



Drug Quantity Management – Per Days Calcitonin Gene-Related Peptide Inhibitors – Emgality

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 111398
Effective 2/7/23: 64949

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National Formulary Medical Necessity

Drugs Affected

- Emgality® (galcanezumab-gnlm subcutaneous injection)

This Drug Quantity Management program has been developed to manage potential dose escalation of Emgality in the treatment of migraine or cluster headache and to provide a sufficient quantity for indications covered by the *Calcitonin Gene-Related Peptide Inhibitors – Emgality Prior Authorization Policy*. 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.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 30 Days
Emgality® (galcanezumab-gnlm SC injection)	100 mg/mL prefilled syringes	3 prefilled syringes*
	120 mg/mL prefilled syringes	1 prefilled syringe*
	120 mg/mL prefilled pens	1 prefilled pen*

SC – Subcutaneous; * This is a quantity sufficient for a 30-day supply.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Emgality 100 mg/mL prefilled syringes

No overrides recommended.

Emgality 120 mg/mL prefilled pens and syringes

1. If the individual is initiating therapy for the preventative treatment of migraine, approve a one-time override for two prefilled pens or two prefilled syringes.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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 a 100 mg/mL single-dose prefilled syringes in cartons containing three syringes.

References

1. Emgality® [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2019.
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.

Revision History

Type of Revision	Summary of Changes*	Approval Date
Annual Revision	No change to criteria. Emgality 100 mg/mL prefilled syringes Language in override criteria was simplified to indicate approval of 3 syringes per 30 days for up to 6 months for a patient treating cluster headaches. Previously, override criteria provided for one-time approvals for a 6-month supply followed by a potential second one-time approval for a 6-month supply per 365 days.	03/22/2022
Selected Revision	Emgality 100 mg/mL prefilled syringes Quantity limit increased from 1 syringe per 30 days to 3 syringes per 30 days. Override criteria were removed as the updated quantity limit provides a quantity sufficient for a 30-day supply.	04/06/2022

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