Eohilia (budesonide)

Summary

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated inflammatory condition of the esophagus characterized by eosinophilic infiltration of the esophageal mucosa. Common symptoms include dysphagia, food impaction, and refractory heartburn. Diagnosis is based on symptoms, endoscopic appearance, the exclusion of other causes responsible for symptoms, and confirmed by endoscopic biopsy showing greater than or equal to (≥)15 eosinophils per high-power field (HPF).

Treatment options for EoE include:

1. Dietary therapy (elimination diets);
2. Proton pump inhibitors (PPIs);
3. Topical corticosteroids (swallowed fluticasone or budesonide);
4. Biologic therapy (dupilumab);
5. Endoscopic dilation (for strictures).

Eohilia (budesonide oral suspension) is a FDA-approved topical oral corticosteroid formulation specifically designed for EoE treatment in individuals 11 years and older. It provides a convenient, standardized method of delivering budesonide directly to the esophageal mucosa.

Definitions

"Biologic therapy" refers to treatments derived from living organisms or containing components of living organisms, typically targeting specific immune pathways.

"Dysphagia" is difficulty or discomfort in swallowing.

"Eosinophilic esophagitis" refers to a chronic immune-mediated disease characterized clinically by symptoms of esophageal dysfunction and histologically by eosinophil-predominant inflammation of the esophagus.

"Food impaction" refers to the lodging of food in the esophagus, often requiring medical intervention for removal.

"Proton pump inhibitor" is a class of medications that reduce gastric acid production by inhibiting the proton pump in gastric parietal cells.

"Topical corticosteroid" in the context of EoE refers to corticosteroid medications that are swallowed to coat and treat the esophageal mucosa directly.

Medical Necessity Criteria for Initial Authorization

The Plan considers Eohilia (budesonide) medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a gastroenterologist or allergist/immunologist; *AND*
2. The member is 11 years of age or older; *AND*
3. The member has a diagnosis of eosinophilic esophagitis (EoE) confirmed by ALL of the following:
    a. Endoscopic biopsy demonstrating ≥15 intraepithelial eosinophils per high-power field; *and*
    b. Symptoms of esophageal dysfunction (e.g. dysphagia, food impaction, heartburn, vomiting, abdominal pain); *and*
    c. Secondary causes of esophageal eosinophilia have been ruled out (e.g. proton pump inhibitor-responsive esophageal eosinophilia, gastroesophageal reflux disease [GERD], achalasia, Crohn's disease, parasitic infection, hypereosinophilic syndrome, connective tissue disorders, etc.); *AND*
4. The member is unable to use, or has tried and failed BOTH of the following:
    a. An adequate trial (e.g., at least 8-weeks) of proton pump inhibitor therapy (e.g. lansoprazole, omeprazole, pantoprazole); *and*
    b. Swallowed/oral administration of an inhaled corticosteroid (e.g., fluticasone or budesonide) OR is currently receiving Dupixent (dupilumab) with inadequate response; *AND*

5. Eohilia (budesonide) will not be used concurrently with Dupixent or other biologics for eosinophilic esophagitis:

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-weeks.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating ALL of the following criteria:

1. Prescribed by or in consultation with a gastroenterologist or allergist/immunologist; *AND*
2. Documentation of positive clinical response to Eohilia therapy as evidenced by improvement in signs/symptoms of EoE compared to baseline (e.g., improved swallowing, reduced food impaction, reduced heartburn); *AND*
3. Eohilia (budesonide oral suspension) will not be used concurrently with Dupixent (dupilumab) or other biologics for eosinophilic esophagitis.

Experimental or Investigational / Not Medically Necessary

Eohilia (budesonide) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Prevention of EoE in high-risk individuals.
- Treatment of EoE in members under 11 years of age.
- Treatment of conditions other than EoE, including but not limited to:
    - Gastroesophageal reflux disease (GERD).
    - Eosinophilic gastroenteritis.
    - Inflammatory bowel disease.
    - Celiac disease.
- Use in combination with other biologic therapies for EoE.

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