Reference number(s)
6393-C

Initial Prior Authorization with Limit Eohilia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Eohilia	budesonide suspension

Indications

FDA-approved Indications

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

Limitations of Use

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

Coverage Criteria

Eosinophilic Esophagitis (EoE)

Authorization may be granted when the patient has the diagnosis of eosinophilic esophagitis (EoE). [ACTION REQUIRED: Documentation is required for approval.] when ALL of the following criteria are met:

- The patient is 11 years of age or older.

- The patient has a history of clinical symptoms of esophageal dysfunction (e.g., eating problems, abdominal pain, heartburn, dysphagia, vomiting, food impaction, weight loss) at baseline.

Continuation of Therapy

Eosinophilic Esophagitis (EoE)

Authorization may be granted when the patient has the diagnosis of eosinophilic esophagitis (EoE). [ACTION REQUIRED: Documentation is required for approval.] when ALL of the following criteria are met:

- The patient is 11 years of age or older.
- The patient has achieved or maintained a positive clinical response (e.g., improvement in symptoms of esophageal dysfunction, histologic remission on biopsy). [ACTION REQUIRED: Documentation is required for approval.].

Quantity Limits Apply

60 unit-dose packets per 25 days or 180 unit-dose packets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 6393-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

References

1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; May 2024.
2. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed August 6, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/06/2024).
4. Dellon E, 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(5):679–692.
5. 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(6):1776-1786.

Document History

Written by: UM Development (DRS)

Date Written: 02/2024

Revised: 04/2024 (amended coverage criteria), (MRS) 09/2024 (no clinical changes)

Reviewed: Medical Affairs: (CHART) 03/07/2024, 04/04/2024, 09/26/2024

External Review: 04/2024, 12/2024

CRITERIA FOR APPROVAL

1	Does the patient have the diagnosis of eosinophilic esophagitis (EoE)? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that support the patient's diagnostic findings of EoE (e.g., eosinophil-predominant inflammation on biopsy). _____ [If Yes, then go to 2. If No, then no further questions.] Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.	Yes	No
2	Have chart notes supporting the patient's diagnostic findings of eosinophilic esophagitis (EoE) (e.g., eosinophil-predominant inflammation on biopsy) been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 3. If No, then no further questions.] Tech Note: MUST obtain a physical copy of chart notes supporting the patient's diagnostic findings of eosinophilic esophagitis (EoE) (e.g., eosinophil-predominate inflammation on biopsy). If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes. If a physical copy of documentation is not received, then the PA should be denied.	Yes	No
3	Is the patient 11 years of age or older? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is this request for continuation of therapy? [If Yes, then go to 5. If No, then go to 8.]	Yes	No
5	Has the patient achieved or maintained a positive clinical response (e.g., improvement in symptoms of esophageal dysfunction, histologic remission on biopsy)? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that support the patient's positive clinical response (e.g., improvement in	Yes	No

symptoms of esophageal dysfunction, histologic remission on biopsy).

_____

[If Yes, then go to 6. If No, then no further questions.]

Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.

6	Have chart notes supporting the patient's positive clinical response (e.g., improvement in symptoms of esophageal dysfunction, histologic remission on biopsy) been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 7. If No, then no further questions.] Tech Note: MUST obtain a physical copy of chart notes supporting the patient's positive clinical response (e.g., improvement in symptoms of esophageal dysfunction, histologic remission on biopsy). If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes. If a physical copy of documentation is not received, then the PA should be denied.	Yes	No
7	Does the patient require MORE than the plan allowance of 60 unit-dose packets per month? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 60 unit-dose packets per 25 days OR 180 unit-dose packets per 75 days of Eohilia.	Yes	No
8	Does the patient have a history of clinical symptoms of esophageal dysfunction (e.g., eating problems, abdominal pain, heartburn, dysphagia, vomiting, food impaction, weight loss) at baseline? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Does the patient require MORE than the plan allowance of 60 unit-dose packets per month? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 60 unit-dose packets per 25 days OR 180 unit-dose packets per 75 days of Eohilia.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**

1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for eosinophilic esophagitis (EoE). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug when records showing you have eosinophilic esophagitis (EoE) are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records or the records did not show what your doctor has told us. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: EoE documentation]
3.	Go to 4	Deny	Your plan only covers this drug if you are 11 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Age]
4.	Go to 5	Go to 8	
5.	Go to 6	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria.

			You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
6.	Go to 7	Deny	Your plan only covers this drug when records showing that this drug works well for you are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records or the records did not show what your doctor has told us. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation documentation]
7.	Deny	[PA Approved for 12 months. Approve 60 unit-dose packets per 25 days OR 180 unit-dose packets per 75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (60 unit-dose packets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]
8.	Go to 9	Deny	Your plan only covers this drug if you have symptoms of esophageal dysfunction (for example: eating problems, stomach pain, heartburn, trouble swallowing, throwing up) before starting therapy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Disease symptoms]
9.	Deny	[PA Approved for 6 months. Approve 60 unit-dose packets per 25 days OR 180 unit-dose packets per 75 days]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (60 unit-dose packets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]