Clinical Policy: Tiotropium/Bromide (Spiriva Respimat 1.25mg/act)

Reference Number: IN.PMN.501
Effective Date: 04/01/2020
Last Review Date: 04/2021
Line of Business: Medicaid

Revision Log

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

Description

Tiotropium/bromide (Spiriva® Respimat®) is a quaternary ammonium derivative long-acting muscarinic antagonist (LAMA)

FDA Approved Indication(s)

Spiriva Respimat is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (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 Managed Health Services (MHS) that Spiriva Respimat 1.25mg/act is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Asthma (must meet all)**:**

1. Diagnosis of Asthma;
2. If no diagnosis of asthma then the following:
    a. Failure of at least two* PDL agents within the same therapeutic class **or** PDL drugs that are recognized as standards of care for the treatment of member's diagnosis at up to maximally indicated doses, each used for the appropriate duration of treatment or for ≥ 30 days for diseases requiring maintenance treatment. Trial and failure of PDL agents must be supported by one of the following (a, b, or c):
        i. Presence of claims in pharmacy claims history;
        ii. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL drugs that are recognized as standards of care for the treatment of member's diagnosis;
        iii. If member received drug samples of PDL medications from the prescriber to meet this requirement, a copy of the sample logs must be submitted for review to be considered at the discretion of the utilization management reviewer. Submitted sample log must include all of the following: medication name,

dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;

3. Dose does not exceed 1 inhalations per day (1 inhaler per month).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Asthma (must meet all)**:**

1. Currently receiving medication via MHS benefit 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 1 inhalations per day (1 inhaler per month).

Approval duration: 12 months

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 – CP.PMN.53 for Medicaid or evidence of coverage documents;

B.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

LAMA: long-acting anticholinergic

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	04.01.20	04.20
Annual Review: No Changes	04/2021	04/13/2021

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.