



Policy:	Inhaled Short-Acting Beta2-Agonists (SABAs)	Annual Review Date: 12/15/2022
Impacted Drugs:	Proventil HFA (albuterol sulfate inhalation aerosol) Xopenex HFA (levalbuterol tartrate inhalation aerosol) Albuterol sulfate inhalation aerosol (branded generics) Levalbuterol tartrate (branded generics) Proair Digihaler (albuterol sulfate inhalation powder) ProAir HFA (albuterol sulfate inhalation aerosol) ProAir Respiclick (albuterol sulfate inhalation)	Last Revised Date: 12/15/2022

OVERVIEW

Inhaled short-acting beta2-agonist (SABAs) are the therapy of choice for relief of acute asthma symptoms and prevention of exercise induced bronchospasm. SABAs relax airway smooth muscle and cause a prompt increase in airflow. Through indicated and used in patients on a chronic basis for prevention of asthma symptoms, it is recommended that these agents be used only for the episodic relief of asthma symptoms on an as-needed basis.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

<u>Automation</u>: Patients with a history of one preferred drug within the 130-day look-back period are excluded from the policy requirements .

Preferred Medications

generic albuterol sulfate inhalation aerosol

Non-Preferred Medications

- Albuterol sulfate inhalation aerosol (branded generics)
- Levalbuterol tartrate authorized generics to Xopenex HFA
- Proair Digihaler (albuterol sulfate inhalation powder)
- ProAir HFA (albuterol sulfate inhalation aerosol)
- ProAir Respiclick (albuterol sulfate inhalation)
- Proventil HFA (albuterol sulfate inhalation aerosol)
- Xopenex HFA (levalbuterol tartrate inhalation aerosol)

PREFERRED STEP THERAPY CRITERIA

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- 1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.
- 2. If the patient is unable to coordinate breath and actuation with a metered-dose inhaler, approve ProAir RespiClick or ProAir Digihaler.

Initial Approval/ Extended Approval.

A) Initial Approval: 1 yearB) Extended Approval: 1 year

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 - 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
 - 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When <u>documentation</u> is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

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medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- 1. National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. Updated 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Accessed on: November 4, 2015.
- 2. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2021. Available at: http://www.ginasthma.org/. Accessed on: December 9, 2021.
- 3. 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 2021. Available at: http://www.goldcopd.org/. Accessed on: December 9, 2021.
- 4. Ventolin HFA Inhalation Aerosol [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
- 5. Proventil HFA inhalation aerosol [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2017.
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- 7. ProAir® HFA inhalation aerosol [prescribing information]. Horsham, PA: Teva Respiratory, LLC; February 2019.
- 8. Xopenex HFA® inhalation aerosol [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; February 2017.
- 9. Albuterol sulfate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 20 April 2020. Accessed on 11 August 2020.
- 10. Levalbuterol tartrate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 20 October 2017. Accessed on 14 August 2018.

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