



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Gastroenterology – Eohilia Drug Quantity Management Policy – Per Days

- Eohilia™ (budesonide oral suspension – Takeda)

REVIEW DATE: 03/03/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Eohilia, a corticosteroid, is indicated for the treatment of eosinophilic esophagitis (EoE) for 12 weeks in adult and pediatric patients ≥ 11 years of age.¹ Use of Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

Dosing

The recommended dose of Eohilia is 2 mg twice daily (BID) for 12 weeks.¹ To prepare, shake the Eohilia packet for 10 seconds or longer prior to opening and then squeeze the packet from the bottom to the top directly into the mouth. Repeat this two to three more times until the packet is empty. Eohilia should not be taken with food or liquid; wait for ≥ 30 minutes to eat or drink following Eohilia

administration. After 30 minutes, rinse the mouth with water and spit out the contents without swallowing.

There are no data to address the time frame at which another 12-week course of Eohilia would be appropriate in patients who initially respond to Eohilia treatment, but relapse following discontinuation. However, an extension study enrolled patients who were full responders to Eohilia in an initial 12-week trial and subsequently re-randomized them to either continue Eohilia or switch to placebo.⁴ Patients who were switched to placebo and then relapsed could reinitiate blinded Eohilia treatment at the next study visit. Over the 36-week extension, seven patients receiving placebo relapsed and reinitiated Eohilia therapy. Of these seven, one patient was an outlier and reinitiated therapy at Week 8 due to an unscheduled endoscopy. The remaining patients relapsed and reinitiated therapy with Eohilia between 4 and 7 months following the initial discontinuation of Eohilia therapy.

Availability

Eohilia is available as a 2 mg/10 mL thixotropic, viscous suspension supplied in unit-dose packets.¹ Each carton of Eohilia contains 60 unit-dose packets.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Eohilia. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below. "One-time" overrides are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Eohilia (budesonide oral suspension)	2 mg/10 mL unit-dose packets (cartons of 60)	1,800 mL (180 packets) per 180 days	
		600 mL (60 packets) per Rx	1,800 mL (180 packets) per Rx

Gastroenterology – Eohilia Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Eohilia 2 mg/10 mL packets "Per Rx" Limit
No overrides recommended.

Eohilia 2 mg/10 mL packets "Per Days" Limit

1. If the patient is experiencing recurrent worsening dysphagia after discontinuing Eohilia therapy, according to the prescriber, approve a one-time override for an additional 1,800 mL (180 packets) at retail or home delivery
Note: The approval quantity should be the number of mLs the patient has received in the last 180 days plus 1,800 mL at retail and home delivery.

REFERENCES

1. Eohilia™ suspension [prescribing information]. Lexington, MA: Takeda; May 2024.
2. Dellon ES, Collins MH, Katzka DA, et al. Long-term treatment of eosinophilic esophagitis with budesonide oral suspension. *Clin Gastroenterol Hepatol*. 2022;20(7):1488-1498.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/13/2024
Update	Eohilia 2 mg/10 mL stick packs: A note was added to the "Per Days" override criteria to clarify that the quantity of 180 stick packs (3 cartons) is sufficient for a 90-day supply. The limit of 60 stick packs (1 carton) per dispensing at retail and 180 stick packs (3 cartons) per dispensing at home delivery continues to apply.	09/06/2024
Annual Revision	Eohilia 2 mg/10 mL unit-dose packets: Throughout the policy, references to "single-dose stick packs" have been changed to "unit-dose packets". Policy statement was updated to clarify that "One-time" overrides are provided for 30 days. The "Per Days" override criteria were clarified to approve an "additional" 180 packets, previously criteria approved 180 packets. The override criteria "Note" was updated to state "The approval quantity should be the number of packets the patient has received in the last 180 days plus 180 packets at retail and home delivery." Previously, this note stated "The quantity of 180 stick packs (3 cartons) is sufficient for a 90-day supply. The limit of 60 stick packs (1 carton) per dispensing at retail and 180 stick packs (3 cartons) per dispensing at home delivery continues to apply."	03/03/2025
DEU Update	Throughout the policy, references to number of "packets" have been changed to "mLs".	03/10/2025

DEU – Drug Evaluation Unit.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2025 The Cigna Group.