

Most plans will require a PA for EOHILIA that includes specific criteria:

Information to include:

- ✓ Confirmed diagnosis (endoscopic biopsy, symptomatic EoE)
- ✓ Past treatments tried or failed
- ✓ Updated documentation and chart notes



Patient information:

- Legal first and last name
- Age ≥11 years
- Insurance policy number

Confirmed diagnosis of eosinophilic esophagitis (EoE):

- ICD-10-CM code K20.0¹

Submission of medical records documenting EoE diagnosis:

- Confirmed by endoscopic biopsy demonstrating ≥15 intraepithelial eosinophils per high-power field (HPF)
- Not due to secondary causes (eg, hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, food allergy)

Symptoms related to esophageal dysfunction, such as:

- Dysphagia
- Food impaction
- Chest pain
- Upper abdominal pain
- Nausea or vomiting
- Refractory heartburn
- Gastroesophageal reflux disease-like symptoms
- Other symptoms or comorbidities associated with EoE

Documented evidence of prior EoE treatments and results, such as:

- Duration of therapy with an over-the-counter or prescription proton pump inhibitor (eg, pantoprazole, omeprazole, esomeprazole, lansoprazole). Refer to your patient's health plan as some may require 6 to 8 weeks of prior therapy
- Inhalation suspension formulation (eg, budesonide, fluticasone) compounded into a slurry or suspension for oral administration
- Dietary modification (eg, elemental diet, elimination diet)

Provider information:

- Confirm prescribing physician specialty (eg, Allergist, Immunologist, Gastroenterologist)
- National Provider Identifier

Provider office information:

- Contact Information
- Tax ID

Use of this checklist does not guarantee that insurance providers will provide reimbursement or coverage for EOHILIA. Please be advised that insurance providers may have specific forms or procedures for the authorization process.

Help streamline patient access to EOHILIA by initiating PA through CoverMyMeds or your EHR. Some plans may require a Letter of Medical Necessity (LMN) in addition to the PA. See next page for more details ➔

EHR=electronic health record; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

EOHILIA is indicated for 12 weeks of treatment in patients 11 years and older with EoE. EOHILIA has not been shown to be safe and effective for more than 12 weeks.

IMPORTANT SAFETY INFORMATION: EOHILIA is contraindicated in patients with hypersensitivity to budesonide. Serious hypersensitivity reactions, including anaphylaxis, have occurred with oral budesonide products.

An LMN may be required for some health plans for approval of EOHILIA in addition to the PA.

A templated **Letter of Medical Necessity** can be downloaded and modified based on your medical judgment and discretion by incorporating details related to your patient's medical history, diagnosis, and treatment plan

Information to include in your LMN:

- National Provider Identifier
- Prior treatments
- Patient-specific clinical notes and medical records detailing EoE diagnosis and symptoms
- Product Prescribing Information

Sample LMN is available to download at:
EohiliaHCP.com/LMN



[Physician's letterhead]

[Date]
[Health plan's name] [Patient's name]
ATTN: [Department] [Date of birth]
[Health plan's address] [Case ID number]
[City, State ZIP] [Dates of service]

Re: Letter of Medical Necessity for EOHILIA™ (budesonide oral suspension)

Dear [Insurance Company/Medical director's name],

I am writing this letter of medical necessity on behalf of [patient's name], whom I have prescribed EOHILIA for their eosinophilic esophagitis (EoE), ICD-10-CM code: K20.0. EOHILIA is the **only FDA-approved oral treatment for people 11 years and older with EoE**. It is my professional opinion that EOHILIA is medically appropriate and necessary and should be covered and reimbursed for this patient.

I have been treating this patient, [a/an] [age]-year-old [male/female], since [Date] to manage their EoE. My rationale for prescribing EOHILIA is:

- Consider providing information that confirms the patient's diagnosis with endoscopic, histologic and symptomatic manifestations of the disease. Consider including a confirmed diagnosis with a peak eosinophil count of over 15 eos/hpf, as per the current Clinical Guidelines for the Diagnosis and Management of EoE.¹
- Consider including additional relevant information, such as whether the patient has tried [diet, PPI, off-label fluticasone, off-label budesonide] to date without sufficient endoscopic, histologic or symptom relief.
- Please include any additional relevant information, which may include confirmation of your patient's healthy liver function.

