Drug Coverage Policy

Effective Date……6/1/2025
Coverage Policy Number……IP0630
Policy Title……Eohilia

Gastroenterology – Eohilia

- Eohilia™ (budesonide oral suspension - Takeda)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Eohilia, a corticosteroid, is indicated for the treatment of **eosinophilic esophagitis (EoE) for 12 weeks in adults and pediatric patients ≥ 11 years of age**.[1] Use of Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

Clinical Efficacy

In two pivotal trials of Eohilia, patients were required to have histologic evidence of EoE, defined as ≥ 15 eosinophils per high-power field despite 6 to 8 weeks of treatment with a high-dose proton pump inhibitor.[2,3] Patients in both trials received 12 weeks of therapy with Eohilia. There are no data to address the time frame at which another 12-week course of Eohilia would be appropriate in patients who initially respond to treatment, but relapse following discontinuation. However, an extension study enrolled patients who were considered to be full responders to Eohilia in an initial 12-week trial and subsequently re-randomized them to either continue Eohilia or switch to placebo.[4] Patients who were switched to placebo and then relapsed could reinitiate blinded Eohilia treatment at the next study visit. Over the 36-week extension, seven patients receiving placebo relapsed and reinitiated Eohilia therapy. Of these seven, one patient was an outlier and reinitiated therapy at Week 8 due to an unscheduled endoscopy. The remaining patients relapsed and reinitiated therapy with Eohilia between 4 and 7 months following the initial discontinuation of Eohilia therapy.

Guidelines
Guidelines for the diagnosis and management of EoE from the American College of Gastroenterology (2025) confirm that the diagnosis of EoE should be based on the presence esophageal dysfunction symptoms and ≥ 15 eosinophils per high-power field on esophageal biopsy.[5] Treatment with a proton pump inhibitor is recommended, as is treatment with swallowed topical corticosteroids. A food elimination diet is recommended. However, it is noted that patient preferences should be taken into account and that any decisions regarding diet should be agreed upon between the patient and the provider.

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POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Eohilia. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Eohilia as well as the monitoring required for adverse events and long-term efficacy, approval requires Eohilia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Eohilia is considered medically necessary when the following is met:

FDA-Approved Indication

1. **Eosinophilic Esophagitis**. Approve for 12 weeks, if the patient meets the following (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 11 years of age; AND
   - **B)** Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating ≥ 15 intraepithelial eosinophils per high-power field; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has received at least 8 weeks of therapy with a proton pump inhibitor; OR
       Note: Treatment with a proton pump inhibitor currently or at any time in the past would count toward this requirement.
     - **ii.** According to the prescriber, the patient has severe disease with esophageal stricture; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried dietary modifications to manage eosinophilic esophagitis; OR
     - **ii.** The prescriber has determined that the patient is not an appropriate candidate for dietary modifications; AND
       Note: Examples of dietary modifications to treat eosinophilic esophagitis include an elemental diet or an elimination diet.

E) Patients meets ONE of the following (i or ii):
- **i.** Patient is currently receiving a course of Eohilia and additional medication is needed to complete a 12-week course of treatment; OR
  Note: The maximum recommended treatment is for 12 weeks. For a patient who has started therapy but has not completed 12 weeks, approve the remaining number of weeks for the patient to receive a total of 12 weeks.
- **ii.** Patient meets ONE of the following (a or b):
  - **a.** Patient has not been treated with Eohilia within the previous 6 months; OR
  - **b.** According to the prescriber, the patient is experiencing recurrent worsening dysphagia after discontinuing Eohilia therapy; AND

F) The medication is prescribed by or in consultation with an allergist or gastroenterologist; AND

G) Preferred product criteria is met for the product as listed in the below table(s)

Employer Plans:

Product	Criteria
Eohilia (budesonide oral suspension)	ONE of the following (1 or 2): 1. Patient has tried budesonide inhalation suspension (Pulmicort Respules, generic) that was made into a slurry or suspension and swallowed (not inhaled). 2. Patient has already been started on a 12-week course of therapy with Eohilia (to allow for completion of up to a 12-week course of therapy).

Individual and Family Plans:

Product	Criteria
Eohilia (budesonide oral suspension)	ONE of the following (1 or 2): 1. Patient has tried budesonide inhalation suspension (Pulmicort Respules, generic) that was made into a slurry or suspension and swallowed (not inhaled). 2. Patient has already been started on a 12-week course of therapy with Eohilia (to allow for completion of up to a 12-week course of therapy).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Eohilia for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Eohilia™ suspension [prescribing information]. Lexington, MA: Takeda; May 2025.
2. Hirano I, Collins MH, Katzka DA, et al. Budesonide oral suspension improves outcomes in patients with eosinophilic esophagitis: results from a phase 3 trial. *Clin Gastroenterol Hepatol*. 2022;20(3):525-534.

3. Dellon ES, Katzka DA, Collins MH, et al. Budesonide oral suspension improves symptomatic, endoscopic, and histologic parameters compared with placebo in patients with eosinophilic esophagitis. *Gastroenterology*. 2017;152(4):776-786.
4. Dellon ES, Collins MH, Katzka DA, et al. Long-term treatment of eosinophilic esophagitis with budesonide oral suspension. *Clin Gastroenterol Hepatol*. 2022;20(7):1488-1498.
5. Dellon ES, Muir AB, Katzka DA, et al. ACG Clinical Guideline: Diagnosis and Management of Eosinophilic Esophagitis. *Am J Gastrenterol*. 2025;120(1):31-59.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	09/01/2024
Annual Revision	No criteria changes.	6/1/2024

The policy effective date is in force until updated or retired.