

Clinical Policy: Tiotropium/Olodaterol (Stiolto Respimat)

Reference Number: IL.ERX.PMN.148

Effective Date: 06.01.21

Last Review Date: 05.21

Line of Business: Illinois Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Tiotropium/olodaterol (Stiolto[®] Respimat[®]) is a combination product containing a long-acting anticholinergic (LAMA) and a long-acting beta-2 agonist (LABA).

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. 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[®]);
4. Dose does not exceed 2 inhalations per day (1 inhaler per month).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 2 inhalations per day (1 inhaler per month).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 beta2 adrenergic agonist
 LAMA: long-acting anticholinergic

Appendix B: Contraindications/Boxed Warnings

- Contraindication(s):
 - 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
 - Hypersensitivity to tiotropium, ipratropium, olodaterol, or any component of this product
- Boxed warning(s): asthma-related death

Appendix C: General Information

- Per the 2019 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	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.; March 2019. Available at <https://www.stiolto.com/>. Accessed April 23, 2019.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2019 report). Published January 2019. Available at: <http://www.goldcopd.org/>. Accessed April 22, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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