



PRIOR AUTHORIZATION POLICY

- POLICY:** Migraine – Calcitonin Gene-Related Peptide Inhibitors – Emgality Prior Authorization Policy
- Emgality® (galcanezumab-gnlm subcutaneous injection – Lilly)

REVIEW DATE: 04/22/2026

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

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

Disease Overview

Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for > 3 months and has the features of migraine headache on ≥ 8 days/month.² Episodic migraine is characterized by headaches that occur < 15 days/month.^{3,4} 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 or very severe unilateral pain which is orbital, supraorbital, temporal, or in any combination of these sites, lasting 15 to 180 minutes.^{2,5} The headaches occur from once every other day to eight times a day. Cluster headache is characterized by intense pain and autonomic symptoms that significantly impact quality of life, mental health, and productivity.⁵ Cluster headache is classified into episodic and chronic subtypes: episodic when attack periods last for 7 days to 1 year and remission periods of at least 3 months; chronic when attacks persist for > 1 year or the remission period is < 3 months.

Guidelines

An updated assessment of the **preventive and acute treatment of migraine** by the **American Headache Society** (AHS) [2018; update 2021] reaffirms previous migraine guidelines.^{6,7} Patients with migraine should be considered for preventive treatment in the following situations: when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); at least moderate disability (Migraine Disability Assessment [MIDAS] score ≥ 11 or six-item Headache Impact Test [HIT-6] score > 50); contraindication to, failure, overuse, or adverse events with acute treatments; or patient preference. The choice of preventive treatment should be based on an individual's history of response to acute and preventive therapies, evidence of efficacy, tolerability, prescriber professional experience, headache subtype, comorbidities/coexistent disease, concomitant medications, patient's potential for childbearing, and patient preference. Before developing a preventive treatment plan, the appropriate use (e.g., drug type, route and timing of administration, frequency) of acute treatments should be initiated and coupled with education and lifestyle modifications. All patients with migraine should be offered a trial of acute treatment. Based on the level of evidence for efficacy and the American Academy of Neurology scheme for classification of evidence, the following oral treatments have established efficacy and should be offered for migraine prevention: antiepileptic drugs (**divalproex sodium, valproate sodium, topiramate**; not for women of childbearing potential without a reliable method of birth control); beta-blockers (**metoprolol, propranolol, timolol**); **candesartan**; and **frovatriptan** (for short-term preventive treatment of menstrual migraine). Parenteral therapies that have established efficacy in the prevention of migraines are **CGRP monoclonal antibodies** (Aimovig[®] [erenumab-aooe subcutaneous {SC} injection], Ajovy[®] [fremanezumab-vfrm SC injection], Emgality[®] [galcanezumab-gnlm SC injection], and Vyepti[®] [eptinezumab-jjmr intravenous infusion]), and **Botox[®] (onabotulinumtoxinA)**. The following treatments are probably effective and should be considered for migraine prevention: antidepressants (**amitriptyline, venlafaxine**); beta-blockers (**atenolol, nadolol**); and **lisinopril; memantine; and Botox + CGRP monoclonal antibody**.

The **AHS** issued an update to their position statement (2024) specifically regarding therapies targeting CGRP for the prevention of migraine.⁸ The evidence for the efficacy, tolerability, and safety of CGRP-targeting migraine-preventive therapies (specifically, the monoclonal antibodies: Aimovig, Ajovy, Emgality, and Vyepti, and the gepants: Nurtec[®] ODT [rimegepant orally disintegrating tablets] and Qulipta[®] [atogepant tablets]) is substantial and consistent across different individual CGRP-targeting treatments. Extensive "real-world" clinical experience corroborates clinical trials. These data indicate that the efficacy and tolerability of CGRP-targeting therapies are equal to or greater than those of previous first-line therapies. The CGRP-targeting therapies are considered as first-line options for migraine prevention along with other first-line treatments.

The **AHS** has published evidence-based guidelines on the **treatment of cluster headache** (2016).¹⁴ The guidelines recommend sumatriptan subcutaneous, zolmitriptan nasal spray, and high flow oxygen for acute treatment. For prophylactic therapy, suboccipital steroid

injection has been established as effective for the prophylactic therapy of episodic and chronic cluster headache (Level A). Lithium, verapamil, and melatonin are considered possibly effective for the prophylactic therapy of episodic and chronic cluster headache (Level C). Currently, there is insufficient evidence to make a recommendation for frovatriptan and prednisone (Level U). A review article (2025) notes pharmacological therapies include acute therapies (e.g., oxygen and subcutaneous or nasal sumatriptan) and preventive therapies (e.g., lithium verapamil, CGRP monoclonal antibodies).⁵ Transitional options include corticosteroids and greater occipital nerve injections.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Emgality. All approvals are provided for the duration noted below.

