Original Effective Date: 06/27/2024
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Last P&T Approval/Version: 04/24/2024
Next Review Due By: 10/2024
Policy Number: C27704-A

Eohilia (budesonide oral suspension)

PRODUCTS AFFECTED

Eohilia (budesonide oral suspension)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Eosinophilic Esophagitis (EoE)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. EOSINOPHILIC ESOPHAGITIS (EoE):
   1. Documented diagnosis of eosinophilic esophagitis (EoE)
      AND
   2. Prescriber attests member has tried and failed elimination diet therapy for a minimum of 6 weeks
      AND

3. Documentation of trial and failure (or labeled contraindication) to BOTH of the following: proton-pump inhibitor and topical glucocorticoids (fluticasone or alternate budesonide product [i.e., viscous budesonide for EoE compounded with budesonide respules and a thickening agent])
   AND
4. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Eohilia (budesonide oral suspension) include: hypersensitivity to budesonide; avoid use in patients with fungal infections, Stongyloides (threadworm) infestation, cerebral malaria, and ocular herpes simplex.]

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: 12 weeks, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified gastroenterologist or physician experienced in the management of eosinophilic esophagitis. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
11 years of age and older

QUANTITY:
2mg twice daily for 12 weeks

Maximum Quantity Limits – 12 weeks of treatment

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Glucocorticosteroid

FDA-APPROVED USES:
Indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE)
Limitations of Use: Eohiliia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The efficacy and safety of Eohilia were evaluated in two multicenter, randomized, double-blind, parallel-group, placebo-controlled 12-week studies (Study 1 [NCT02605837] and Study 2 [NCT01642212]). Patients in Study 1 and Study 2 had esophageal inflammation defined as ≥15 eosinophils/high-power field (hpf) at baseline following a treatment course of a proton pump inhibitor (PPI) and dysphagia as measured by the Dysphagia Symptom Questionnaire (DSQ) over a 2-week period prior to randomization. Concomitant use of stable doses of inhaled or intranasal steroids (for conditions other than EoE), PPIs, H2-receptor antagonists, antacids, antihistamines or anti-leukotrienes, and maintenance immunotherapy was allowed. In Study 1, subjects were enrolled after maintaining a stable diet for at least 3 months prior to screening and were instructed to maintain a stable diet throughout the study. Subjects were excluded if they were on a full liquid or 6-food elimination diet. In Study 2, subjects were instructed to maintain a stable diet throughout the study. A total of 318 subjects (277 adults and 41 pediatric subjects) were randomized and received at least one dose of study drug (Eohilia or placebo) in Study 1. Over 80% of the subjects were on concomitant PPI. The mean (SD) DSQ combined scores at baseline were 30.3 (13.9) and 30.4 (13.1) in the Eohilia and placebo groups, respectively. A total of 92 subjects (58 adults and 34 pediatric subjects) were randomized and received at least one dose of study drug (Eohilia or placebo) in Study 2. Over 65% of the subjects were on concomitant PPI. The mean (SD) DSQ combined scores at baseline were 30.7 (16.0) and 29.0 (13.5) in the Eohilia and placebo groups, respectively. Study 1 and Study 2 evaluated efficacy endpoints of histologic remission (defined as a peak eosinophil count of ≤6/hpf across all available esophageal levels) and the absolute change from baseline in subject-reported DSQ combined score after 12 weeks of treatment. During the last 2 weeks of the 12-week treatment periods in Study 1 and Study 2, a greater proportion of subjects randomized to Eohilia experienced no dysphagia or only experienced dysphagia that “got better or cleared up on its own” compared to placebo, as measured by the subject-reported DSQ. Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Eohilia (budesonide oral suspension) are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy. Contraindications to Eohilia (budesonide oral suspension) include: hypersensitivity to budesonide; avoid use in patients with fungal infections, Stongyloides (threadworm) infestation, cerebral malaria, and ocular herpes simplex.

OTHER SPECIAL CONSIDERATIONS:
Eohilia (budesonide oral suspension) is a thixotropic suspension that becomes viscous when swallowed.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Eohilia SUSP 2MG/10ML

REFERENCES

1. Eohilia (budesonide oral suspension) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.
2. Dellon ES, Liacouras CA, Molina-Infante J, et al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference. Gastroenterology2018; 155:1022.
3. Hirano, I., Chan, E. S., Rank, M. A., Sharaf, R. N., Stollman, N. H., Stukus, D. R., … Sultan, S. (2020). AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. Gastroenterology, 158(6), 1776–1786. https://doi.org/10.1053/j.gastro.2020.02.038
4. Dohil, R., Newbury, R., Fox, L., Bastian, J., & Aceves, S. (2010). Oral Viscous Budesonide Is Effective in Children With Eosinophilic Esophagitis in a Randomized, Placebo-Controlled Trial. Gastroenterology, 139(2), 418-429.e1. doi: 10.1053/j.gastro.2010.05.001

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q2 2024