

Eohilia (budesonide oral suspension)

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.

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Summary

Eosinophilic esophagitis (EoE) is a chronic, type 2 immune-mediated inflammatory disease 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 ($\geq$)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 (e.g., Dupixent [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 of age 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.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Eosinophilic Esophagitis

The Plan considers Eohilia (budesonide oral suspension) 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 (either in a step wise approach or in combination)^[s]:
 - a. A trial (e.g., of 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 oral suspension) will not be used concurrently with Dupixent (duilumab) 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.^[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Eosinophilic Esophagitis

The Plan considers Eohilia (budesonide oral suspension) medically necessary when ALL of the following criteria are met (within the last 3 months):

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

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.^[5]

Experimental or Investigational or Unproven / Not Medically Necessary^[5]

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

- Prevention of EoE.
- 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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Clinical Guideline Revision / History Information

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