BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

EOHILIA™ (budesonide) oral suspension Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Eohilia (budesonide) oral suspension and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Allergist or Gastroenterologist

  2. Individual is 11 years of age or older

  3. Individual has a confirmed diagnosis of eosinophilic esophagitis (EoE)

  4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:

a. Individual has a history of clinical symptoms of esophageal dysfunction (e.g., eating problems, abdominal pain, heartburn, dysphagia, vomiting, food impaction, weight loss) intermittently or continuously
b. Endoscopic biopsy results demonstrate 15 or greater intraepithelial eosinophils per high power field (or 60 eosinophils per mm^2) [must submit copy of endoscopy report]
c. Screening for hepatitis B infection

5. **If available:** Individual has failure after an adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for at least a 2-month trial of medication from **EACH** of the following treatment classes: [Note: Relapse of symptoms after discontinuing therapy is not considered a failure]
   a. Proton Pump Inhibitor (PPI) (e.g., pantoprazole, omeprazole)
   b. Topical corticosteroid using swallowed (not inhaled) fluticasone

7. Individual is not currently taking other drugs which may result in significant drug interactions requiring discontinuation such as use with CYP3A4 Inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, grapefruit juice)

8. Individual does **NOT** have the FDA-label contraindication of hypersensitivity to any budesonide product

9. Individual does not have fungal infection, *Strongyloides* infestation, cerebral malaria, or active ocular herpes simplex

10. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Initial approval duration: 3 months (12 weeks) maximum duration of treatment

- **Criteria for continuation of coverage (renewal request):** Eohilia (budesonide) oral suspension and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Allergist or Gastroenterologist

2. Individual's condition has responded while on therapy with response defined as achieved and maintains **TWO** of the following:
   a. Significant reduction in dysphagia
   b. Improvement in abdominal pain, reflux or heartburn, abdominal pain or vomiting
   c. Endoscopic biopsy results demonstrate less than 7 eosinophils per high power field (eos/hpf) or greater than 50% reduction from baseline

3. Individual's requires continuation to reach treatment duration maximum of 12 weeks

4. Individual has been adherent with the medication

5. **If available:** Individual has failure after an adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual is not currently taking other drugs which may result in significant drug interactions requiring discontinuation such as use with CYP3A4 Inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, grapefruit juice)

7. Individual does **NOT** have the FDA-label contraindication of hypersensitivity to any budesonide product

8. Individual does not have new or worsening localized or systemic infection (bacterial, fungal, viral, protozoal, helminthic), including oropharyngeal and esophageal candidiasis

9. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Renewal duration: Duration will be adjusted to meet the recommended maximum duration of 12 weeks

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

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

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated, esophageal disease characterized by symptoms related to esophageal dysfunction and histologically by eosinophil-predominant inflammation. Diagnostic criteria include symptoms related to esophageal dysfunction, esophageal biopsy, characteristically consisting of ≥15 eosinophils per high power field (HPF) (or 60 eosinophils per mm), and exclusion of other causes responsible for or contributing to symptoms and eosinophilia.

Established treatments for EoE include dietary therapy, proton pump inhibitors (PPIs), topical corticosteroids, and dupilumab. While PPIs and corticosteroids are not FDA approved treatment options, both are recognized as standard treatment per American College of Gastroenterology guidelines.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Eohilia (budesonide oral suspension) product information, revised by Takeda Pharmaceuticals America, Inc. 01-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 19, 2025.

Gonsalves N. Eosinophilic gastrointestinal diseases. In: UpToDate, Friedman LS, Robson KM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated May 09, 2024. Accessed March 17, 2025.

Bonis PAL, Gupta SK. Clinical manifestations and diagnosis of eosinophilic esophagitis (EoE). In: UpToDate, Talley NJ, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated January 15, 2025. Accessed March 17, 2025.

Rothenberg ME. Eosinophilic esophagitis (EoE): Genetics and immunopathogenesis. In: UpToDate, Sicherer SH, TePas E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated January 10, 2023. Accessed March 17, 2025.

Bonis PAL, Sandeep SK. Treatment of eosinophilic esophagitis (EoE). In: UpToDate, Talley NJ, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through February 2025. Topic last updated February 05, 2025. Accessed March 17, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT02605837: Oral Budesonide Suspension (OBS) in Adolescent and Adult Subjects (11 to 55 Years of Age, Inclusive) With Eosinophilic Esophagitis: A Phase 3 Randomized, Double-blind, Placebo-controlled Study. Available from: http://clinicaltrials.gov. Last update posted June 08, 2021. Last verified May 2021. Accessed March 19, 2024. Re-evaluated March 17, 2025.