

QUANTITY LIMIT CRITERIA

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

BRAND NAME

(generic) (albuterol inhalation solution)

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

Ref # 1086-H

FDA-APPROVED INDICATIONS

Albuterol Inhalation Solution 0.021% and 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%

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.

Albuterol Inhalation Solution 0.5%

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 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 (albuterol sulfate) inhalation powder is indicated for the treatment or prevention of bronchospasm in patients 12 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 12 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 4 years of age and older with reversible obstructive airway disease.

Exercise-Induced Bronchospasm

Ventolin HFA is indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age 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

XopenexHFA 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.

RATIONALE

If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that quantity limits are exceeded.

More frequent administration or higher doses or a larger number of inhalations is not recommended. If a previously effective dosage regimen fails to provide the usual response, this may be a marker of destabilization of asthma and requires reevaluation of the patient and the treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.

Albuterol Sulfate Inhalation Solution

0.021% and 0.042%

The usual starting dosage for patients 2 to 12 years of age is 1.25mg or 0.63mg of albuterol administered 3 or 4 times daily, as needed, by nebulization. Patients 6 to 12 years of age with more severe asthma, weight >40kg, or patients 11 to 12 years of age may achieve a better initial response with the 1.25mg dose.

Albuterol Sulfate Inhalation Solution 0.021%, 0.63mg, and 0.042%, 1.25mg, are supplied as 3mL unit-dose vials available in cartons containing 25 vials and 30 vials.

Albuterol Sulfate Inhalation Solution

0.083%

The usual dosage for adults and for children weighing at least 15kg is 2.5mg of albuterol (one vial) administered three to four times daily by nebulization. Children weighing < 15kg who require < 2.5mg/dose should use albuterol inhalation solution, 0.5% instead of albuterol inhalation solution, 0.083%.

Albuterol Sulfate Inhalation Solution 0.083%, 2.5mg/3mL, equivalent to 0.5mL albuterol 0.5% (2.5mg albuterol) diluted to 3mL, is supplied in cartons of 25 vials, 30 vials, and 60 vials.

Albuterol Sulfate Inhalation Solution

0.5%

For children 2 to 12 years of age, initial dosing should be based upon body weight (0.1 to 0.15 mg/kg per dose), with subsequent dosing titrated to achieve the desired clinical response. Dosing should not exceed 2.5mg three to four times daily by nebulization. The appropriate volume of the 0.5% inhalation solution should be diluted in sterile normal saline solution to a total volume of 3mL prior to administration via nebulization. The usual dosage for adults and children 12

years of age and older is 2.5mg of albuterol administered three to four times daily by nebulization. To administer 2.5mg of albuterol, dilute 0.5mL of the 0.5% inhalation solution with 2.5mL of sterile normal saline solution.

Albuterol Sulfate Inhalation Solution, 0.5%, 2.5mg / 0.5mL, is supplied in bottles of 20mL in a box of one and as 30 vials (0.5mL each) per carton.

ProAir HFA

For treatment of acute episodes of bronchospasm or prevention of symptoms associated with bronchospasm, the usual dosage for adults and children 4 years and older is two inhalations repeated every 4 to 6 hours. In some patients, one inhalation every 4 hours may be sufficient. For prevention of exercise-induced bronchospasm the usual dosage for adults and children 4 years of age or older is two inhalations 15 to 30 minutes before exercise.

ProAir HFA Inhalation Aerosol is supplied as an 8.5g canister in boxes of one providing 200 actuations.

ProAir RespiClick

For treatment of acute episodes of bronchospasm or prevention of symptoms associated with bronchospasm, the recommended dosage for adults and adolescents 12 years and older is 2 inhalations repeated every 4 to 6 hours. More frequent administration or a larger number of inhalations is not recommended. In some patients, 1 inhalation every 4 hours may be sufficient. For prevention of exercise-induced bronchospasm, the recommended dosage for adults and adolescents 12 years of age or older is 2 inhalations 15 to 30 minutes before exercise.

ProAir RespiClick inhalation powder is supplied as an inhaler in boxes of one and provides 200 actuations.

Proventil HFA

For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage for adults and children 4 years of age and older is two inhalations repeated every 4 to 6 hours. In some patients, one inhalation every 4 hours may be sufficient. For exercise induced bronchospasm prevention, the usual dosage for adults and children 4 years of age and older is two inhalations 15 to 30 minutes before exercise.

Proventil HFA Inhalation Aerosol is supplied as a canister with net weight of 6.7g containing 200 inhalations.

Ventolin HFA

For treatment of acute episodes of bronchospasm or prevention of symptoms associated with bronchospasm, the usual dosage for adults and children is 2 inhalations repeated every 4 to 6 hours; in some patients, 1 inhalation every 4 hours may be sufficient. For the prevention of exercise-induced bronchospasm the usual dosage for adults and children 4 years of age and older is 2 inhalations 15 to 30 minutes before exercise.

Ventolin HFA is supplied as an 18g canister containing 200 actuations, and as an 8g canister containing 60 actuations.

Xopenex Solution

The recommended dosage of Xopenex Inhalation Solution for patients 6–11 years old is 0.31mg administered three times a day, by nebulization. Routine dosing should not exceed 0.63mg three times a day. The recommended starting dosage of Xopenex Inhalation Solution for patients 12 years of age and older is 0.63mg administered three times a day, by nebulization. Patients 12 years of age and older with more severe asthma or patients who do not respond adequately to a dose of 0.63mg of Xopenex Inhalation Solution may benefit from a dosage of 1.25mg three times a day.

Xopenex Inhalation Solution is available in 3mL vials in strengths of 0.31mg, 0.63mg, and 1.25mg in a carton containing 24 unit-dose vials. Levalbuterol Inhalation Solution is also available as 25 vials (3mL each) per carton.

Xopenex Concentrate

Patients 12 years of age and older with more severe asthma or patients who do not respond adequately to a dose of 0.63mg of Xopenex Inhalation Solution may benefit from a dosage of 1.25mg three times a day.

For dosages less than 1.25mg, the non-concentrate (i.e., Xopenex Inhalation Solution, 3 mL) formulation must be used.

Xopenex Inhalation Solution Concentrate is to be diluted with sterile normal saline before administration by nebulization.

Xopenex Inhalation Solution Concentrate is supplied in 0.5mL unit-dose vials containing 1.25mg of levalbuterol and is available in cartons of 30 vials.

Xopenex HFA

For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage of Xopenex HFA for adults and children 4 years of age and older is 2 inhalations (90 mcg) repeated every 4 to 6 hours; in some patients, 1 inhalation every 4 hours may be sufficient.

Xopenex HFA is supplied as a canister with a net weight of 15gm containing 200 metered actuations.

REFERENCES

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10. Proventil HFA [package insert]. Whitehouse Station, NJ: Merck&Co., Inc.; December 2014.
11. Ventolin HFA [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2014.
12. Xopenex inhalation solution [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; January 2015.
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14. Xopenex HFA [package insert]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; March 2015.

Written by: UM Development (KB)

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LIMIT CRITERIA

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.

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

*The limit criteria apply to both brand and generic, if available.