Clinical Policy: Topical Steroid Use For Eosinophilic Esophagitis

Reference Number: GA.PMN.11
Effective Date: 09/01/16
Last Review Date: 4/2021
Line of Business: Medicaid

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

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® medical policy for the use of Pulmicort Respules, Flovent and Alvesco for the treatment of eosinophilic esophagitis (EoE).

FDA Approved Indication(s)
- Budesonide (Pulmicort Respules®) is indicated for maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.
- Ciclesonide (Alvesco®) is indicated for maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.
- Fluticasone (Flovent HFA) is indicated for maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older.

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 Pulmicort Respules, Flovent HFA and Alvesco are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Eosinophilic Esophagitis (must meet all):
      1. Diagnosis of eosinophilic esophagitis (EoE);
      2. Prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist;
      3. Failure of an 8-week trial of a proton pump inhibitor (PPI) at up to maximally indicated doses (Adults: 20-40mg twice daily omeprazole equivalent, Children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced;
      4. If Alvesco is requested, medical justification supports inability to use Flovent and Pulmicort Respules;
      5. Dose does not exceed recommended dosing regimens and medication will be swallowed.

Approval Duration: 2 months
B. Other diagnosis/indication
Not applicable

II. Continued Therapy
A. Eosinophilic Esophagitis (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Prescription records or chart notes documenting continued adherence to therapy since last authorization;
   3. For relapse, prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval;
   4. For non-responders, prior authorization form or chart notes documenting lack of response since last approval;
   5. For maintenance, request meets one of the following:
      a. Severe dysphagia or food impaction
      b. High grade esophageal stricture
      c. Rapid symptomatic/histological relapse after initiation

Approval duration:
For relapse - 6 months
For non-responders - 6 months
For maintenance - 12 months

B. Other diagnosis/indication
Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized:
Not applicable

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
EoE: Eosinophilic Esophagitis
FDA: Food and Drug Administration
GERD: gastroesophageal reflux disease
IgE: immunoglobulin E
PPI: proton pump inhibitor

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: General Information
Eosinophilic esophagitis is a chronic immunological condition that involves inflammation of the esophagus. The disease can happen at any age with patients typically presenting in childhood (mean age 8.6 years) or in the third or fourth decade of life. Males are three times more likely to have a diagnosis of eosinophilic esophagitis than females. Signs and symptoms of esophageal dysfunction include unexplained feeding difficulties, vomiting, solid-food dysphagia, esophageal strictures and GERD-like symptoms. Children with eosinophilic esophagitis are more
likely to display GERD-like symptoms than adults. The exact cause of eosinophilic esophagitis is unknown; however, there is a strong association with other immunologic conditions such as asthma, allergic rhinitis, IgE mediated food allergy and atopic dermatitis. Topical steroids are first line therapy for patients with eosinophilic esophagitis. Goals of treatment are improvement in symptoms and inflammation. The following glucocorticoids were studied in patients with eosinophilic esophagitis: fluticasone metered dose inhaler, budesonide and ciclesonide. In children, swallowed topical steroids like fluticasone metered dose inhaler and budesonide were shown to improve symptoms and stimulate histological remission. Clinical trials displayed a 50% complete and 95% partial response when using topical steroids over 1-3 months. In addition, swallowed fluticasone metered dose inhaler may improve nausea which is often observed in patients with eosinophilic esophagitis. Patients should not eat or drink for 30 minutes after taking fluticasone metered dose inhaler.

Appendix E: Signs and Symptoms of Esophageal Dysfunction

<table>
<thead>
<tr>
<th>Children</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeding dysfunction</td>
<td>Dysphagia</td>
</tr>
<tr>
<td>Vomiting</td>
<td>Food impaction</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>Chest pain</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>GERD/Heartburn</td>
</tr>
<tr>
<td>Food impaction</td>
<td>Abdominal pain</td>
</tr>
</tbody>
</table>

Appendix F: Examples of Secondary Causes of EoE
- GERD
- Recurrent vomiting
- Parasitic/Fungal infections
- Crohn’s disease
- Drug hypersensitivity

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Recommended Dosing Regimen</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluticasone (Flovent HFA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>44mcg, 110 mcg, 220 mcg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-11 years old:</td>
<td>110mcg/spray, 8 sprays daily in divided doses.</td>
<td>1-11 years old: Divide total daily dose as two to four times daily</td>
</tr>
<tr>
<td>&gt;12 years old:</td>
<td>220mcg/spray, 8 sprays daily in divided doses.</td>
<td>&gt;12 years old: Divide total daily dose as two to four times daily</td>
</tr>
<tr>
<td>≥ 18 years old:</td>
<td>220mcg/spray, 4 sprays daily in divided doses.</td>
<td>&gt;18 years old: Divide total daily dose as twice daily</td>
</tr>
<tr>
<td>Adults:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10 years old:</td>
<td>1mg/day</td>
<td>Oral viscous slurry dosing:</td>
</tr>
<tr>
<td>≥ 10 years old:</td>
<td>2mg/day</td>
<td>Mix and swallow 10-1 gram</td>
</tr>
</tbody>
</table>

*Doses are swallowed*
CLINICAL POLICY
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<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Recommended Dosing Regimen</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respules) 0.5mg/2 ml</td>
<td></td>
<td>packets of Splenda per 1 mg of Budesonide. Maybe divided in 2 doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nebulized dosing: Swallow accumulated liquid</td>
</tr>
<tr>
<td>Ciclesonide (Alvesco) 80 mcg, 160 mcg</td>
<td>≥ 4 years old: 80 or 160mcg, Swallow 2 sprays twice daily</td>
<td><em>Doses are swallowed</em></td>
</tr>
</tbody>
</table>

VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budesonide (Pulmicort Respules)</td>
<td>Inhalation suspension: 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2 ml</td>
</tr>
<tr>
<td>Ciclesonide (Alvesco)</td>
<td>Inhalation aerosol: 80mcg/actuation, 160mcg/actuation</td>
</tr>
<tr>
<td>Fluticasone (Flovent HFA)</td>
<td>Inhalation aerosol: 44mcg, 110mcg, 220 mcg</td>
</tr>
</tbody>
</table>

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tbody>
<tr>
<td>Policy created.</td>
<td>09.01.16</td>
<td>09.16</td>
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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.
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**Note:**

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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