

# QUANTITY LIMIT CRITERIA

**DRUG CLASS** SHORT ACTING BETA2-ADRENERGIC AGONIST ORAL INHALATION

**BRAND NAME**  
(generic)

(albuterol inhalation solution)

**PROAIR DIGIHALER**  
(albuterol)

**PROAIR HFA**  
(albuterol)

**PROAIR RESPICLICK**  
(albuterol)

**PROVENTIL HFA**  
(albuterol)

**VENTOLIN HFA**  
(albuterol)

**XOPENEX SOLUTION**  
(levalbuterol)

**XOPENEX CONCENTRATE**  
(levalbuterol)

**XOPENEX HFA**  
(levalbuterol)

**Status: CVS Caremark Criteria**

**Type: Quantity Limit**

## POLICY

### FDA-APPROVED INDICATIONS

**Albuterol Inhalation Solution 0.63mg/3mL (0.021%) and 1.25mg/3mL (0.042%)**

Albuterol sulfate inhalation solution is indicated for the relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease).

**Albuterol Inhalation Solution 0.083% (2.5mg/3mL)**

Albuterol sulfate inhalation solution 0.083% is indicated for the relief of bronchospasm in patients 2 years of age and older with reversible obstructive airway disease and acute attacks of bronchospasm.

**Albuterol Inhalation Solution 0.5% (2.5mg / 0.5mL)**

0.5mL Vial

Albuterol sulfate inhalation solution is indicated for the relief of bronchospasm in patients 12 year of age and older with reversible obstructive airway disease and acute attacks of bronchospasm.

20mL Bottle

Albuterol sulfate inhalation solution is indicated for the relief of bronchospasm in patients 2 years of age and older with reversible obstructive airway disease and acute attacks of bronchospasm.

#### **ProAir Digihaler**

##### Bronchospasm

ProAir Digihaler inhalation powder is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

##### Exercise-Induced Bronchospasm

ProAir Digihaler is indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

#### **ProAir HFA**

##### Bronchospasm

ProAir HFA Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

##### Exercise-Induced Bronchospasm

Proair HFA Inhalation Aerosol is indicated for the prevention of exercise induced bronchospasm in patients 4 years of age and older.

#### **ProAir Respiclick**

##### Bronchospasm

ProAir Respiclick is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

##### Exercise-Induced Bronchospasm

ProAir Respiclick is indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

#### **Proventil HFA**

Proventil HFA Inhalation Aerosol is indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

#### **Ventolin HFA**

##### Bronchospasm

Ventolin HFA is indicated for the treatment or prevention of bronchospasm in patients aged 4 years and older with reversible obstructive airway disease.

##### Exercise-Induced Bronchospasm

Ventolin HFA is indicated for the prevention of exercise-induced bronchospasm in patients aged 4 years and older.

#### **Xopenex Solution**

Xopenex (levalbuterol HCl) Inhalation Solution is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

#### **Xopenex Concentrate**

Xopenex (levalbuterol HCl) Inhalation Solution Concentrate is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.

#### **Xopenex HFA**

Xopenex HFA is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

## **REFERENCES**

1. Albuterol sulfate 0.63mg and 1.25mg inhalation solution [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2018.
2. Albuterol 0.083% inhalation solution [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; April 2017.
3. Albuterol 0.5% inhalation solution (0.5mL)[package insert]. Orlando, FL: Nephron Pharmaceuticals Corporation; February 2019.
4. Albuterol sulfate inhalation solution, 0.5% (20mL) [package insert]. Amityville, NY: HI-Tech Pharmacal Co., Inc.; February 2017.
5. ProAir Digihaler [package insert]. Frazer, PA: Teva Respiratory, LLC; October 2020.
6. ProAir HFA [package insert]. Frazer, PA: Teva Respiratory, LLC; August 2020.
7. ProAir Respiclick [package insert]. Horsham, PA: Teva Respiratory LLC; October 2020.
8. Proventil HFA [package insert]. Whitehouse Station, NJ: Merck&Co., Inc.; September 2017.
9. Ventolin HFA [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
10. Xopenex inhalation solution [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; December 2018.
11. Xopenex inhalation solution concentrate [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; December 2018.

