



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Calcitonin Gene-Related Peptide Inhibitors – Emgality Drug Quantity Management Policy – Per Days
- Emgality® (galcanezumab-gnlm subcutaneous injection – Eli Lilly)

REVIEW DATE: 03/06/2025

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

Emgality, a calcitonin gene-related peptide (CGRP) antagonist, is indicated for the following uses:¹

- **Episodic cluster headache treatment** in adults.
- **Migraine headache prevention** in adults.

Migraine headaches have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for more than 3 months, which has the features of migraine headache on ≥ 8 days/month.² Episodic migraine is characterized by headaches that occur < 15 days/month.³ Episodic migraine is more common than chronic migraine; however, chronic migraine is associated with a markedly greater personal and societal burden.

Cluster headaches are associated with attacks of severe, strictly unilateral pain, lasting 15 to 180 minutes.² The headaches occur from once every other day to eight times per day. Cluster headache is considered among the most severe of the primary headache disorders.⁴ Episodic cluster headache is defined as cluster headache attacks occurring in periods lasting from 7 days to 1 year, separated by pain-free periods lasting ≥ 3 months. Typically, episodic cluster periods last between 2 weeks and 3 months. Chronic cluster headache attacks affect 10% to 15% of patients with cluster headache, lasting for ≥ 1 year without remission, or with remission periods lasting < 3 months.

Dosing

The recommended dosage of Emgality for preventative treatment of migraine is a 240 mg loading dose (two consecutive subcutaneous [SC] injections of 120 mg each), followed by 120 mg SC once a month.¹ The recommended dosage of Emgality for episodic cluster headache is 300 mg (three consecutive SC injections of 100 mg each) at the onset of the cluster period, and then monthly thereafter until the end of the cluster period.

Availability

Emgality is available as 120 mg/mL single-dose prefilled pens and prefilled syringes supplied in cartons containing one or two pens or syringes.¹ It is also available as 100 mg/mL single-dose prefilled syringes in cartons containing three syringes.

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Emgality. 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 per 30 Days	Home Delivery Maximum Quantity per 90 Days
Emgality® (galcanezumab-gnlm SC injection)	100 mg/mL prefilled syringes	3 mL (3 syringes)	9 mL (9 syringes)
	120 mg/mL prefilled syringes	1 syringe (1 mL)	3 syringes (3 mL)
	120 mg/mL prefilled pens	1 pen (1 mL)	3 pens (3 mL)

SC – Subcutaneous.

Calcitonin Gene-Related Peptide Inhibitors - Emgality 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

Emgality 100 mg/mL prefilled syringes

No overrides recommended.

Emgality 120 mg/mL prefilled pens and syringes

1. If the patient is initiating therapy for the preventative treatment of migraine, approve a one-time override for two pens or syringes (2 mL) at retail or four pens or syringes (4 mL) at home delivery.

REFERENCES

1. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; May 2022.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalalgia*. 2018;38:1-211.
3. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
4. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of cluster headache: the American Headache Society evidence-based guidelines. *Headache*. 2016;56:1093-1106.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	03/23/2023
Annual Revision	No criteria changes.	03/27/2024
Annual Revision	Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration.	03/06/2025

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