Clinical Policy: Galcanezumab-gnlm (Emgality)

Reference Number:IN.CP.PHAR.404
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Galcanezumab-gnlm (Emgality®) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)
Emgality is indicated in adults for the:
- Preventive treatment of migraine
- Treatment of episodic cluster headache

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Migraine Prophylaxis:
1. Diagnosis of migraine with or without aura
2. Age ≥ 18 years;
3. One of the following:
    a. Previous trial and failure of propranolol or topiramate
    b. • Documented intolerance or contraindication to propranolol and topiramate
4. Dose does not exceed:
    a. Loading dose: 240 mg (2 injections) once;
    b. Maintenance dose: 120 mg (1 injection) once monthly.

Approval duration: 12 months

B. Episodic Cluster Headaches:
1. Diagnosis of episodic cluster headache;
2. Age ≥ 18 years;
3. Dose does not exceed 300 mg (3 injections) once monthly.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all)**:**
1. History of the requested agent within the past 90 days

2. If request is for a dose increase, new dose does not exceed 120 mg (1 injection) once monthly.
Approval duration: 12 months

B. Episodic Cluster Headaches (must meet all)**:**
1. History of the requested agent within the past 90 days
2. If request is for a dose increase, new dose does not exceed 300 mg (3 injections) once monthly.
Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
ICHD: International Classification of Headache Disorder

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine prophylaxis	Loading dose: 240 mg SC once Maintenance dose: 120 mg SC once monthly	120 mg/month
Episodic cluster headaches	300 mg (administered as three consecutive injections of 100 mg each) SC at the onset of the cluster period, and then monthly until the end of the cluster period	300 mg/month

V. Product Availability

- Single-dose prefilled pen: 120 mg/mL
- Single-dose prefilled syringe: 100 mg/mL, 120 mg/mL

VI. References

1. Emgality Prescribing Information. Indianapolis, IN: Eli Lilly and Company; December 2019. Available at: http://www.emgality.com. Accessed November 18, 2020.

2. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45.
3. Stauffer VL, Dodick DW, Zhang Q, et al. Evaluation of galcanezumab for the prevention of episodic migraine: the EVOLVE-1 randomized clinical trial. JAMA Neurol. 2018; 75(9):1080-1088.
4. Skljarevski V, Matharu M, Millen BA, et al. Efficacy and safety of galcanezumab for the prevention of episodic migraine: results of the EVOLVE-2 phase 3 randomized controlled clinical trial. Cephalalgia. 2018; 38(8):1442-1454.
5. Detke H, Wang S, Skljarevski V, et al A phase 3, randomized, double-blind, placebo-controlled study of LY2951742 in patients with chronic migraine – the REGAIN study. Poster session presented at: International Headache Congress; Sept 7-10, 2017; Vancouver, Canada.
6. Headache Classification Committee of the International Headache Society. The International classification of headache disorders, 3rd edition (beta version). Cephalalgia. 2013; 33(9): 629-808.
7. Francis BJ, Becker WJ, and Pringsheim TM. Acute and preventative pharmacologic treatment of cluster headache. Neurology. 2010; 75: 463-473.
8. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, and Schwedt TJ. Treatment of cluster headache: The American Headache Society evidence-based guidelines. Headache. 2016; 56: 1093-1106.
9. Digre KB. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019; 59: 1-18.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created dur to IN Medicaid State Moratorium	12.2021	01.2022