Clinical Policy: Respiratory Agents: Chronic Obstructive Pulmonary Disease

Reference Number: OH.PHAR.PPA.83
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description:

RESPIRATORY AGENTS: COPD ANTICHOLINERGICS (LAMA)

NO PA REQUIRED " PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATROVENT HFA® (ipratropium) COMBIVENT Respimat® (ipratropium/albuterol) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® Handihaler® (tiotropium)† SPIRIVA® Respimat® (tiotropium)	INCRUSE ELLIPTA® (umeclidinium)† LONHALA™ MAGNAIR™ (glycopyrrolate) SEEBRI™ NEOHALER® (glycopyrrolate)† TUDORZA® (aclidinium bromide)† YUPELRI™ (revefenacin)

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: COPD GLUCOCORTICOID-MUSCARINIC-BETA-ADRENERGIC COMBINATION

NO PA REQUIRED " PREFERRED"	PA REQUIRED "NON-PREFERRED"
	TRELEGY ELLIPTA (fluticasone, umeclidinium and vilanterol) †

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: PHOSPHODISTERASE-4 INHIBITORS *

NO PA REQUIRED " PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DALIRESP® (roflumilast)

* Note: Clinical criteria must be met. Concurrent therapy with long-acting beta agonist required

FDA Approved Indication(s):

Anticholinergics, Glucocorticoid/Muscarinic/Beta-Adrenergic Combinations, and Phosphodiesterase-4 (PDE4) Inhibitors are indicated for the treatment of **chronic obstructive pulmonary disease (COPD)**, including chronic bronchitis and/or emphysema. Spiriva Respimat is additionally indicated for the long-term maintenance treatment of **asthma**.

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 Buckeye Health Plan, an affiliate of Centene Corporation®, that Incruse Ellipta, Lonhala Magnair, Seebri Neohaler, Tudorza, Yupelri, Trelegy Ellipta, and Daliresp are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. For Incruse Ellipta, Lonhala Magnair, Seebri Neohaler, Tudorza, Yupelri, and Trelegy Ellipta (must meet all)**:**

1. Diagnosis of chronic obstructive pulmonary disease (COPD);
2. Age ≥ 18 years;
3. Documentation that there has been a therapeutic failure to no less than a 14 day trial of at least two medications not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval duration: 12 months.

B. For Daliresp (must meet all)**:**

1. Diagnosis of chronic obstructive pulmonary disease (COPD);
2. Age ≥ 18 years;
3. Current (within the past 30 days) forced expiratory volume in one second (FEV_1) < 50% predicted;
4. Documentation that there has been a therapeutic failure to no less than a 14 day trial of at least two medications not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.
5. Daliresp is prescribed concurrently with a long-acting bronchodilator (i.e., LABA or LAMA) AND member is adherent to therapy.
6. Dose does not exceed 500 mcg per day (1 tablet per day).

Approval duration: 12 months.

C. Other diagnoses/indications:

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A;
   b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):

i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
ii. Adequate representation of the prescribed drug regimen;
iii. Clinically meaningful outcomes as a result of the drug therapy in question;
iv. Appropriate experimental design and method to address research questions;

c. Micromedex DrugDex® with strength of recommendation Class I, IIa, or IIb;

3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: 12 months.

II. Diagnoses/Indications for which coverage is NOT authorized:

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

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: Chronic Obstructive Pulmonary Disease
FDA: Food and Drug Administration
FEV_1: Forced expiratory volume in one second
ICS: Inhaled Corticosteroid
LABA: Long-Acting Beta Agonist
LAMA: Long-Acting Muscarinic Antagonist
PA: Prior Authorization
PDE4: Phosphodiesterase-4

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Atrovent HFA® (ipratropium)	2 puffs inhaled 3 or 4 times per day (no more frequent than every 4 hours)	204 mcg (12 puffs) per 24 hour period
Combivent Respimat® (ipratropium/albuterol)	1 actuation inhaled 4 times per day	6 inhalations per 24 hours
ipratropium nebulizer solution	500 mcg via nebulizer 3 to 4 times per day	2,000 mcg/day (4 doses) via nebulizer

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ipratropium/albuterol nebulizer solution (Duoneb®)	One 3-mL vial inhaled via nebulizer 4 times per day. Each 3-mL vial contains 3 mg albuterol sulfate (2.5 mg of albuterol base) and 0.5 mg of ipratropium	6 vials/day via nebulization
Spiriva® Handihaler® (tiotropium)	2 inhalations of the contents of a single capsule (18 mcg) once daily	18 mcg (contents of 1 capsule) inhaled per 24 hours
Spiriva® Respimat® (tiotropium)	Asthma: 2 actuations (1.25 mcg per actuation) once daily COPD: 2 actuations (2.5 mcg per actuation) once daily	Asthma: 2.5 mcg (2 actuations) per 24 hrs COPD: 5 mcg (2 actuations) per 24 hrs

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Albuterol Hypersensitivity
  - Bromide Hypersensitivity
  - Levalbuterol Hypersensitivity
  - Milk Protein Hypersensitivity

IV. Dosage and Administration

- Varies by drug product. See FDA approved dosing and administration AND Appendix B.

V. Product Availability

Drug Name	Availability
Atrovent HFA	Inhalation aerosol: 17 mcg/actuation
Combivent Respimat	Inhalation spray: 20 mcg-100 mcg/actuation
Daliresp	Tablets: 250mcg, 500mcg
Incruse Ellipta	Inhalation powder: 62.5 mcg/actuation
ipratropium nebulizer solution	Inhalation solution: 0.02% (0.5 mg/2.5 mL)
ipratropium/albuterol nebulizer solution	Inhalation solution: 0.5 mg-3 mg/3 mL
Lonhala Magnair	Inhalation solution: 25 mcg/mL
Seebri Neohaler	Inhalation powder: 15.6 mcg
Spiriva Handihaler	Inhalation powder: 18 mcg
Spiriva Respimat	Inhalation spray: 1.25 mcg/actuation
Spiriva Respimat	Inhalation spray: 2.5 mcg/actuation
Trelegy Ellipta	Inhalation powder: 100 mcg-62.5 mcg-25 mcg
Tudorza Pressair	Inhalation powder: 400 mcg/actuation
Yupelri	Inhalation solution: 175 mcg/3 mL

VI. References

- Atrovent. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Daliresp. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Trelegy Ellipta. Clinical Pharmacology. Elsevier. Tampa, FL. Available at https://www.clinicalpharmacology-ip.com. Accessed November 11, 2019.
- Yupelri (revefenacin) [package insert]. Morgantown, WV; Mylan Specialty; Revised 05/2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.