

Policies Repository



Policy Title Budesonide/Formoterol Fumarate Dihydrate (Symbicort®)

Policy Number FS.CLIN.55

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Budesonide/formoterol fumarate dihydrate (Symbicort®)** is indicated for the long-term maintenance treatment of asthma in individuals 12 years of age and older and for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

The use of budesonide/formoterol fumarate dihydrate (Symbicort®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Budesonide/formoterol fumarate dihydrate (Symbicort®) inhalation aerosol** is a combination corticosteroid (budesonide) and long-acting selective beta2-adrenergic agonist (formoterol) that maintains control of airway inflammation and dilation of airways. Budesonide exhibits a wide range of actions on multiple cell types and mediators involving allergic and irritant-mediated inflammation; formoterol relaxes bronchial smooth muscle and blocks the release of hypersensitivity mediators.

Policy Guideline Inclusion **Budesonide/formoterol fumarate dihydrate (Symbicort®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of **one** of the following:
 - Diagnosis of asthma in patients 12 years of age and older
 - Diagnosis of chronic obstructive pulmonary disease (COPD)
- Documentation of trial and failure of or contraindication/intolerance/allergy to concurrent use of a long-acting beta2-agonist and an inhaled corticosteroid

Policy Guideline Exclusion **Budesonide/formoterol fumarate dihydrate (Symbicort®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of **one** of the following:
 - Diagnosis of asthma in patients 12 years of age and older
 - Diagnosis of chronic obstructive pulmonary disease (COPD)
- No documentation of trial and failure of or contraindication/intolerance/allergy to concurrent use of a long-acting beta2-agonist and an inhaled corticosteroid

Policy List of Applicable Drugs

Brand Name	Generic Name
Symbicort	budesonide/formoterol fumarate dihydrate

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Facts & Comparisons. Symbicort®. [Facts & Comparisons Web site]. Available at: <http://online.factsandcomparisons.com> [via subscription only]. Accessed March 5, 2009.

Micromedex. Symbicort®. [Micromedex web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed March 5, 2009.

National Heart, Lung, and Blood Institute (NHLBI). Clinical Practice Guidelines. Guidelines for the diagnosis and management of asthma (EPR-3). [NHLBI Web site]. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/index.htm>. Accessed March 5, 2009.

Symbicort® [package insert]. Wilmington, DE: AstraZeneca; 2007. Also available online at: <http://www.astrazeneca-us.com/pi/symbicort.pdf>. Revised 2/09. Accessed March 5, 2009.

Policy Link to Related Policies

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