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# 5.22.004

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	October 1, 2024
<b>Subsection:</b>	Corticosteroids	<b>Original Policy Date:</b>	March 1, 2024
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**Last Review Date:** September 6, 2024

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## Eohilia

### Description

#### Eohilia (budesonide) oral suspension

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#### Background

Eohilia (budesonide) is an anti-inflammatory corticosteroid and has a high glucocorticoid effect and a weak mineralocorticoid effect. The precise mechanism of corticosteroid actions on inflammation in eosinophilic esophagitis (EoE) is not known. Inflammation is an important component in the pathogenesis of EoE and corticosteroids have a wide range of inhibitory activities against multiple cell types involved in allergic inflammation (1).

#### Regulatory Status

FDA-approved indications: Eohilia is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE) (1).

#### Limitations of Use: (1)

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

Eohilia has warnings for hypercorticism and adrenal axis suppression; immunosuppression and increased risk of infection; erosive esophagitis; effect on growth; symptoms of steroid withdrawal in patients transferred from other systemic corticosteroids; other corticosteroid effects; and Kaposi's Sarcoma (1).

The safety and effectiveness of Eohilia in pediatric patients less than 11 years of age have not been established (1).

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## Related policies

Dupixent

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Eohilia may be considered **medically necessary** if the conditions indicated below are met.

Eohilia may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 11 years of age or older

### Diagnosis

Patient must have the following:

Eosinophilic esophagitis (EoE)

**AND ALL** of the following:

1. Patient has  $\geq 15$  intraepithelial eosinophils per high-power field (eos/hpf)
2. Symptoms of EoE (e.g., dysphagia, heartburn, chest pain, GERD-like symptoms, etc.)
3. Inadequate treatment response, intolerance, or contraindication to a proton pump inhibitor (PPI)
4. Prescriber agrees to limit treatment to 12 weeks

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## Prior – Approval *Renewal* Requirements

Same as above

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

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**Quantity** 180 single-dose oral suspension stick packs\*

**Duration** 12 months\*

\*Quantity is sufficient for 12 weeks of therapy and the Service Benefit Plan's maximum benefit is 1 cycle of Eohilia therapy per 12 month period.

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## Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Eohilia (budesonide) is an anti-inflammatory corticosteroid indicated for the treatment of patients 11 years of age or older with eosinophilic esophagitis (EoE). Therapy should be limited to 12 weeks only due to potential side effects of long-term corticosteroid use. The safety and effectiveness of Eohilia in pediatric patients less than 11 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Eohilia while maintaining optimal therapeutic outcomes.

### References

1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.

## Policy History

Date	Action
March 2024	Addition to PA
June 2024	Annual review. Per SME, changed requirement of symptoms of dysphagia to symptoms of EoE
September 2024	Annual review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.**