Clinical Policy: Ciclesonide (Alvesco)
Reference Number: HIM.PA.65
Effective Date: 09.01.18
Last Review Date: 08.19
Line of Business: HIM

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Ciclesonide (Alvesco®) is an inhaled corticosteroid.

FDA Approved Indication(s)
Alvesco is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.

Limitation(s) of use: Alvesco is not indicated for the relief of acute bronchospasm.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Alvesco is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Asthma (must meet all):
      1. Diagnosis of asthma;
      2. Age ≥ 12 years;
      3. Failure of one formulary inhaled corticosteroid (e.g., Asmanex® Twisthaler®, Flovent®, Pulmicort Flexhaler®, QVAR®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      4. Dose does not exceed 640 mcg per day (2 inhalers per 30 days).

   Approval duration: 12 months

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy
   A. Asthma (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 640 mcg per day (2 inhalers per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asmanex Twisthaler (mometasone)</td>
<td>Starting dose for patients ≥ 12 years who received bronchodilators or inhaled corticosteroids: 220 mcg inhaled QD in the evening</td>
<td>440 mcg/day (can be administered as 220 mcg BID or 440 mcg QD)</td>
</tr>
<tr>
<td></td>
<td>Starting dose for patients ≥ 12 years who received oral corticosteroids: 440 mcg inhaled BID</td>
<td>880 mcg/day</td>
</tr>
<tr>
<td></td>
<td>Starting dose for patients 4-11 years: 110 mcg inhaled QD in the evening</td>
<td>110 mcg/day</td>
</tr>
<tr>
<td>Flovent Diskus (fluticasone)</td>
<td>≥ 12 years: 100 mcg inhaled BID 4-11 years: 50 mcg inhaled BID</td>
<td>≥ 12 years: 2000 mcg/day 4-11 years: 200 mcg/day</td>
</tr>
<tr>
<td>Flovent HFA (fluticasone)</td>
<td>88 mcg inhaled BID</td>
<td>≥ 12 years: 1760 mcg/day 4-11 years: 176 mcg/day</td>
</tr>
<tr>
<td>Pulmicort Flexhaler (budesonide)</td>
<td>≥ 18 years: 360 mcg inhaled BID 6-17 years: 180 mcg inhaled BID; some patients may start with adult dosing</td>
<td>≥ 18 years: 1440 mcg/day 6-17 years: 720 mcg/day</td>
</tr>
<tr>
<td>QVAR, QVAR RediHaler (beclomethasone)</td>
<td>≥ 12 years: 40 mcg, 80 mcg, 160 mcg, or 320 mcg inhaled BID</td>
<td>≥ 12 years: 640 mcg/day 4-11 years: 160 mcg/day</td>
</tr>
</tbody>
</table>
Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): status asthmaticus or other acute episodes of asthma where intensive measures are required, known hypersensitivity to ciclesonide or any of the ingredients of Alvesco
- Boxed warning(s): none reported

Appendix D: General Information

- Use in pediatric patients < 12 years of age: Two identically designed randomized, double-blind, parallel, placebo-controlled clinical trials of 12-weeks treatment duration were conducted in 1018 patients aged 4 to 11 years with asthma but efficacy was not established. In addition, one randomized, double-blind, parallel, placebo-controlled clinical trial did not establish efficacy in 992 patients aged 2 to 6 years with asthma.
- Historical management of asthma has involved an as-needed short-acting beta agonist for reliever therapy, with stepwise approach to add on controller maintenance therapies such as inhaled corticosteroids and long-acting beta agonists. The 2019 Global Initiative for Asthma (GINA) pocket guidelines for asthma management and prevention now recommend that inhaled corticosteroids be initiated as soon as possible after diagnosis of asthma, including use as reliever therapy (to be administered as-needed alongside a short-acting beta agonist).

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Starting dose for patients who received bronchodilators alone: 80 mcg inhaled BID</td>
<td>320 mcg/day</td>
</tr>
<tr>
<td></td>
<td>Starting dose for patients who received inhaled corticosteroids: 80 mcg inhaled BID</td>
<td>640 mcg/day</td>
</tr>
<tr>
<td></td>
<td>Starting dose for patients who received oral corticosteroids: 320 mcg inhaled BID</td>
<td>640 mcg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability
Inhalation aerosol: 80 mcg/actuation, 160 mcg/actuation

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>3Q 2018 annual review: policy split from HIM.PA.73 Inhaled corticosteroids to individual Alvesco policy; no significant changes; age added; quantity limit added based on maximum dose; references reviewed and updated.</td>
<td>04.17.18</td>
<td>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>04.22.19</td>
<td>08.19</td>
</tr>
</tbody>
</table>

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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