EOHILIA was studied in two randomized, double-blind, placebo-controlled, 12-week studies (Study 1 and Study 2) in 410 patients (ages 11 to 56 and 11 to 42, respectively) with EoE.² Significantly more patients receiving EOHILIA achieved histologic remission vs. placebo in Studies 1 and 2: 53.1% vs. 1%; treatment difference 52.4% (95% CI: 43.3, 59.1) and 38% vs. 2.4%; treatment difference 35.8% (95% CI: 17.2, 50.0), respectively. Additionally, in both studies, patients receiving EOHILIA vs. placebo experienced a greater absolute change from baseline in the Dysphagia Symptom Questionnaire (DSQ) combined score after 12 weeks. The absolute change from baseline in DSQ combined score, LS mean (SE) for Study 1 in EOHILIA-treated patients vs. placebo: -10.2 (1.5) vs. -6.5 (1.8), treatment difference 3.7 (95% CI: -6.8, -0.6); for Study 2 in EOHILIA-treated patients vs. placebo: -14.5 (1.8) vs. -5.9 (2.1), treatment difference -8.6 (95% CI: -13.7, -3.5). The most common adverse reactions seen in the studies (≥2%) were respiratory tract infection, gastrointestinal mucosal candidiasis, headache, gastroenteritis, throat irritation, adrenal suppression and erosive esophagitis.²

I have reviewed the patient's clinical status and am providing supporting documentation, [including clinical information] that supports treatment with EOHILIA. For these reasons, I am requesting the appropriate coverage of EOHILIA, the only FDA-approved steroid therapy for EoE, for my patient.

If you have any further questions about this matter, please feel free to contact me at [physician's phone number] or via email at [physician's email]. Your prompt attention and review of this request is greatly appreciated.

Sincerely,
[Physician's signature]
[Physician sign-off including Specialty]

Enclosures: [EOHILIA Prescribing Information, clinical notes/medical records, and/or clinical practice guidelines].

References: 1. IACG Clinical Guideline: Diagnosis and Management of Eosinophilic Esophagitis; 2. EOHILIA Prescribing Information. Takeda Pharmaceuticals, Inc.

Reference: 1. 2026 ICD-10-CM Diagnosis Code K20.0. ICD10Data. Accessed October 10, 2025. <https://www.icd10data.com/ICD10CM/Codes/K00-K95/K20-K31/K20-/K20.0>

See below for additional information on resubmissions:

If a PA is denied...

- ✓ Check denial letter
- ✓ Submit LMN/LOA

LOA=Letter of Appeal.

Information to include:

- ✓ Confirmed diagnosis (endoscopic biopsy, symptomatic EoE)
- ✓ Past treatments tried or failed
- ✓ LMN/LOA addressing reason(s) for denial
- ✓ Updated documentation and chart notes



This resource is provided for informational purposes only and is not intended to provide reimbursement or legal advice. Contact third-party payers for specific information on their current coverage, reimbursement, and coding policies.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Hypercorticism and Adrenal Axis Suppression

Monitor patients for signs and symptoms and consider reducing the EOHILIA dosage. Use is not recommended in severe hepatic impairment (Child-Pugh Class C). Monitor for hypercorticism in moderate hepatic impairment (Child-Pugh Class B). Where patients are subject to stress situations (e.g., trauma, surgery, infection) supplementation with a systemic corticosteroid is recommended.

Please see Important Safety Information on page 3 and click here for full Prescribing Information.

Indication and Limitations of Use

EOHILIA (budesonide oral suspension) is indicated for 12 weeks of treatment in patients 11 years and older with eosinophilic esophagitis (EoE).