12. Xopenex HFA [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; February 2017.
13. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed November 2020.
14. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed November 2020.

### **LIMIT CRITERIA**

**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

<b>Medication*</b>	<b>Maintenance Dose</b>	<b>Maximum Daily Dose</b>	<b>Package Size</b>	<b>1 Month Limit*</b> <b>3 Months Limit*</b>
Albuterol 0.63mg / 3mL, 1.25mg / 3mL (0.021%, 0.042%) Inhalation Soln	nebulization of 1 vial (3mL) three-four times daily	4 vials (3mL each)	25 vials (3mL each) per carton	5 packages (125 vials x 3mL) / 25 days 15 packages (375 vials x 3mL) / 75 days
			30 vials (3mL each) per carton	4 packages (120 vials x 3mL) / 25 days 12 packages (360 vials x 3mL) / 75 days
Albuterol 0.083%, 2.5mg / 3mL Inhalation Solution	nebulization of 1 vial (3mL) three-four times daily	4 vials (3mL each)	25 vials (3mL each) per carton	5 packages (125 vials x 3mL) / 25 days 15 packages (375 vials x 3mL) / 75 days
			30 vials (3mL each) per carton	4 packages (120 vials x 3mL) / 25 days 12 packages (360 vials x 3mL) / 75 days
			60 vials (3mL each) per carton	2 packages (120 vials x 3mL) / 25 days 6 packages (360 vials x 3mL) / 75 days
Albuterol 0.5%, 2.5mg / 0.5mL Inhalation Solution	nebulization of 0.25mL-0.5mL three-four times daily	2mL	20mL per bottle	3 packages (20mL each) / 25 days 9 packages (20mL each) / 75 days
			30 vials (0.5mL each) per carton	4 packages (120 vials x 0.5mL) / 25 days 12 packages (360vials x 0.5mL) / 75 days
ProAir Digihaler (albuterol)	1-2 inhalations every 4-6 hours	12 inhalations	200 inhalations per inhaler	2 packages / 25 days 6 packages / 75 days
ProAir HFA (albuterol)	1-2 inhalations every 4-6 hours	12 inhalations	200 inhalations per 8.5gm canister	2 packages (8.5gm each) / 25 days 6 packages (8.5gm each) / 75 days
ProAir RespiClick (albuterol)	1-2 inhalations every 4-6 hours	12 inhalations	200 inhalations per inhaler	2 packages / 25 days 6 packages / 75 days
Proventil HFA (albuterol)	1-2 inhalations every 4-6 hours	12 inhalations	200 inhalations per 6.7gm canister	2 packages (6.7gm each) / 25 days 6 packages (6.7gm each) / 75 days
Ventolin HFA (albuterol)	1-2 inhalations every 4-6 hours	12 inhalations	60 inhalations per 8gm canister	6 packages (8gm each) / 25 days 18 packages (8gm each) / 75 days
			200 inhalations per 18gm canister	2 packages (18gm each) / 25 days 6 packages (18gm each) / 75 days
Xopenex 0.31mg,0.63mg, 1.25 mg / 3 mL (levalbuterol)	nebulization of 1 vial (3mL) three times daily	3 vials (3mL each)	24 vials (3mL each) per carton	4 packages (96 vials x 3mL) / 25 days 12 packages (288 vials x 3mL) / 75 days
			25 vials (3mL each) per carton	4 packages (100 vials x 3mL) / 25 days 12 packages (300 vials x 3mL) / 75 days
			30 vials (3mL each) per carton	3 packages (90 vials x 3mL) / 25 days 9 packages (270 vials x 3mL) / 75 days
Xopenex Concentrate 1.25mg / 0.5mL (levalbuterol)	nebulization of 1 vial (0.5mL) three times daily	3 vials (0.5mL each)	30 vials (0.5mL each) per carton	3 packages (90 vials x 0.5mL) / 25 days 9 packages (270 vials x 0.5mL) / 75 days
Xopenex HFA (levalbuterol)	1-2 inhalations every 4 to 6 hours	12 inhalations	200 inhalations per 15gm canister	2 packages (15gm each) / 25 days 6 packages (15gm each) / 75 days

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.