



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 12, 2012 January 22, 2018

LONG-ACTING BETA AGONISTS

- **Arcapta (indacaterol)**
- **Brovana (arformoterol)**
- **Foradil (formoterol)**
- **Perforomist (formoterol)**
- **Serevent (salmeterol)**

LENGTH OF AUTHORIZATION: Up to one year

CLINICAL NOTES:

The U.S. Food and Drug Administration issued a public health advisory announcing that drugs in the class of long-acting beta agonists (LABAs) should never be used alone in the treatment of asthma in children or adults. Manufacturers have been required to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medications.

These new requirements are based on FDA analysis of data from a large placebo-controlled US study that compared the safety of salmeterol or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. The finding of an increased risk of asthma related death with salmeterol is considered a class-effect of LABA including Arcapta (indacaterol), Brovana (arformoterol), Foradil (formoterol), Perforomist (formoterol) and Serevent (salmeterol).

The FDA now requires that the product labels reflect the following:

- The use of LABAs is contraindicated without the use of an asthma controller medication such as inhaled corticosteroid. Single-agent LABAs should only be used in combination with an asthma controller medication; they should not be used alone;
- LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications;
- LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.
- Pediatric and adolescent patients who require a LABA in addition to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA to ensure compliance with both medications.

LABAs are approved to treat both people with asthma or with chronic obstructive pulmonary disease (COPD). The new recommendations only apply to the use of LABAs in the treatment of asthma.

REVIEW CRITERIA:

1. Patient must be ≥ 18 years of age for Arcapta, Brovana, and Perforomist; ≥ 5 years of age for Foradil; and ≥ 4 years of age for Serevent.
2. Must have a documented diagnosis (in medical records or diagnoses codes) of asthma or chronic obstructive pulmonary disease (eg. chronic bronchitis, emphysema).



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- For Asthma – all criteria requirements must be met
 - For COPD - #1 and #2 must be met only.
3. Patients with diagnosis of asthma (not COPD) must be currently on at least one other asthma controller medication (in medical records or claims history):
- Inhaled corticosteroids
 - Extended release theophylline
 - Mast-cell stabilizers
 - Leukotriene modifiers