This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutic Subcommittee.

**Drugs:** budesonide/formoterol (Symbicort), ciclesonide (Alvesco), fluticasone/salmeterol (Advair Diskus, Advair HFA), fluticasone/vilanterol (BREO ELLIPTA), mometasone/formoterol (Dulera), fluticasone (ARNUITY ELLIPTA)

**Class:** Inhaled Corticosteroids (ICS)

**Formulary Medications:** beclomethasone (QVAR), budesonide (Pulmicort Respules, Pulmicort Flexhaler), fluticasone (Flovent HFA, Flovent Diskus), mometasone (Asmanex)

**Line of business:** Non-Medicare

**Effective Date:** August 2015

**Revision Date:** August 2015

**Policy/Criteria:**

1. **Ciclesonide (Alvesco)**
   a. Diagnosis of persistent asthma
      • Failure of two formulary ICS (e.g. Asmanex, QVAR, Flovent, Pulmicort, etc.) for two consecutive months, unless contraindicated

2. **Budesonide/formoterol (Symbicort), fluticasone/salmeterol (Advair Diskus)**
   a. Diagnosis of persistent asthma
      • Failure of two formulary ICS (e.g. Asmanex, QVAR, Flovent, Pulmicort, etc.) for two consecutive months, unless contraindicated
      OR
   b. Diagnosis of high risk chronic obstructive pulmonary disease (COPD)
      • Failure of one formulary long-acting inhaled anticholinergic (e.g. Tudorza, Incruse Ellipta) or long-acting beta-agonist (e.g. Serevent), unless contraindicated

3. **Fluticasone/salmeterol (Advair HFA), mometasone/formoterol (Dulera)**
   a. Diagnosis of persistent asthma
      • Failure of two formulary ICS (e.g. Asmanex, QVAR, Flovent, Pulmicort, etc.) for two consecutive months, unless contraindicated

4. **Fluticasone/vilanterol (BREO ELLIPTA)**
   a. Diagnosis of persistent asthma
      • Failure of two formulary ICS (e.g. Asmanex, QVAR, Flovent, Pulmicort, etc.) for two consecutive months, unless contraindicated
      OR
b. Diagnosis of high risk chronic obstructive pulmonary disease (COPD)
   • Failure of one formulary long-acting inhaled anticholinergic (e.g. Tudorza, Incruse Ellipta) or long-acting beta-agonist (e.g. Serevent), unless contraindicated

5. Fluticasone (ARNUITY ELLIPTA)
   a. Diagnosis of persistent asthma
      • Failure of two formulary ICS (e.g. Asmanex, QVAR, Flovent, Pulmicort, etc.) for two consecutive months, unless contraindicated

Clinical Justification:
Guidelines:
1. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, long-term treatment with inhaled corticosteroids added to long-acting bronchodilators is recommended for patients at high risk of exacerbations; and long-term monotherapy with oral or inhaled corticosteroids is not recommended in COPD.
2. According to the National Asthma Education and Prevention Program Expert Panel Report 3 (NAEPP EPR-3), inhaled corticosteroids are first-line controller agents for the management of persistent asthma. Inhaled corticosteroids reduce the frequency of symptoms, improve quality of life, and decrease the risk of serious exacerbations of asthma. Combination use of LABA and inhaled corticosteroids is recommended for children whose asthma is not well controlled with medium-dose inhaled corticosteroids.
3. If a patient’s asthma is not well controlled, providers must assess medication adherence, inhaler technique, and environmental control (avoiding known triggers) before stepping up therapy. Stepping down therapy is recommended if symptoms become infrequent. After change in therapy, patients should be reevaluated in two to six weeks.

Comparison of FDA-Approved Indications

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<tr>
<th></th>
<th>Breo Ellipta</th>
<th>Symbicort</th>
<th>Advair Diskus</th>
<th>Advair HFA</th>
<th>Dulera</th>
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<tr>
<td>COPD maintenance therapy</td>
<td>X</td>
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<tr>
<td>Reduction of COPD exacerbations</td>
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<td>Asthma treatment (age &gt; 12 years)</td>
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<td>Asthma treatment (age 4-11 years)</td>
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<th></th>
<th>Qvar</th>
<th>Pulmicort</th>
<th>Alvesco</th>
<th>Aero span and AeroBid</th>
<th>Flovent HFA</th>
<th>Asmanex Twishaler</th>
<th>Arnuity ELLIPTA</th>
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<td>Asthma maintenance therapy as prophylaxis</td>
<td>X</td>
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<td>Patients requiring systemic corticosteroids, whom ICS may</td>
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**Additional Considerations:**

1. Mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort) and fluticasone/salmeterol (Advair) have similar efficacy and safety for chronic asthma maintenance therapy, confirmed by a Cochrane review conducted by Lasserson and the Oregon Drug Effectiveness Review Project. These agents offer the convenience of a combination inhaler. Dulera has fewer FDA-approved indications. According to the National Institute for Health and Clinical Excellence, “if a combination device is chosen then the least costly device that is suitable for the individual is recommended.”

2. Fluticasone/vilanterol (BREO ELLIPTA) is the once-daily inhalation powder for the management of COPD and asthma. There is insufficient data comparing Breo Ellipta to other inhaled corticosteroid and long acting beta-agonist combination products approved for COPD.

3. Ciclesonide (Alvesco) is a new inhaled corticosteroid that may be associated with less systemic effect on endogenous cortisol, when assessed once-daily administration. Nevertheless, there is insufficient data on efficacy and safety comparing twice-daily administration with other usual regimens of inhaled corticosteroids. As of now, due to the lack of comparative data, the advantage of ciclesonide over other agents is not well established.

4. Fluticasone (Arnuity ELLIPTA) is the once-daily inhalation powder that is another alternative for the treatment of asthma. It contains fluticasone furoate (not propionate).

**References:**

1. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (Updated 2015) @ Global Initiative for Chronic Obstructive Lung Disease, Inc.