

STEP THERAPY POLICY

- POLICY:** Pulmonary – Short-Acting Beta₂-Agonist Inhalers Step Therapy Policy
- albuterol sulfate inhalation aerosol (generic to Ventolin[®] HFA)
 - ProAir[®] Digihaler[®] (albuterol sulfate inhalation powder – Teva)
 - ProAir[®] HFA (albuterol sulfate inhalation aerosol – Teva, generic)
 - ProAir[®] RespiClick (albuterol sulfate inhalation powder – Teva)
 - Proventil[®] HFA (albuterol sulfate inhalation aerosol – Merck, generic)
 - Xopenex HFA[®] (levalbuterol tartrate inhalation aerosol – Sunovion, generic)

REVIEW DATE: 12/06/2023

OVERVIEW

Inhaled short-acting beta₂-agonists are indicated for relief of acute **asthma** symptoms and prevention of **exercise induced bronchospasm**.¹⁻⁶ All of the short-acting beta₂-agonists inhalers are indicated in patients ≥ 4 years of age. The short-acting beta₂-agonist inhalers are all metered-dose inhalers that utilize a hydrofluoroalkane propellant, with the exception of ProAir Digihaler and ProAir RespiClick, which are dry-powder inhalers. All of the devices contain dose-counters. ProAir Digihaler is unique in that it contains a built-in electronic module which detects, records, and stores data on inhaler events, including peak inspiratory flow rate, for transmission to a mobile application where inhaler events are categorized.⁶ Use of the application is not required for administration and there are no data to show that the use of the application results in enhanced safety or effectiveness, or improved clinical outcomes.

All synthetic beta₂-agonists exist chemically as racemic mixtures; however, the therapeutic activity primarily resides in the R-enantiomers and not the S-enantiomers.¹ *In vitro* data have suggested a possible deleterious effect of the S-enantiomer of albuterol on airway smooth muscle responsiveness and other airway cells. Therefore, levalbuterol, which contains only the R-enantiomer of albuterol, was developed and approved for clinical use. Some studies suggested an improved efficacy of levalbuterol over racemic albuterol when administered in equal R-albuterol doses; however, other trials have failed to detect any advantage of levalbuterol.^{1,7,8}

Guidelines

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention (2023)¹² and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) Global Strategy for the Diagnosis, Management, and Prevention of chronic obstructive pulmonary disease (2023)¹³ do not prefer any one product in this category, but rather refer to them as a class of medications.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Note: Brand Ventolin HFA is not targeted in this policy.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic albuterol sulfate inhalation aerosol

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Step 2: albuterol sulfate inhalation aerosol (branded generics), levalbuterol tartrate inhalation aerosol (branded generics), ProAir Digihaler, ProAir HFA, ProAir RespiClick, Proventil HFA, Xopenex HFA

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient is unable to coordinate breath and actuation with a metered-dose inhaler, approve ProAir Digihaler or ProAir RespiClick.
3. No other exceptions are recommended.

REFERENCES

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2. Proventil[®] HFA inhalation aerosol [prescribing information]. Whitehouse Station, NJ: Merck; September 2017.
3. ProAir[®] RespiClick inhalation powder [prescribing information]. Horsham, PA: Teva; September 2020.
4. ProAir[®] HFA inhalation aerosol [prescribing information]. Horsham, PA: Teva; February 2019.
5. Xopenex HFA[®] inhalation aerosol [prescribing information]. Marlborough, MA: Sunovion; February 2017.
6. ProAir[®] Digihaler[®] inhalation powder [prescribing information]. Horsham, PA: Teva; September 2020.
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8. Jat KR, Khairwa A. Levalbuterol versus albuterol for acute asthma: a systematic review and meta-analysis. *Pulm Pharmacol Ther*. 2013;26(2):239-248.
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11. National Institutes of Health, National Heart, Lung, and Blood Institute. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2023. Available at: <http://www.goldcopd.org/>. Accessed on November 7, 2023.