

EOHILIA is a new-to-market, FDA-approved medication and may not yet be covered by insurance companies. Healthcare providers should submit a Letter of Medical Exception to the patient's insurance provider to support a patient's access to EOHILIA. Below is a checklist for documenting the medical need for EOHILIA based on your patient's specific medical history and diagnosis.

Get started now! Go to EohiliaHCP.com/LME to access a digital version of this file.

Information and documents that are typically included in a Letter of Medical Exception

- Include your patient's name, date of birth, policy number, and dates of service
- Include the appropriate ICD-10/ICD-11 code for your patient's diagnosis. The ICD-10 code for eosinophilic esophagitis is K20.0¹ and the ICD-11 code for eosinophilic esophagitis is DA24.1²
- Include setting of care
- Provide the diagnosis for your patient, including details about the endoscopy and resulting histology that confirm the presence of eosinophilic esophagitis. Include the dates and relevant medical history
- List previous treatments including over-the-counter medications, and patient's response to previous treatments
- Include brief description of the patient's recent symptoms and condition
- Clearly state the rationale for treatment with EOHILIA and why it is appropriate for your patient
- Include documents that support your rationale for EOHILIA treatment:
 - Patient's medical records and clinical notes/diagnostic pathology report
 - Laboratory work
 - Other supporting documentation
- Provide a phone number and an email address should any additional information be required

If you have any questions about access support for EOHILIA, please reach out to your Takeda Regional Business Manager or visit EohiliaHCP.com.

References: 1. ICD10Data.com. The Web's Free 2023 ICD-10-CM/PCS Medical Coding Reference. October 1, 2022. Accessed February 2024.
2. World Health Organization. *International Classification of Diseases*. 11th revision. World Health Organization; 2022. Accessed January 2024.

Indication and Limitations of Use

EOHILIA is indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE).

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information on pages 3 and 4, and click here for full [Prescribing Information](#).

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

See page 2 for sample Letter of Medical Exception.

Sample Letter of Medical Exception for EOHILIA™ (budesonide oral suspension)

The following is a sample Letter of Medical Exception that can serve as a template and can be customized by incorporating details related to your patient's medical history, diagnosis, and treatment plan. Please be advised that insurance providers may have specific forms or procedures for the authorization process.

[Physician's letterhead]

[Date]

[Health plan's name]
ATTN: [Department]
[Medical director's name]
[Health plan's address]
[City, State ZIP]

[Patient's name]
[Date of birth]
[Case ID number]
[Dates of service]

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

Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical exception on behalf of [Patient Name], who is diagnosed with eosinophilic esophagitis (EoE) [insert appropriate ICD-10-CM/ICD-11-CM code here]. I have read your coverage policy regarding my patient's diagnosis and am requesting coverage for EOHILIA since it is medically necessary for [Patient Name]. This letter provides my clinical rationale and relevant information you may need to consider the request.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage their eosinophilic esophagitis. My rationale for prescribing EOHILIA is:

- Provide the diagnosis for your patient, including details about the endoscopy and resulting histology that confirms EoE
- Include the dates and relevant medical history, previous treatments, and the patient's response to previous treatments
- List your recommendations of why EOHILIA is appropriate for this patient
- Include documents that support your rationale for the recommended treatment, including the patient's medical records
- Additional information may include supporting documentation

In my medical judgment, this patient is an appropriate candidate for treatment with EOHILIA.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

[Physician sign-off]

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, and/or clinical practice guidelines.]

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypercorticism and Adrenal Axis Suppression

Systemic effects such as hypercorticism and adrenal axis suppression may occur. Monitor patients for signs and symptoms and consider reducing the dosage of EOHILIA. Use is not recommended in patients with severe hepatic impairment (Child-Pugh Class C) and monitoring for signs and/or symptoms of hypercorticism is recommended in patients with moderate hepatic impairment (Child-Pugh Class B).

Corticosteroids, including EOHILIA, can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to trauma, surgery, infection, or other stress situations, supplementation with a systemic corticosteroid is recommended.

Immunosuppression and Increased Risk of Infection

Corticosteroids, including EOHILIA, suppress the immune system and increase the risk of infection with any pathogen. Corticosteroid-associated infections can be mild, severe, and at times fatal. Monitor patients and consider discontinuation of EOHILIA if the patient develops an infection.

- **Tuberculosis reactivation may occur.** Closely monitor patients with latent tuberculosis or tuberculin reactivity while receiving EOHILIA.
- **Varicella Zoster and Measles** can be serious or fatal in non-immune patients taking corticosteroids. Avoid exposure. If a patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered. If a patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.
- **Hepatitis B Virus Reactivation can occur.** Prior to starting EOHILIA for patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.
- **Amebiasis:** It is recommended that latent or active amebiasis be ruled out before starting EOHILIA in patients who have spent time in the tropics or have unexplained diarrhea.
- **Avoid EOHILIA in patients with:** systemic fungal infections, known or suspected *Strongyloides* (threadworm) 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. If oropharyngeal or esophageal candidiasis develops, treat with appropriate antifungal therapy and consider discontinuing EOHILIA.

Erosive Esophagitis

Erosive esophagitis occurred in subjects who received EOHILIA in a 12-week clinical trial. None of the subjects had erosions at baseline esophagogastroduodenoscopy (EGD), and most were receiving concomitant therapy with a proton pump inhibitor (PPI). Advise patients or caregivers to report new onset or worsening signs or symptoms of erosive esophagitis to their healthcare provider. Consider endoscopic evaluation as appropriate.

Effect on Growth

Use of corticosteroids may cause a reduction of growth velocity in pediatric patients. Monitor the growth of pediatric patients on EOHILIA. The maximum recommended duration of treatment with EOHILIA is 12 weeks.

Symptoms of Steroid Withdrawal in Patients Transferred from Other Systemic Corticosteroids

Monitor patients who are transferred from corticosteroids with high systemic effects to corticosteroids with lower systemic availability, such as EOHILIA, since symptoms attributed to withdrawal of steroid therapy, including those of acute adrenal axis suppression or benign intracranial hypertension, may develop. Adrenocortical function monitoring may be required in these patients and the dose of corticosteroid treatment with high systemic effects should be reduced cautiously. Replacement of systemic corticosteroids with EOHILIA may unmask allergies (e.g., rhinitis and eczema) previously controlled by the systemic drug.

Other Corticosteroid Effects

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

Kaposi's Sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma. The maximum recommended duration of treatment with EOHILIA is 12 weeks.

Please see additional Important Safety Information on page 4 and click here for full [Prescribing Information](#).

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

DRUG INTERACTIONS

Budesonide is a substrate for CYP3A4. Avoid concomitant use with CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, and grapefruit juice), which can increase systemic budesonide concentrations.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Infants should be carefully observed for signs of hypoadrenalism and managed accordingly.
- **Lactation:** Lactation studies have not been conducted with EOHILIA. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EOHILIA and any potential adverse effects on the breastfed infant from EOHILIA, or from the underlying maternal condition.
- **Hepatic Impairment:** Not recommended in patients with severe hepatic impairment (Child-Pugh Class C). In patients with moderate hepatic impairment (Child-Pugh Class B), monitor for signs and/or symptoms of hypercorticism.

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