EOHILIA has not been shown to be safe and effective for more than 12 weeks.

 **Eohilia**[™]
(budesonide oral suspension) 2mg

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

EOHILIA is contraindicated in patients with hypersensitivity to budesonide. Serious hypersensitivity reactions, including anaphylaxis, have occurred with oral budesonide products.

WARNINGS AND PRECAUTIONS

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Immunosuppression and Increased Risk of Infection

Corticosteroid-associated infections can be mild, severe, and at times fatal. Monitor patients and consider discontinuation if infection develops.

- **Tuberculosis and Hepatitis B Virus (HBV) reactivation may occur.** Closely monitor EOHILIA patients. Screen for HBV.
- **Varicella Zoster (VZ) and Measles** can be serious or fatal. Avoid exposure. If a patient is exposed to varicella, consider prophylaxis with VZ immune globulin (IG); if varicella develops, consider antiviral treatment. If a patient is exposed to measles, consider prophylaxis with IG.
- **Rule out amebiasis** before starting EOHILIA in patients who were in the tropics or have unexplained diarrhea.
- **Avoid EOHILIA in patients with:** systemic fungal infections, known or suspected *Strongyloides* infection, cerebral malaria, and active ocular herpes simplex.
- **Localized Infections:** In clinical trials, some patients developed *Candida albicans* infections in the mouth, throat, and esophagus. Instruct patients: do not eat or drink for 30 minutes after taking EOHILIA; after 30 minutes rinse mouth with water and spit without swallowing. Treat candidiasis infections with appropriate antifungal therapy and consider discontinuing EOHILIA.

Erosive Esophagitis

Patients who experienced erosive esophagitis in clinical trials did not have erosions at baseline and most were receiving a proton pump inhibitor. Advise patients or caregivers to report new onset or worsening of erosive esophagitis to their healthcare provider. Consider endoscopic evaluation.

Symptoms of Steroid Withdrawal in Patients Transferred from Other Systemic Corticosteroids

Adrenocortical function monitoring may be required in patients who are transferred from high systemic effects corticosteroids to EOHILIA, since symptoms attributed to withdrawal of steroid therapy, including those of acute adrenal axis suppression or benign intracranial hypertension, may develop.

Taper slowly from high systemic effects corticosteroids. Replacing systemic corticosteroids with EOHILIA may unmask previously controlled allergies (e.g., rhinitis and eczema).

Other Corticosteroid Effects

Monitor patients with or family history of: hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, or cataracts or with other conditions where corticosteroids may have unwanted effects.

Additional Established Class Effects of Corticosteroids not seen in EOHILIA 12-week clinical trials. The maximum recommended duration of treatment with EOHILIA is 12 weeks:

- **Effect on Growth:** Use of corticosteroids may cause a reduction of growth velocity. Monitor the growth of pediatric patients on EOHILIA.
- **Kaposi's Sarcoma:** Reported to occur with corticosteroids, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

ADVERSE REACTIONS

Most common adverse reactions ($\geq 2\%$) are: respiratory tract infection (13%), gastrointestinal mucosal candidiasis (8%), headache (5%), gastroenteritis (3%), throat irritation (3%), adrenal suppression (2%), and erosive esophagitis (2%).

DRUG INTERACTIONS

Avoid concomitant use with CYP3A4 inhibitors (including grapefruit juice), which can increase systemic budesonide concentrations.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Hypoadrenalism may occur in infants whose mothers received corticosteroids during pregnancy. Carefully observe infants for hypoadrenalism and manage accordingly.
- **Lactation:** Lactation studies have not been conducted. Consider the benefits of breastfeeding, the mother's need for EOHILIA, and any potential adverse effects on the infant from EOHILIA, or from the underlying maternal condition.
- **Hepatic Impairment:** Not recommended in severe hepatic impairment (Child-Pugh Class C). Monitor for hypercorticism in moderate hepatic impairment (Child-Pugh Class B).

Please click [here](#) for full **Prescribing Information**.

