

## Spiriva (tiotropium) Policy Number: C5109-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
10/2018	10/9/2019	10/9/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
J3535-Drug administered through metered dose inhaler	RxPA	Q4 2019 20191030C5109-A

**PRODUCTS AFFECTED:**

Spiriva and Spiriva Respimat (tiotropium)

**DRUG CLASS:**

Bronchodilators- Anticholinergics  
AKA- Long-Acting Muscarinic Antagonists (LAMAs)

**ROUTE OF ADMINISTRATION:**

Inhalation

**PLACE OF SERVICE:**

Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**

Spiriva HandiHaler 18mcg capsules (5 doses, 30 doses & 90 doses), Spiriva Respimat 1.25mcg/actuation MDI (4g=60 doses), and Spiriva Respimat 2.5mcg/actuation MDI (4g=60 doses)

**FDA-APPROVED USES:**

indicated for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations  
SPIRIVA RESPIMAT ONLY: long-term, once-daily, maintenance treatment of asthma in members 6 years of age and older  
Orphan drug designation: To improve pulmonary function in conjunction with standard therapy in the management of members with maintenance treatment of asthma

**COMPENDIAL APPROVED OFF-LABELED USES:** None

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:**

chronic obstructive pulmonary disease (COPD), maintenance treatment of asthma, maintenance treatment of asthma

**REQUIRED MEDICAL INFORMATION:**

A. CHRONIC OBSTRUCTIVE PULMONARY DISEASE- (for Spiriva HandiHaler and Spiriva Respimat 2.5mcg)

1. Treatment failure after a compliant 3-month trial of a majority of preferred formulary LAMAs

**B. PERSISTENT ASTHMA: (for Spiriva Respimat 1.25mcg)**

1. Treatment failure with or clinical contraindication to a compliant 3-month trial of an inhaled corticosteroid, long-acting beta agonist, AND a leukotriene receptor antagonist or theophylline

**DURATION OF APPROVAL:**

Initial authorization: 6 months, Continuation of Therapy: 12 months

**QUANTITY:**

Spiriva Respimat: 1 inhaler every 30 days, Spiriva HandiHaler: 30 capsules every 30 days

**PRESCRIBER REQUIREMENTS:**

None

**AGE RESTRICTIONS:**

≥18 years old, Spiriva Respimat 1.25mcg (asthma): ≥6 years old

**GENDER:**

Male and female

**CONTINUATION OF THERAPY:****A. FOR ALL INDICATIONS:**

1. Documentation of stable or improved disease (e.g., reduced exacerbations, improved objective measurements of lung function, improved respiratory symptoms)

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

Acute episodes of bronchospasm, Closed-angle glaucoma, Pre-existing bladder obstruction/other urinary tract obstruction/prostatic hypertrophy

**OTHER SPECIAL CONSIDERATIONS:**

None

**BACKGROUND:**

None

**APPENDIX:**

None

**Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

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**REFERENCES:**

1. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. 2018. Available from: <http://www.clinicalpharmacology.com>
2. Ferguson, GT and Make, B. Management of stable chronic obstructive pulmonary disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on September 12, 2018.)
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). GOLD 2018 global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, 2018 report. Accessed September 12, 2018.
4. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma Clinical Practice Guidelines. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2007 Aug.