

# PHARMACY POLICY STATEMENT

## Marketplace

DRUG NAME

Emgality (

## Episodic Cluster Headache

For initial authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or headache specialist; AND
3. Member has a documented diagnosis of episodic cluster headache defined as all of the following:
  - a) At least two cluster periods lasting 7 days to 1 year, separated by pain-free remission periods of at least 3 months
  - b) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated)
  - c) Attack frequency typically between one every other day and eight per day; AND
4. Member has tried and failed or is unable to tolerate at least 2 of the following prophylactic medications for at least 2 weeks each, one of which must be verapamil unless contraindicated:
  - a) Verapamil (titrate up to 360 ±960 mg per day)
  - b) Lithium
  - c) Topiramate
  - d) Melatonin; AND
5. Medication is not being used in combination with any other prophylactic CGRP product (e.g., Aimovig, Ajovy, Vyepti).
6. Dosage allowed /Quantity limit : 300mg (3 injections of 100mg) subQ at onset of cluster period, then once per month until cluster period ends. QL: 3mL (3 syringes or autoinjectors) per 28 days.

If all the above requirements are met, the medication will be approved for 6 months .

For reauthorization :

1. 5 Hduction in the frequency of cluster headache attacks F R P S D U H G W R E D V H O L Q H

If all the above requirements are met , the medication will be approved for an additional 12 months .

CareSource considers Emgality (galcanezumab -gnlm ) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- X Chronic cluster headache
- X Hemiplegic migraine headache

DATE	ACTION/DESCRIPTION
03/05/2019	New policy for Emgality created.
06/05/2020	New diagnoses added: episodic migraine prophylaxis and episodic cluster headache treatment. Pregnancy exclusion was removed. Definition of chronic migraine simplified to just frequency and headache days. Trial of Botox added as an additional option under chronic migraine. CGRP products added as exclusion of concurrent use. Length of prophylactic and abortive trials reduced to 2 months/trial.
09/16/2021	Annual Review, no changes
03/07/2022	Combined criterion for chronic and episodic migraines. Required number of migraines decreased to 4 per month. Provider specialty removed. Botox trial moved to be grouped with other prophylactic trials. Trial and failure of abortive therapies removed. Differential diagnosis removed.
08/10/2022	Updated section for cluster headaches

	summary. Added/updated references. Added specialist requirement. Removed steroid/prednisone from prophylactic trial (should only be used as bridge). Added lithium as option. Changed anticonvulsants to only topiramate (listed valproate has negative evidence per guidelines). Specified 1 of 2 trials must be verapamil. Added verapamil dosing note. Added melatonin (alternative option). Changed trial durations from 2 months to 2 weeks. Reworded renewal criteria.
03/06/2023	Removed chart note requirement from re-auth criteria. Corrected update history to remove duplicate records.

References:

1. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March, 2021.
2. ICHD-3 The International Classification of Headache Disorders. www.ichd-3.org.
3. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the Differences Between Episodic Migraine and Chronic Migraine. *Current Pain and Headache Reports*. 2012;16(1):86-92. doi:10.1007/s11916-011-0233-z.
4. ClinicalTrials.gov. Identifier: NCT02614183. Evaluation of Galcanezumab in the Prevention of Episodic Migraine- the EVOLVE-1 Study (EVOLVE-1). Available at: <https://clinicaltrials.gov/ct2/show/NCT02614183?term=NCT02614183&rank=1>.
5. ClinicalTrials.gov. Identifier: NCT02614196. Evaluation of Efficacy & Safety of Galcanezumab in the Prevention of Episodic Migraine- the EVOLVE-2 Study (EVOLVE-2). Available at: <https://clinicaltrials.gov/ct2/show/NCT02614196?term=NCT02614196&rank=1>.
6. Detke HC, et al. Galcanezumab in chronic migraine: The randomized, double-blind, placebo-controlled REGAIN study. *Neurology*. 2018;91(24):e2211-e2221.
7. Ailani J, Burch R, et al. Consensus Statement: The American Headache Society Consensus Statement: Update 2005 (-)-28