

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

Reference Number: PA.CP.PMN.146

Effective Date: 10.17.18

Last Review Date: 07/17/19

[Revision Log](#)

Description

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

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.

Limitation(s) of use: Trelegy Ellipta is not indicated for relief of acute bronchospasm or 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 PA Health & Wellness® 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. 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 long-acting beta-2 agonist (e.g., Serevent®) in combination with one long-acting anticholinergic (e.g., Tudorza® Pressair®, Incruse® Ellipta®);
 - b. One inhaled corticosteroid in combination with a long-acting beta-2 agonist (e.g., Symbicort®);
3. Dose does not exceed 1 inhalation per day (60 blisters per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 inhalation 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53;
- 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Incruse Ellipta (umeclidinium)	1 inhalation (62.5 mcg) QD	62.5 mcg/day
Symbicort (budesonide/ formoterol)	2 inhalations of 80/4.5 mcg BID	2 inhalations of 80/4.5 mcg BID
Serevent (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Tudorza Pressair (aclidinium)	1 inhalation (400 mcg) BID	800 mcg/day

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

- Severe hypersensitivity to milk proteins

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	1 inhalation 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; April 2018. Available at: www.trelegyellipta.com. Accessed May 3, 2018.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2018 report). Published January 2018. Available at: <http://www.goldcopd.org/>. Accessed April 9, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	