

Short Acting Beta Agonists (Proair HFA, Proventil HFA, Xopenex HFA)

Origination: 12/29/11	Revised:	Annual Review:
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

- Albuterol is a moderately selective beta-2-receptor agonist. Albuterol is a racemic mixture of R- and S-isomers, and is widely used as a bronchodilator. It is indicated for the management of asthma exacerbations or other chronic obstructive airway diseases. Short-acting beta-2 agonists, such as albuterol, are considered first line therapy for mild intermittent asthma during pregnancy. Short-acting beta-2 agonists (SABAs) are considered the preferred pharmacologic treatment to relieve acute bronchospasm. Albuterol is also indicated to prevent exercise-induced bronchospasm. Albuterol inhalational aerosols containing hydrofluoroalkanes (HFAs) have replaced albuterol inhalation aerosols containing CFCs after December 31, 2008. These products include Proair HFA, Proventil HFA, and Ventolin HFA.
- Levalbuterol (Xopenex HFA) is the R-enantiomer of racemic albuterol and is a moderately selective beta-2-receptor agonist. When given in equimolar doses of R-albuterol (i.e., 2.5 mg of racemic albuterol or 1.25 mg of levalbuterol), levalbuterol produces bronchodilation and clinical activity similar to the parent drug. Levalbuterol is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children with reversible obstructive airway disease (e.g., asthma).It is NOT indicated to prevent exercise-induced bronchospasm.
- Both albuterol and levalbuterol stimulates receptors of the smooth muscle in the lungs, uterus, and vasculature supplying skeletal muscle. The net result of beta₂-receptor agonism in the lungs is relaxation of bronchial and tracheal smooth muscles, which in turn relieves bronchospasm, reduces airway resistance, facilitates mucous drainage, and increases vital capacity.

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

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Background Information, continued:

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Any hypersensitivity to albuterol, levalbuterol, or hydrofluoroalkanes.

Procedure:

- 1.0 Request for *initial therapy* with Proair HFA, Proventil HFA or Xopenex HFA requires documentation from the Member's medical records maintained by the requesting independent practitioner's office verifying the following:
 - 1.1 Member has a documented contraindication or has had a serious adverse reaction to Ventolin HFA;
 - 1.2 If all criteria are met, request may be approved for one (1) month with quantity limit of two (2) metered dose inhalers for 30 days.
- 2.0 *Continuation therapy:*
 - 2.1 Refills should continue to process every month thereafter.

References:

1. DRUGDEX[®] System (electronic version). Thomson MICROMEDEX, Greenwood Village, Colorado, USA. Available at: <http://csi.micromedex.com>.
2. Lexi-Comp Online (electronic version) Lexi-Comp Inc. 1978-2010, Hudson, Ohio, USA. Available at: <http://online.lexi.com/crlsql/servlet/crlonline>.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2011. URL: <http://www.clinicalpharmacology.com>. Accessed December 23, 2011.



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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.