VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Gastroenterology – Eohilia Prior Authorization Policy
- Eohilia™ (budesonide oral suspension – Takeda)

REVIEW DATE: 03/06/2024

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.

POLICY STATEMENT

Prior Authorization is recommended 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Eohilia is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Eosinophilic Esophagitis**. Approve for 12 weeks, if the patient meets the following (A, B, C, D, E and F):
   - **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Eohilia is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/06/2024