- **Emgality® (galcanezumab-gnlm subcutaneous injection – Lilly)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Episodic Cluster Headache Treatment.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has between one headache every other day and eight headaches per day; AND
 - C)** Patient has tried at least one standard prophylactic (preventive) pharmacologic therapy for cluster headache; AND
Note: Examples of standard prophylactic (preventive) pharmacologic therapies for cluster headache include lithium, verapamil, melatonin, frovatriptan, prednisone, suboccipital steroid injection, topiramate, and valproate.
 - D)** According to the prescriber, patient has had inadequate efficacy or has experienced adverse event(s) severe enough to warrant discontinuation of the standard prophylactic (preventive) pharmacologic therapy.
- 2. Migraine Headache Prevention.** Approve for 1 year if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve if the patient meets BOTH of the following (i and ii):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient has ≥ 4 migraine headache days per month (prior to initiating a migraine-preventive medication); OR
 - B) Patient is Currently Receiving Emgality.** Approve if the patient meets ALL of the following (i, ii, and iii):
 - i.** Patient is ≥ 18 years of age; AND
 - ii.** Patient has ≥ 4 migraine headache days per month (prior to initiating a migraine-preventive medication); AND
 - iii.** Patient has had a significant clinical benefit from the medication, as determined by the prescriber.

Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated.

CONDITIONS NOT COVERED

- **Emgality® (galcanezumab-gnlm subcutaneous injection – Lilly)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Acute Treatment of Migraine.** Emgality has not been studied for the acute treatment of migraine.
- 2. Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention.**
Note: CGRP inhibitors that are indicated for migraine headache prevention include Aimovig (erenumab-aooe subcutaneous injection), Ajovy (fremanezumab-vfrm subcutaneous injection), Vyepti (eptinezumab-jjmr intravenous infusion), and Qulipta (atogepant tablets). Ajovy, Aimovig, Emgality, and Vyepti are injectable CGRP inhibitors for migraine prevention and have not been studied for use in combination with another agent in the same class.⁹⁻¹¹ Qulipta is an oral CGRP inhibitor for the preventive treatment of migraine in adults.¹²
- 3. Concurrent use with Nurtec ODT (rimegepant sulfate orally disintegrating tablet) when used as a preventive treatment of episodic migraine.** Nurtec ODT is an oral CGRP inhibitor for the acute treatment of migraine and for the preventive treatment of episodic migraine in adults.¹³

REFERENCES

1. Emgality® injection for subcutaneous use [prescribing information]. Indianapolis, IN: Lilly; October 2025.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. Cephalalgia. 2018;38:1-211.
3. Damen JAA, Yang B, Idema DL, et al. Comparative effectiveness of pharmacologic treatments for the prevention of episodic migraine headache: A systematic review and network meta-analysis for the American College of Physicians. Ann Intern Med. 2025;178(3):369-380.
4. Burch R. Chronic migraine in adults. JAMA. 2025;333(5):423-424.
5. De Freitas Dias B, Robinson CL, Villar-Martinez MD, et al. Current and novel therapies for cluster headache: a narrative review. Pain Ther. 2025;14:1-19.
6. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache. 2019;59:1-18.
7. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;00:1-19.

8. Charles AC, Digre KB, Goadsby PJ, et al; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
9. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; August 2025.
10. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; March 2025.
11. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; October 2025.
12. Qulipta® tablets [prescribing information]. North Chicago, IL: AbbVie; September 2025.
13. Nurtec® ODT [prescribing information]. New York, NY: Pfizer; March 2026.
14. 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
Early Annual Revision	Migraine Headache Prevention: The criteria requiring a patient to have tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.	04/10/2024
Annual Revision	No criteria changes.	04/16/2025
Selected Revision	Episodic Cluster Headache Treatment: Approval duration was changed from 6 months to 1 year.	05/28/2025
Annual Revision	Migraine Headache Prevention: Existing requirements were reformatted into separate sets of requirements for Initial Therapy and Continuation of Therapy	04/22/2026

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