

Clinical Policy: Levalbuterol MDI (Xopenex HFA)

Reference Number: HIM.PA.75

Effective Date: 12/14

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Levalbuterol (Xopenex HFA[®]) is a beta₂-adrenergic agonist.

FDA approved indication

Xopenex HFA is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

Policy/Criteria

Provider *must* submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Request for Xopenex HFA (must meet all):

1. Member is unable to use formulary alternatives (e.g., Proair HFA, Proventil HFA, Ventolin HFA) due to one of the following (a or b):
 - a. Presence of cardiac disease;
 - b. Member experienced clinically significant adverse effects from albuterol use;
2. Member does NOT have history of allergy or hypersensitivity to albuterol or levalbuterol;
3. Request does not exceed 2 inhalers per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. Request for Xopenex HFA (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., resolution of adverse effects as compared with prior treatment with albuterol);
3. Albuterol HFA has not been used within the past 3 months as evidenced by pharmacy claims history;
4. Request does not exceed 2 inhalers per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

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1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

V. References

1. Xopenex HFA Prescribing Information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; March 2015. Available at: <http://www.xopenex.com>. Accessed April 17, 2017.
2. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: <http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report/>. Accessed April 17, 2017.
3. Nelson HS, Bensch G, Pleskow WW, et al. Improved bronchodilation with levalbuterol compared with racemic albuterol in patients with asthma. *J Allergy Clin Immunol.* 1998; 102: 943-952.
4. Gawchik SM, Consuelo SL, Noonan M, et al. The safety and efficacy of nebulized levalbuterol compared with racemic albuterol and placebo in the treatment of asthma in pediatric patients. *J Allergy Clin Immunol.* 1999; 103: 615-21
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 24, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Added Workflow reference document.	12/15	12/15
Updated verbiage and references. Removed workflow document.	08/16	11/16
Converted to new template. Updated clinical policy title to reflect only levalbuterol HFA inhaler since PA was removed off of levalbuterol inhalation solution per formulary; removed diagnosis; added requirement related to hypersensitivity to albuterol/levalbuterol; re-auth: added a requirement that albuterol HFA has not been used within the past 3 months; added QL per formulary; updated references.	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date

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.

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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.

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