Division: Pharmacy Policy	Subject: 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, February 9, 2024

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.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as solution for inhalation (unit-dose vial for nebulization) 0.31 mg/3 mL, 0.63 mg/3 mL and 1.25 mg/3 mL and HFA inhalation aerosol 15 g pressurized canister containing 200 actuations (each actuation delivers 59 mcg of levalbuterol tartrate)

QUANTITY LIMIT:

- Solution for inhalation: Maximum of 288 mL per 30 days.

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- HFA inhalation aerosol: 2 inhalers/month.