

### Clinical Pharmacy Program Guidelines for Xopenex Respules

Program	Step Therapy
Medication	Xopenex (levalbuterol HCl inhalation solution)
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

**1. Background:**

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.

**2. Coverage Criteria:**

<p><b>A. <u>Automated Step Therapy Criteria</u></b></p> <p>1. A claim for Xopenex inhalation solution will process at the point of sale if the patient’s drug fill history shows a previous trial of <b><u>one</u></b> of the following:</p> <p style="margin-left: 40px;">a. Albuterol 0.083% inhalation solution</p> <p style="text-align: center;"><b>-OR-</b></p> <p style="margin-left: 40px;">b. Albuterol 0.5% inhalation solution</p> <p><b>B. <u>Requests That DO NOT Meet Automated Step Criteria</u></b></p> <p>1. Xopenex inhalation solution will be approved for patients who have not met the automated step criteria when the following circumstance is met:</p> <p style="margin-left: 40px;">a. The patient has a history of failure, contraindication, or intolerance to treatment with albuterol inhalation solution</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p>
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**3. References:**

1. Xopenex Inhalation Solution® Prescribing Information. Sunovion Pharmaceutical Inc., September 2012.
2. Clinical Pharmacology Gold Standard. 2012.
3. Facts and Comparisons 4.0; 2012.

Program	Step Therapy –Xopenex Respules
<b>Change Control</b>	
Date	Change
6/2009	New policy
9/2012	Revision
12/2016	Annual review, updated policy template and added standard 12 month authorization duration
11/2017	Combined the criteria for requests that do not meet step therapy into one section to match language found in other policies. Updated references.