BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

PROVENTIL® HFA (albuterol sulfate) inhalation aerosol
XOPENEX HFA® (levalbuterol tartrate) inhalation aerosol
LEVALBUTEROL HFA (levalbuterol tartrate) inhalation aerosol

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Proventil HFA (albuterol sulfate)
Xopenex HFA (levalbuterol tartrate)
Levalbuterol HFA (levalbuterol tartrate)

Medication class:
Antiasthmatic and Bronchodilator Agents - Sympathomimetics, Beta Adrenergics

FDA-approved indication(s):
- For the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

Recommended Dose:
- See Full Prescribing Information for important administration and dosage instructions.

Available Dosage Forms:
Proventil HFA:
- Inhalation Aerosol is supplied as a pressurized aluminum canister with a yellow plastic actuator and orange dust cap each in boxes of one. Each actuation delivers 120 mcg of albuterol sulfate from the valve and 108 mcg of albuterol sulfate from the mouthpiece (equivalent to 90 mcg of albuterol base). Canisters with a labeled net weight of 6.7 g contain 200 inhalations (NDC 0085-1132-01).

Xopenex HFA and Levalbuterol HFA:
- Inhalation Aerosol: Each actuation delivers 59 mcg of levalbuterol tartrate (equivalent to 45 mcg of levalbuterol free base) from the actuator mouthpiece. 15 g pressurized canister containing 200 actuations.

Warnings and Precautions:
- Life-threatening paradoxical bronchospasm may occur. Discontinue immediately and treat with alternative therapy.
- Need for more doses than usual may be a sign of deterioration of asthma and requires reevaluation of treatment.
- Cardiovascular effects may occur. Consider discontinuation if these effects occur. Use with caution in patients with underlying cardiovascular disorders.
- Excessive use may be fatal. Do not exceed recommended dose.
- Immediate hypersensitivity reactions may occur. Discontinue immediately.
- Hypokalemia and changes in blood glucose may occur.
- Xopenex HFA and Levalbuterol HFA are not a substitute for corticosteroids.

PROVENTIL® HFA (albuterol sulfate) inhalation aerosol
XOPENEX HFA® (levalbuterol tartrate) inhalation aerosol
LEVALBUTEROL HFA (levalbuterol tartrate) inhalation aerosol (cont.)

Criteria:

- **Criteria for initial therapy:** Proventil HFA, Xopenex HFA, or Levalbuterol HFA is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual has failure, contraindication, or intolerance to **BOTH** ProAir HFA or ProAir Respiclick **AND** Ventolin HFA.

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Proventil HFA, Xopenex HFA, or Levalbuterol HFA is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual has been adherent with the medication

  Renewal duration: 12 months

Resources:

Proventil HFA. Package Insert. Revised by manufacturer 10/2016. Accessed 10/27/17.

Xopenex HFA. Package Insert. Revised by manufacturer 2/2017. Accessed 10/27/17.

Levalbuterol HFA. Package Insert. Revised by manufacturer 3/2015. Accessed 10/27/17.

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.