



Therapeutic Class ReviewSM

Respiratory: Short-Acting Beta Agonists – Albuterol HFA Inhalers (Proventil HFA[®], Ventolin HFA[®], ProAir HFA[®])

April 2007

Executive Summary:

- The FDA mandated the removal of albuterol inhalers containing chlorofluorocarbons (CFCs) from the U.S. to protect the environment and prevent the depletion of the ozone layer by December 2008.¹⁻³
- With this removal, patients need to transition from albuterol CFC inhalers to a non-ozone-depleting propellant, hydrofluoroalkane (HFA) product.
 - There are three albuterol HFA metered-dose inhalers marketed in the United States: Proventil HFA, Ventolin HFA (GlaxoSmithKline), and ProAir HFA.
 - Generic albuterol inhalers are no longer available because they contain CFCs.
- HFA products are in short supply because of the large population of patients converting from CFC to HFA albuterol inhalers.
- There is continued concern that manufacturers of albuterol HFA products cannot meet the current and future market demands.
- ProAir or Ventolin may provide an additional source for members needing a short-acting beta-agonist.
- Prescribers indicate and recognize ProAir as an acceptable therapeutic alternative for albuterol HFA inhalers.

Decision

ProAir HFA is preferred/formulary because this product will provide an additional option for members during anticipated intermittent shortages of HFA products.

Albuterol HFA Inhaler Product Comparison ^{2,4-5}

Product	Patent Exp.	FDA Approved Indication	Qty	Usual Dose	Puffs per canister
Proventil HFA [®]	11/09 – 2/14	Adults and children ages 4 and older for treatment or prevention of reversible obstructive airway disease and prevention of exercised-induced bronchospasms	6.7 gm	Up to 2 puffs every 4 – 6 hours prn	200
Ventolin HFA [®]	4/15 – 12/17	Adults and children ages 4 and older for treatment or prevention of reversible obstructive airway disease and prevention of exercised-induced bronchospasms	18 gm	Up to 2 puffs every 4 – 6 hours prn	200
ProAir HFA [®]	11/09 – 2/14	Adults and children ages 12 and older for treatment or prevention of reversible obstructive airway disease and prevention of exercised-induced bronchospasms	8.5 gm	Up to 2 puffs every 4 – 6 hours prn	200

F = Formulary; N = Non formulary

References:

1. National Institutes of Health, National Heart, Lung and Blood Institute, “Guidelines for the Diagnosis and Management of Asthma,” 1997
2. ProAir[®] HFA Package Insert, IVAX Pharmaceuticals, Miami, Florida, February 2006.
3. The Montreal Protocol on Substances that Deplete the Ozone Layer as adjusted and/or amended in London 1990, Copenhagen 1992, Vienna 1995, Montreal 1997, Beijing 1999, "Preamble," http://www.unep.org/ozone/Montreal-Protocol/Montreal-Protocol2000.shtml#_Toc483027784. Accessed June 2, 2006.
4. Ventolin HFA Package Insert, GlaxoSmithKline, Inc., Research Triangle Park, NC, December 2005.
5. Proventil HFA Package Insert, Key Pharmaceuticals, Inc., Kenilworth, NJ, October 2001.