MEDICAL MUTUAL®

Drug Policy

Policy:	Eohilia (Budesonide oral suspension)	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024

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.

POLICY STATEMENT

This policy involves the use of Eohilia. Prior authorization is recommended for pharmacy benefit coverage of Eohilia. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Eohilia be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Eosinophilic Esophagitis**. Approve 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.

Initial Approval.
A) *Initial Approval:* 12 weeks

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Eohilia has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.