# Clinical Policy: Tiotropium/Olodaterol (Stiolto Respimat)

Reference Number: PA.CP.PMN.148
Effective Date: 10.17.18
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Revision Log

**Description**
Tiotropium/olodaterol (Stiolto® Respimat®) is a combination product containing a long-acting anticholinergic and a long-acting beta-2 agonist.

**FDA Approved Indication(s)**
Stiolto Respimat is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation(s) of use:
- Stiolto Respimat is not indicated to treat asthma.
- Stiolto Respimat is not indicated to treat acute deteriorations of COPD.

**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 Stiolto Respimat 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. 
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 long-acting beta-2 agonist (e.g., Serevent®) in combination with one formulary long-acting anticholinergic (e.g., Tudorza® Pressair®, Incruse® Ellipta®);
   b. One formulary inhaled corticosteroid in combination with a formulary long-acting beta-2 agonist (e.g., Symbicort®);
4. Dose does not exceed 2 inhalations/day (1 inhaler/month).

**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 2 inhalations/day (1 inhaler/month).
   **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*
- All long-acting beta-2 agonists are contraindicated in patients with asthma without use of a long-term asthma control medication. Stiolto Respimat is not indicated for the treatment of asthma.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| COPD | Two inhalations by mouth QD at the same time of day | 2 inhalations/day |

## VI. Product Availability

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

## VII. References

1. Stiolto Respimat Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016. Available at https://www.stiolto.com/. Accessed April 17, 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 | |