

Galcanezumab-gnlm (Emgality®)

Place of Service

Self-Administration

(Pharmacy Benefit - see Section 1)

HCPCS: J3590

NDCs:

- 0002-1436-11: 120 mg/mL solution in a single-dose prefilled pen (carton of 1)
- 0002-1436-27: 120 mg/mL solution in a single-dose prefilled pen (carton of 2)
- 0002-2377-11: 120 mg/mL solution in a single-dose prefilled syringe (carton of 1)
- 0002-2377-27: 120 mg/mL solution in a single-dose prefilled syringe (carton of 2)

Condition(s) listed in policy (see criteria for details)

- [Episodic cluster headache](#)
- [Prevention of migraine headache](#)

AHFS therapeutic class: Antimigraine agents, Miscellaneous

Mechanism of action: calcitonin gene-related peptide receptor antagonist

(1) Special Instructions and Pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for galcanezumab-gnlm (Emgality®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Episodic cluster headache

1. Patient is currently being followed by a neurologist or a headache specialist, **AND**
2. One of the following:
 - a. Inadequate response or intolerable side effect to one standard of care preventive drug for cluster headaches (e.g., prednisone, dexamethasone, verapamil, lithium, topiramate) OR

b. Contraindication to all standard of care preventive drugs for cluster headaches

Covered Doses

Up to 300 mg SC at the onset of cluster period, followed by 300 mg SC monthly until the end of the cluster period

Coverage Period

Cover for 3 months

ICD-10:

G44.001, G44.009

Prevention of migraine headache

1. Patient is at least 18 years old, **AND**
2. Being used as prophylaxis of headaches in patients with episodic or chronic migraines, **AND**
3. Patient experiences at least 4 migraine headache days per month, **AND**
4. Either of the following:
 - a. Patient has had an inadequate response or intolerance to at least one preventive therapy from any of the following drug classes: beta blockers, antidepressants, anticonvulsants, **or**
 - b. Patient has contraindication to all AAN Level A or B guideline-endorsed preventive agents

Covered Doses:

Up to 240 mg SC x 1 loading dose, followed by monthly doses of 120 mg SC

Coverage period

Indefinite

ICD-10:

G43.001-G43.819

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for galcanezumab-gnlm (Emgality®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 100 mg/mL solution in a single-dose prefilled syringe
- 120 mg/mL solution in a single-dose prefilled syringe
- 120 mg/mL solution in a single-dose prefilled pen

AAN 2012¹ Level A and B Recommended Preventive Anti-Migraine Agents by Drug Class:

Antiepileptic Drugs	Beta Blockers	Antidepressants	Other
Level A	Level A	Level A	Level A
• divalproex sodium	• metoprolol	(None listed)	(None listed)

• sodium valproate	• propranolol		
• topiramate	• timolol		
Level B	Level B	Level B	Level B
(None listed)	• atenolol • nadolol	• amitriptyline • venlafaxine	• naratriptan^ • zolmitriptan^

Level A = Established efficacy (≥ 2 Class I trials)

Level B = Probably effective (1 Class I or 2 Class II studies)

^= for short term prophylaxis of menstrual migraine only

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
 - DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
 - Emgality® (galcanezumab-gnlm) [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; 3/2021.
 - The American Headache Society Position Statement on Integrating New Migraine Treatments Into Clinical Practice. AHS Consensus Statement. Headache. 2021; 61:1021-39.
1. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. (reaffirmed 2015). Neurology. 2012 Apr 24;78(17):1337-45 available online at: <http://n.neurology.org/content/neurology/78/17/1337.full.pdf>

(7) Policy Update

Date of last revision: 4Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- Section (2): Prevention of migraine headaches – Updated criteria to require 1 preventative therapy in place of the previously required 2 preventative therapies

Rationale: Increase access to cost-effective alternative

BSC Drug Coverage Criteria to Determine Medical Necessity

Reviewed by P&T Committee