

## Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

### **Therapeutic class:**

Oral inhaled corticosteroids

### **Overview:**

Asthma is a chronic inflammatory disorder of the airways that contributes to airway hyperresponsiveness and airflow limitation. Airflow limitation is comprised of acute bronchoconstriction, airway edema, mucus plug formation and airway wall remodeling. These features lead to bronchial obstruction. The immunohistopathologic features responsible for this inflammation process consist of denudation of airway epithelium, collagen deposition beneath basement membrane, edema, mast cell activation, and inflammatory cell infiltration by cells such as neutrophils, eosinophils and lymphocytes.

Pharmacologic therapy helps prevent and control asthma symptoms, reduce the frequency and severity of exacerbations, and reverse airflow obstruction. Both acute and maintenance medications are used to achieve and maintain control of persistent asthma. Corticosteroids have consistently demonstrated effectiveness for long-term control of asthma by reducing symptom severity, improving peak expiratory flow, diminishing airway hyperresponsiveness and potentially preventing airway wall remodeling.

The oral corticosteroid inhaler therapeutic class is comprised of several medications with numerous delivery systems. All agents within this class are indicated for the chronic treatment of asthma in adults while treatment ages for pediatric patients vary. The agents within this class are similar in terms of efficacy and safety. Advair is also indicated for the treatment of chronic obstructive pulmonary disease (COPD). Long-acting beta<sub>2</sub>-adrenergic agonists, such as salmeterol, one of the active ingredients in Advair<sup>®</sup> Diskus/ Advair<sup>®</sup> HFA, may increase the risk of asthma-related death. Therefore, when treating patients with asthma, physicians should only prescribe Advair<sup>®</sup> Diskus/Advair<sup>®</sup> HFA for patients not adequately controlled on other asthma-controller medications (eg, low- to medium-dose inhaled corticosteroids) or whose disease severity clearly warrants initiation of treatment with 2 maintenance therapies. Asmanex<sup>®</sup> Twisthaler<sup>®</sup> is a new mometasone product and is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Asmanex is also indicated for the treatment of asthma patients who require oral corticosteroid therapy, where adding Asmanex therapy may reduce or eliminate the need for oral corticosteroids. Beclomethasone products Vanceryl<sup>®</sup>, Vanceryl<sup>®</sup> DS, and Beclovent<sup>®</sup> are no longer available in the United States, however, QVAR<sup>®</sup> is currently marketed. Flunisolide is now available in an HFA formulation; Aerospan<sup>™</sup> HFA. Pulmicort Turbuhaler will soon be phased out and replaced with Pulmicort Flexhaler, which comes in different strengths, and has a dose counter.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Pediatric Indication</b>	<b>Manufacturer</b>
Beclomethasone Dipropionate HFA	QVAR <sup>®</sup>	≥ 5 Years of Age	IVAX
Triamcinolone	Azmacort <sup>®</sup>	≥ 6 Years of Age	Abbott
Flunisolide	AeroBID <sup>®</sup> , AeroBID <sup>®</sup> -M, Aerospan <sup>™</sup> HFA	≥ 6 Years of Age	Forest
Fluticasone	Flovent <sup>®</sup> Diskus, Flovent <sup>®</sup> HFA	≥ 4 Years of Age	Glaxo SmithKline
Budesonide	Pulmicort Turbuhaler <sup>®</sup> , Pulmicort Respules <sup>®</sup> , Pulmicort Flexhaler <sup>®</sup>	≥ 1 Year of Age	AstraZeneca
Mometasone Furoate	Asmanex <sup>®</sup> Twisthaler <sup>®</sup>	≥ 12 years of Age	Schering
Fluticasone/salmeterol	Advair <sup>®</sup> , Advair <sup>®</sup> HFA*	≥ 4 Years of Age	Glaxo SmithKline

\*Information on Advair<sup>®</sup> is discussed in a separate monograph.

**Summary:**

The oral steroid inhalers include the following agents: beclomethasone dipropionate HFA (QVAR<sup>®</sup>), triamcinolone (Azmacort<sup>®</sup>), flunisolide (AeroBID<sup>®</sup>, AeroBID<sup>®</sup>-M, Aerospan<sup>™</sup> HFA), fluticasone (Flovent<sup>®</sup> Diskus, Flovent<sup>®</sup> HFA), budesonide (Pulmicort Flexhaler<sup>®</sup>, Pulmicort Turbuhaler<sup>®</sup>, Pulmicort Respules<sup>®</sup>), mometasone furoate (Asmanex<sup>®</sup> Twisthaler<sup>®</sup>), fluticasone/salmeterol (Advair<sup>®</sup> HFA). These agents decrease airway hyperresponsiveness by blocking late reaction to allergens, inhibit cytokine production, adhesion protein activation, and inflammatory cell migration and activation, reverse beta<sub>2</sub>-receptor down-regulation, and inhibit microvascular leakage. The agents within this class are similar in terms of efficacy and safety; however, Long-acting beta<sub>2</sub>-adrenergic agonists, such as salmeterol, one of the active ingredients in Advair<sup>®</sup> Diskus/Advair<sup>®</sup> HFA, may increase the risk of asthma-related death. Advair<sup>®</sup> Diskus/Advair<sup>®</sup> HFA should be added to the asthma treatment plan only if other medicines do not control asthma, including the use of low-or-medium dose corticosteroids.