Original Effective Date: 07/29/2021
Current Effective Date: 12/14/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
Policy Number: C5109-A

Spiriva (tiotropium)

PRODUCTS AFFECTED

Spiriva Handihaler (tiotropium), Spiriva Respimat (tiotropium)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

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.

DIAGNOSIS:
Chronic obstructive pulmonary disease (COPD), Maintenance treatment of asthma

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (for Spiriva HandiHaler and Spiriva Respimat 2.5mcg):
   1. Documented diagnosis of chronic obstructive pulmonary disease (COPD)
      AND

2. Documentation of an inadequate response (3-month trial), serious side effects, or contraindication to a majority (not more than 3) of the preferred formulary/PDL LAMAs
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., frequency of exacerbations, objective measurements of lung function, respiratory symptoms) [DOCUMENTATION REQUIRED]

B. PERSISTENT ASTHMA (for Spiriva Respimat 1.25mcg):
1. Documented diagnosis of asthma
AND
2. Treatment failure with a compliant 3-month trial of an inhaled corticosteroid AND long-acting beta agonist (as a combination inhaler or separate inhalers)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., frequency of exacerbations, objective measurements of lung function, respiratory symptoms) [DOCUMENTATION REQUIRED]

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)
AND
2. Documentation member has been adherent to therapy at least 85% of the time as verified by Prescriber and member's medication fill history
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization:12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Spiriva Respimat 2.5 mcg (COPD), Spiriva Handihaler: 18 years or age and older
Spiriva Respimat 1.25 mcg (asthma): 6 years of age and older

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

PLACE OF ADMINISTRATION:
The recommendation is that inhalation medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Inhalation

DRUG CLASS:
Bronchodilators- Anticholinergics, AKA Long-Acting Muscarinic Antagonists (LAMAs)

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: Indicated for the long-term, once-daily, maintenance treatment of asthma in patients 6 years of age and older
Limitation of use: Not indicated for relief of acute bronchospasm
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

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of tiotropium are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to tiotropium include: hypersensitivity to tiotropium, ipratropium, or any component of the product.

OTHER SPECIAL CONSIDERATIONS:
Worsening of narrow-angle glaucoma may occur. Worsening of urinary retention may occur. Use with caution in these patients.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Spiriva HandiHaler CAPS 18mcg (5 doses, 30 doses & 90 doses)
Spiriva Respimat AERS 1.25mcg/ACT MDI (4g=60 doses)
Spiriva Respimat AERS 2.5mcg/ACT MDI (4g=60 doses)
Tiotropium Bromide Monohydrate CAPS 18MCG

REFERENCES

1. Spiriva Respimat (tiotropium bromide inhalation spray), for oral inhalation use [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; November 2021.
2. Spiriva HandiHaler (tiotropium bromide inhalation powder), for oral inhalation use [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; November 2021.
3. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2021. Available at:http://www.ginasthma.org.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease: 2021 Report. http://www.goldcopd.org
5. National Asthma Education and Prevention Program (NAEPP): 2020 Focused updates to the asthma management guidelines. Bethesda, MD: National Heart, Lung, and Blood Institute, 2020. (NIH publication no. 20-HL-8140). Available at https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines. Accessed September 2022.
6. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org
7. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org
8. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease: 2024 Report. http://www.goldcopd.org
9. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update	Q4 2024
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2023
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Age Restrictions References	Q1 2023
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Age Restrictions References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file