Drug Coverage Policy

Effective Date.....09/01/2024
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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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 management of EoE from the American Gastroenterological Association and the Joint Task Force on Allergy-Immunology Practice Parameters (2020) have not been updated since the FDA approval of Dupixent® (dupilumab subcutaneous injection) for this indication.[5] In patients with symptomatic disease, use of a proton pump inhibitor is recommended over no treatment, as is treatment with topical swallowed corticosteroids (formulations not specified). Guidelines recommend diet modifications, such as an elemental diet (amino-acid based formulas) or an elimination diet, over no treatment. However, it is noted that patients who put a higher value on avoiding the challenges of adherence to these diets and the prolonged process of dietary reintroduction may reasonably decline this treatment option.

Medical Necessity Criteria

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.

G) Preferred product criteria is met for the product(s) 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.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Eohilia™ suspension [prescribing information]. Lexington, MA: Takeda; February 2024.
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. Hirano I, Chan ES, Rank MA, et al. AGA Institute and Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. *Gastroenterology*. 2020;158(6):1776-1786.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	09/01/2024

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