

Long-Acting Muscarinic Antagonist (LAMA) Drug Use Criteria

Created: 4/5/2021

Reviewed: 4/14/21

Includes:

Spiriva Handihaler®: inhalation capsule 18mcg *tiotropium*
Spiriva Respimat®: inhalation aerosol solution 1.25mcg and 2.5mcg/actuation *tiotropium*

GUIDELINE FOR USE:

1. Is the request for a funded condition?
 - a. Yes, go to #2.
 - b. No, deny as BTL.
2. Is use an FDA-approved indication?
 - a. Yes, go to #3 if diagnosis is COPD.
 - b. Yes, go to #5 if diagnosis is asthma.
 - c. No, deny as criteria not met. Off-label use of a medication is not a covered benefit.
3. Is request for treatment of COPD and has diagnosis been confirmed by history of respiratory symptoms and spirometry?
 - d. Yes, go to #4.
 - e. No, deny as criteria not met. Please submit spirometry confirming COPD diagnosis.
4. Has the member had an adequate trial and failure of Incruse Ellipta? (Adequate trial is defined as adherent to therapy for at least 90 consecutive days and documentation of persistent symptoms).
 - a. Yes, approve for 12 months.
 - b. No, deny as criteria not met. Recommend trial with formulary alternative, Incruse Ellipta.
5. Is request for treatment of asthma and has diagnosis been confirmed by history of respiratory symptoms and spirometry/Nitric Oxide testing?
 - a. Yes, go to #6.
 - b. No, deny as criteria not met. Please submit documentation, including respiratory symptoms and spirometry/Nitric Oxide testing, confirming asthma diagnosis OR forward to MD for review.
6. Is Spiriva Respimat (tiotropium) prescribed as add-on therapy to ICS/LABA? (Per GINA guidelines, add-on Spiriva Respimat (tiotropium) is supported for members aged 6 years and

older whose asthma is not well-controlled with ICS-LABA. Add-on Spiriva Respimat (5mcg once daily) modestly improves lung function (Evidence A) and modestly increases the time to severe exacerbation requiring oral corticosteroids (Evidence B). Pulmonology consult is recommended for members aged 6-11 years).

- a. Yes, approve for up to 6 months.
- b. No, deny as criteria not met. Recommend formulary ICS/LABA, but will require PA request.

Renewal Request:

1. Have symptoms improved and does documentation support continued therapy?
 - a. Yes, approve for 12 months for COPD
 - b. Yes, approve for up to 6 months for asthma
 - c. No, deny as criteria not. Please consider stepping down treatment or alternative treatment options or forward to MD for review.

Rationale: To ensure medical appropriateness and optimization of less costly formulary alternatives.

FDA Approved Indication:

Asthma (Spiriva Respimat only): Maintenance treatment of asthma in patients ≥ 6 years.

Chronic obstructive pulmonary disease: Maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; reduction of COPD exacerbations.

Mechanism of Action:

Competitively and reversibly inhibits the action of acetylcholine at type 3 muscarinic (M_3) receptors in bronchial smooth muscle causing bronchodilation.

Dosing:

Asthma: Oral inhalation: Spiriva Respimat (1.25 mcg/actuation): Soft-mist inhaler: Two inhalations (2.5 mcg) once daily (maximum: 2 inhalations per 24 hours). **Note:** Maximum benefits may take up to 4 to 8 weeks of dosing. 5 mcg once daily has been recommended for patients with insufficient response to inhaled corticosteroid plus long-acting beta agonist (GINA 2020) with efficacy found in adults with severe asthma (ERS/ATS [Holguin 2019]).

COPD: Oral inhalation:

Spiriva HandiHaler: Dry powder inhaler: Contents of 1 capsule (18 mcg) inhaled once daily

Spiriva Respimat (2.5 mcg/actuation): Soft-mist inhaler: Two inhalations (5 mcg) once daily (maximum: 2 inhalations per 24 hours).

Contraindications:

Hypersensitivity to ipratropium, tiotropium, or any component of the formulation.

References:

Canadian Thoracic Society Clinical Practice Guideline on pharmacotherapy in patients with COPD – 2019 update of evidence. <https://doi.org/10.1080/24745332.2019.1668652>

Global Initiative for Asthma (GINA). https://ginasthma.org/wp-content/uploads/2020/06/GINA-2020-report_20_06_04-1-wms.pdf.

Global Initiative for Chronic Obstructive Lung Disease (GOLD). https://goldcopd.org/wp-content/uploads/2020/11/GOLD-REPORT-2021-v1.1-25Nov20_WMV.pdf

National Institute for Health and Care Excellence (NICE).
<https://www.nice.org.uk/guidance/ng80/chapter/Recommendations#principles-of-pharmacological-treatment>

UpToDate: Tiotropium: Drug information