Accessed June 23, 2021.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published November 2019. Available at: http://www.goldcopd.org. Accessed October 29, 2020.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: www.ginasthma.org. Accessed October 29, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PMN.146 Fluticasone-Umeclidinium-Vilanterol (Trelegy Ellipta) policy.	12.10.19	1.7.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changes: **Added new indication:** **A. Asthma (must meet all):** 1. Diagnosis of asthma; 2. Age ≥ 18 years; 3. Failure of one ICS in combination with a LABA (e.g. Symbicort®); 4. Dose does not exceed 1 inhalation (200/62.5/26 mcg) per day (60 blisters per 30 days). **Approval duration: 12 months**	11.06.20	
2Q 2021 Annual Review: no significant changes; Updated Appendix C General information; reviewed and updated the references.	6.23.21	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.