

Clinical Policy: Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting

Reference Number: OH.PHAR.PPA.81

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: BETA-ADRENERGIC, SHORT-ACTING

Metered Dose Inhalers or Other Devices

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALBUTEROL HFA (authorized generics ProAir®, Proventil®, Ventolin®) PROAIR RESPICLICK® (albuterol)	XOPENEX HFA® (levalbuterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING NEBULIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALBUTEROL (generic of Proventil®, Ventolin®) 0.083% Premixed nebulizers, 0.5% Concentrated Solution ALBUTEROL 1.25mg/3ml, 0.63mg/3ml (generic of Accuneb®) (no PA required for ages 12 and under)	ALBUTEROL 1.25mg/3ml, 0.63mg/3ml (generic of Accuneb®) (PA required for over age 12) LEVALBUTEROL (generic of Xopenex®)

FDA Approved Indication(s):

Beta-Adrenergic Agonists, Short-Acting medications are indicated for the treatment of:

- acute bronchospasm
- asthma
- bronchospasm prophylaxis
- chronic bronchitis
- chronic obstructive pulmonary disease (COPD)
- emphysema
- exercise-induced bronchospasm prophylaxis

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 Xopenex HFA, Albuterol 1.25mg/3ml (over the age of 12), Albuterol 0.63mg/3ml (over the age of 12), and Xopenex nebulizer solution are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. For Albuterol 1.25mg/3ml (over the age of 12) and Albuterol 0.63mg/3ml (over the age of 12) (must meet all):**

1. FDA-approved or supported by standard pharmacopeias;
2. Documentation that there has been a therapeutic failure to no less than a 14 day trial of at least one medication not requiring prior approval within the same class and formulation (i.e., nebulizers for nebulizers) 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 Xopenex (must meet all):

1. FDA-approved or supported by standard pharmacopeias;
2. Member meets one of the following (a or b):
 - a. Presence of cardiac disease;
 - b. Documentation that there has been a therapeutic failure to no less than a 14 day trial of at least one medication not requiring prior approval within the same class and formulation (i.e., nebulizers for nebulizers) 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.

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

PA: Prior Authorization

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
albuterol HFA (generic for ProAir HFA)	2 puffs every 4 to 6 hours as needed	12 inhalations/day
ProAir RespiClick (albuterol)	2 puffs every 4 to 6 hours as needed	12 inhalations/day
albuterol HFA (generic for Proventil HFA)	2 puffs every 4 to 6 hours as needed	12 inhalations/day
albuterol HFA (generic for Ventolin HFA)	2 puffs every 4 to 6 hours as needed	12 inhalations/day
albuterol 0.083% Premixed Neb	1 vial via oral inhalation every 4 to 6 hours as needed	4 doses/day or 10 mg/day
albuterol 0.5% Concentrated Solution	1 vial via oral inhalation every 4 to 6 hours as needed	4 doses/day or 10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
albuterol 1.25mg/3ml (Accuneb) (ages 12 and under)	1 vial via oral inhalation every 4 to 6 hours as needed	4 doses/day or 5 mg/day
albuterol 0.63mg/3ml (Accuneb) (ages 12 and under)	1 vial via oral inhalation every 4 to 6 hours as needed	4 doses/day or 2.5 mg/day

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
 - 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
Albuterol HFA	Inhalation aerosol: 90 mcg/actuation
Albuterol	Inhalation solution: 0.083% (2.5 mg/3 mL)
Albuterol	Inhalation solution: 0.5% (2.5 mg/0.5 mL)
Albuterol	Inhalation solution: 0.5% (5 mg/mL)
Albuterol	Inhalation solution: 0.63 mg/3 mL
Albuterol	Inhalation solution: 1.25 mg/3 mL
Levalbuterol HFA	Inhalation aerosol: 45 mcg/actuation
Levalbuterol	Inhalation solution: 0.31 mg/3 mL
Levalbuterol	Inhalation solution: 0.63 mg/3 mL
Levalbuterol	Inhalation solution: 1.25 mg/0.5 mL
Levalbuterol	Inhalation solution: 1.25 mg/3 mL
ProAir HFA	Inhalation aerosol: 90 mcg/actuation
ProAir RespiClick	Inhalation powder: 90 mcg/actuation
Proventil HFA	Inhalation aerosol: 90 mcg/actuation
Ventolin HFA	Inhalation aerosol: 90 mcg/actuation

VI. References

- Albuterol. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 11, 2019.
- Levalbuterol. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 11, 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.

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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.

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