Effective Date: 8/1/2024
Reviewed Date: 5/8/24
Scope: Medicaid

EOHILIA (budesonide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Eohilia is indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).

Limitations of Use
Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Member's chart or medical record showing endoscopic biopsy details including intraepithelial esophageal eosinophil count and chart notes, medical record documentation, or claims history supporting previous medications tried.

III. CRITERIA FOR APPROVAL

Authorization of 3 months may be granted for treatment of EoE in members 11 years of age or older when all of the following criteria are met:

A. The patient has a documented diagnosis of eosinophilic esophagitis (EoE), confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field; AND
B. The drug is prescribed by or in consultation with an allergist/immunologist or gastroenterologist; AND
C. The patient has a history of clinical symptoms of esophageal dysfunction (e.g., eating problems, abdominal pain, heartburn, dysphagia, vomiting, food impaction, weight loss) at baseline
D. The patient has had an inadequate treatment response to both of the following:
    a. Proton pump inhibitor for at least 8 weeks
    b. Systemic corticosteroid or local therapies (e.g., budesonide or fluticasone swallowed), unless contraindicated or not tolerated.

**Note: Coverage may not be renewed, as Eohilia is not indicated for chronic use or maintenance use*

IV. QUANTITY LIMIT

- Eohilia Suspension 2 mg/10mL packets: 2 single-dose stick packs per day (20mL per day)

REFERENCES

1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed May 7, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *05/07/2024*).
4. Dellon E, Gonsalves N, Hirano I, et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). *Am J Gastroenterol.* 2013;108:679–692.
5. Hirano I, Chan ES, Rank MA, et al. AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. *Gastroenterology.* 2020;158(6):1776-1786.