

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 2333-1
Program	Prior Authorization/Medical Necessity
Medication	Eohilia [™] (budesonide oral suspension)*
P&T Approval Date	5/2024
Effective Date	8/1/2024

1. Background:

Eohilia (budesonide oral suspension)* is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE). Guidelines from the American College of Gastroenterology and consensus recommendations from the American Gastroenterological Association (AGA) and the Joint Task Force on Allergy-Immunology Practice Parameters (JTF) on the management of eosinophilic esophagitis recommend oral administration of inhalational corticosteroids (eg, fluticasone, budesonide) as first-line therapy in adults and children with eosinophilic esophagitis.

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

2. Coverage Criteria^a:

A. Authorization

- 1. Eohilia* will be approved based on <u>all</u> of the following criteria:
 - a. Diagnosis of eosinophilic esophagitis (EoE)

-AND-

b. Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

-AND-

c. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy, consisting of a peak value of ≥15 intraepithelial eosinophils per high power field (HPF)

-AND-

d. Secondary causes of esophageal eosinophilia have been ruled out

-AND-



- e. Failure, contraindication or intolerance to an 8-week trial^b of <u>both</u> of the following (document name and date tried):
 - 1) Proton pump inhibitor (e.g., pantoprazole, omeprazole)
 - Inhalational corticosteroid administered orally [e.g., budesonide nebulized solution (Pulmicort respules*), Fluticasone HFA* (Flovent HFA* authorized generic)]

-AND-

f. Prescribed by or in consultation with one of the following:

1) Allergist/Immunologist

2) Gastroenterologist

Authorization will be issued for 12 weeks

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b For Connecticut, Kentucky and Mississippi business, only a 30-day trial will be required.

*Eohilia, Fluticasone HFA, Flovent HFA and brand Pulmicort Respules are typically excluded from coverage

3. Additional Clinical Rules:

• Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

- 1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc; February 2024.
- 2. 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: 1776-86.
- 3. Delton, ES, 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: 679-92.

Program	Prior Authorization/Medical Necessity - Eohilia	
Change Control		
Date	Change	
5/2024	New program.	