Title: Inhaled Corticosteroid (ICS)
Policy #: Rx.01.152

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

**Intent:**
The intent of this policy is to communicate the medical necessity criteria for Inhaled corticosteroids (fluticasone proionate [Flovent HFA/Diskus®], ciclesonide [Alvesco®], budesonide [Pulmicort Flexhaler®], flunisolide [Aerospan®], and Fluticasone furoate [Arnuity™ Ellipta®]) as provided under the member’s pharmacy benefit.

**Description:**
Inhaled corticosteroids are indicated for the treatment of asthma as prophylactic therapy in adult patient to reduce or eliminate the need for oral corticosteroids in steroid-dependent asthma patients. Corticosteroids may have direct inhibitory effects on many cells involved in airway inflammation in asthma (e.g., macrophages, T lymphocytes, eosinophils, airway epithelial cells). In vitro, corticosteroids decrease cytokine-mediated survival of eosinophils, reducing the number of eosinophils in the circulation and airways of patients with asthma during corticosteroid therapy. While corticosteroids may not inhibit the release of mast cells in an allergic reaction, they do reduce the number of mast cells within the airway. Corticosteroids may also inhibit plasma exudation and the secretion of mucus in inflamed airways.
Inhaled corticosteroids have anti-inflammatory effects of the bronchial mucosa in asthma patients. Treatment with inhaled corticosteroids for 1 to 3 months results in a reduction in mast cells, macrophages, T lymphocytes, and eosinophils in the epithelium and submucosa in the bronchioles. By reducing airway inflammation, inhaled corticosteroids lessen airway hyperresponsiveness in asthmatic adults and children. Long-term therapy reduces airway responsiveness to histamine cholinergic agonists and allergens. Treatment also lowers responsiveness to exercise, fog, cold air, bradykinin, adenosine, and irritants. Inhaled corticosteroids make the airways less sensitive to these spasmogens and limit the maximal narrowing of the airway. Maximal effects of inhaled corticosteroid treatment may not be seen for several months.

**Policy:**
Fluticasone propionate (Flovent (HFA/Diskus®), ciclesonide (Alvesco®), budesonide (Pulmicort Flexhaler®), flunisolide (Aerospan®), and Fluticasone furoate [Arnuity™ Ellipta®]) are approved as follows:

1. Diagnosis of asthma AND
2. Inadequate response or inability to tolerate ONE of the following:
   a. Asmanex
   b. Qvar

**Black Box Warning:**
None

**Guidelines:**
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
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<tr>
<td>Flovent® (HFA/Diskus)</td>
<td>fluticasone propionate</td>
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<tr>
<td>Pulmicort Flexhaler®</td>
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<tr>
<td>Aerospan®</td>
<td>flunisolide</td>
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<td>Arnuity™ Ellipta®</td>
<td>fluticasone furoate</td>
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**Cross References:**
<table>
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<th>Policy Version Number:</th>
<th>5.00</th>
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<tr>
<td>P&amp;T Approval Date:</td>
<td>October 13, 2016</td>
</tr>
<tr>
<td>Policy Effective Date:</td>
<td>December 01, 2016</td>
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<td>Next Required Review Date:</td>
<td>October 13, 2017</td>
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