DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Gastroenterology – Eohilia Drug Quantity Management Policy – Per Days
- Eohilia™ (budesonide oral suspension – Takeda)

REVIEW DATE: 03/13/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 stick pack for 10 seconds or longer prior to opening and then squeeze the stick pack from the bottom to the top directly into the mouth until the stick 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 considered to be 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 single-dose stick packs.[1] Each carton of Eohilia contains 60 single-dose stick packs.

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 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Eohilia (budesonide oral suspension)	2 mg/10 mL single-dose stick packs (cartons of 60)	180 stick packs (3 cartons) per 180 days	
		60 stick packs (1 carton) per Rx	180 stick packs (3 cartons) 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.

CRITERIA

Eohilia 2 mg/10 mL stick packs "Per Rx" Limit

No overrides recommended.

Eohilia 2 mg/10 mL stick packs "Per Days" Limit

1. Approve a one-time override for 180 stick packs (3 cartons) at retail or home delivery if, according to the prescriber, the patient is experiencing recurrent worsening dysphagia after discontinuing Eohilia therapy.

REFERENCES

1. Eohilia™ suspension [prescribing information]. Lexington, MA: Takeda; February 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