



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 26, 2009 January 25, 2010; February 28, 2012; June 20, 2012, March 30, 2015

Xopenex® (levalbuterol) solutions for inhalation and HFA

Length of Authorization: Up to one year

Review Criteria:

- Trial and failure of all of the following when request for Xopenex solution for inhalation: (must provide supporting documentation):
 1. Rescue or maintenance therapy: Trial of the correct therapeutically equivalent dose of racemic albuterol as compared to the requested levalbuterol dose (or a lower concentration if applicable):
 - 2.5mg/3ml Albuterol = 1.25mg/3ml Xopenex
 - 1.25mg/3ml Albuterol (generic for Accuneb) = 0.63mg/3ml Xopenex
 - 0.63mg/3ml Albuterol (generic for Accuneb) = 0.31mg/3ml Xopenex
 2. Rescue or maintenance therapy: Reduction of nebulization therapy time of Albuterol Sulfate to 5 minutes.
 3. Maintenance therapy: Combination maintenance therapy (i.e. inhaled corticosteroid, long acting beta agonist, leukotriene inhibitors, steroids, etc.) if request is due to failure of Albuterol therapy in a chronic condition.
- Trial and failure of the following(as applicable) when request for Xopenex HFA: (must provide supporting documentation):
 1. Rescue or maintenance therapy: Albuterol HFA with spacer if request is due to failure of Albuterol therapy.
 2. Maintenance therapy: Combination maintenance therapy (i.e. inhaled corticosteroid, long acting beta agonist, leukotriene inhibitors, steroids, etc.) if request is due to failure of Albuterol therapy in a chronic condition.

Quantity Limit:

Solution for Inhalation: Maximum of 288 mL per 30 days.

HFA Inhaler: 2 inhalers/month.

Dosing:

Oral inhalation dosage (levalbuterol nebulizer solution):

Adults, Adolescents, and Children ≥ 12 years: The usual starting dose is 0.63 mg inhaled by nebulization three times per day, given every 6—8 hours. Patients with more severe asthma or patients who do not respond adequately to a dose of 0.63 mg may benefit from a dosage of 1.25 mg by nebulization three times per day.

Children 6—11 years: The usual starting dose is 0.31 mg inhaled by nebulization three times per day, given every 6—8 hours. For routine dosing, do not exceed 0.63 mg three times per day.

Children < 6 years†: Safe and effective use has not been established.



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Oral inhalation dosage (levalbuterol metered-dose inhaler):

Adults and Adolescents: 90 mcg (2 inhalations) every 4—6 hours; in some patients.

Children 4—12 years: 90 mcg (2 inhalations) every 4—6 hours; in some patients.

Children < 4 years†: Safe and effective use has not been established.