

## **Clinical Policy: Umeclidinium/Vilanterol (Anoro Ellipta)**

Reference Number: HIM.PA.106

Effective Date: 09.01.18

Last Review Date: 08.20

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Umeclidinium/vilanterol (Anoro<sup>®</sup> Ellipta<sup>®</sup>) 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<sup>®</sup> 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 clinically significant adverse effects are experienced or all are contraindicated:
  - a. One formulary LABA (e.g., Arcapta Neohaler<sup>®</sup>, Serevent<sup>®</sup>, Striverdi Respimat<sup>®</sup>) in combination with one formulary LAMA (e.g., Incruse<sup>®</sup> Ellipta<sup>®</sup>, Spiriva<sup>®</sup> Handihaler<sup>®</sup>/Respimat<sup>®</sup>);
  - b. One formulary inhaled corticosteroid (ICS) in combination with a formulary LABA (e.g., fluticasone/salmeterol [generic Advair<sup>®</sup> Diskus<sup>®</sup>], Breo<sup>®</sup> Ellipta<sup>®</sup>, budesonide/formoterol [generic Symbicort<sup>®</sup>]);
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.

**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): 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 beta<sub>2</sub> 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.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Arcapta Neohaler (indacaterol)	1 inhalation (75 mcg) QD	75 mcg/day
Serevent <sup>®</sup> (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Stiverdi Respimat (olodaterol)	2 inhalations (total 5 mcg) QD	5 mcg/day
Incruse Ellipta <sup>®</sup> (umeclidinium)	1 inhalation (62.5 mcg) QD	62.5 mcg/day
Spiriva <sup>®</sup> Handihaler/ Respimat (tiotropium)	Handihaler: 2 inhalations (total 18 mcg) QD	Handihaler: 18 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Respimat: 2 inhalations (total 5 mcg) QD	Respimat: 5 mcg/day
fluticasone/salmeterol (Advair Diskus <sup>®</sup> )	1 inhalation (250/50 mcg) BID	500/100 mcg/day
Breo Ellipta <sup>®</sup> (fluticasone/vilanterol)	1 inhalation (100/25 mcg) QD	100/25 mcg/day
budesonide/formoterol (Symbicort <sup>®</sup> )	2 inhalations of 80/4.5 mcg BID	2 inhalations of 80/4.5 mcg BID

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): severe hypersensitivity to milk proteins; use of a LABA, including Anoro Ellipta, without an ICS in patients with asthma
- Boxed warning(s): none reported

*Appendix D: General Information*

- Per the 2020 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**

Indication	Dosing Regimen	Maximum Dose
COPD	One inhalation by mouth QD	1 inhalation/day

**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**

1. Anoro Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; July 2019. Available at: <http://www.anoro.com/>. Accessed April 13, 2020.
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 January 2020. Available from: <http://www.goldcopd.org/>. Accessed April 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from HIM.PA.74 Inhaled Long-Acting Beta <sub>2</sub> 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.	05.21.18	08.18
3Q 2019 annual review: no significant changes; modified FDA approved indication section to align with updated labeling language; references reviewed and updated.	06.25.19	08.19
Removed Tudorza Pressair from list of preferred LAMA as this will be non-formulary per SDC.	10.22.19	
3Q 2020 annual review: no significant changes; added Arcapta Neohaler and Striverdi Respimat as preferred LABAs and specified that generic (as opposed to brand) Advair Diskus and Symbicort are preferred per core Ambetter formulary status; updated Appendix C to reflect revised CI language; references reviewed and updated.	04.13.20	08.20

**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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