

Eohilia (budesonide)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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 confirmed by endoscopic biopsy showing ≥ 15 eosinophils per high-power field.

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 corticosteroid formulation specifically designed for EoE treatment in patients 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, 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 ALL of the following treatments, each for at least 8 weeks:
 - a. High-dose proton pump inhibitor therapy (e.g. omeprazole 40 mg twice daily or equivalent); **and**
 - b. Swallowed/oral administration of an inhaled corticosteroid (e.g. fluticasone or budesonide); **and**
 - c. Dupixent (dupilumab); **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 12-weeks.

Medical Necessity Criteria for Reauthorization

Reauthorization for 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.

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.

References

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Clinical Guideline Revision / History Information

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