

Clinical Policy: Inhaled Combination Long-acting Anticholinergic & Beta-2-agonist Agents

Reference Number: PA.CP.PMN.69

Effective Date: 01/18

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

Description

The following are inhaled combination long-acting anticholinergic & beta-2-agonist agents requiring prior authorization: umeclidinium-vilanterol (Anoro Ellipta[®]), tiotropium-olodaterol (Stiolto Respimat[®]), and indacaterol-glycopyrrolate (Utibron Neohaler[®]).

FDA approved indication

Inhaled combination long-acting anticholinergic & beta-2-agonist agents are indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation of use: Not indicated for relief of acute bronchospasm or for the treatment of asthma. Stiolto Respimat is not indicated to treat acute deterioration of COPD.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness[®] that inhaled combination long-acting anticholinergic & beta-2-agonist agents are **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 agonist (LABA) (e.g., Serevent) and one long-acting anticholinergic (LAA) (e.g., Tudorza);
 - b. One inhaled corticosteroid (ICS) in combination with a LABA (e.g., budesonide/formoterol [Symbicort]);
3. An inhaled LABA, ICS/LABA combination, or LAA must have been used in the last 60 days, unless all agents are contraindicated;
4. Dose does not exceed the following:
 - a. Anoro Ellipta: 1 inhalation/day (1 inhaler/month);
 - b. Stiolto Respimat: 2 inhalations/day (1 inhaler/month)
 - c. Utibron Neohaler: 2 inhalations/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications

Inhaled Combination Long-acting Anticholinergic & Beta-2-agonist Agents

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 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 (a, b, or c):
 - a. Anoro Ellipta: 1 inhalation/day (1 inhaler/month);
 - b. Stiolto Respimat: 2 inhalations/day (1 inhaler/month);
 - c. Utibron Neohaler: 2 inhalations/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy 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 PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – PA.CP.PMN.53 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
- ICS: inhaled corticosteroid
- LAA: long-acting anticholinergic
- LABA: long-acting beta agonist

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Umeclidinium-vilanterol (Anoro Ellipta)	One inhalation by mouth once daily	1 inhalation/day
Tiotropium-olodaterol (Stiolto Respimat)	Two inhalations by mouth once-daily at the same time of day	2 inhalations/day
Indacaterol-glycopyrrolate (Utibron Neohaler)	The inhalation of the powder contents of one capsule twice daily	Contents of 2 capsules/day

Inhaled Combination Long-acting Anticholinergic & Beta-2-agonist Agents

VI. Product Availability

Drug	Availability
Umeclidinium-vilanterol (Anoro Ellipta)	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.
Tiotropium-olodaterol (Stiolto Respimat)	Inhalation spray: Each actuation from the mouthpiece contains 3.124 mcg tiotropium bromide monohydrate, equivalent to 2.5 mcg tiotropium, and 2.736 mcg olodaterol hydrochloride, equivalent to 2.5 mcg olodaterol.
Indacaterol-glycopyrrolate (Utibron Neohaler)	Inhalation powder: Capsules contain 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate inhalation powder for use with the Neohaler device.

VII. Workflow Document

N/A

VIII. References

1. Tiotropium bromide-olodaterol. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2016. Available at <http://www.clinicalpharmacology-ip.com>. Accessed June 2017.
2. Umeclidinium-vilanterol. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2016. Available at <http://www.clinicalpharmacology-ip.com>. Accessed June 2017.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease 2017. <http://www.goldcopd.org/>. Accessed June 2017.
4. Anoro Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2017. Available at <http://www.startwithanoro.com/> Accessed June 2017.
5. Stiolto Respimat Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016. Available at <https://www.stiolto.com/>. Accessed June 2017.
6. Utibron Neohaler Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2017. Available at <https://www.utibron.com/>. Accessed June 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date