CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Emgality (galcanezumab-gnlm)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage Allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Emgality (galcanezumab-gnlm) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

MIGRAINE WITH OR WITHOUT AURA

For **initial** authorization:

1. Member is 18 years of age or older with a history of migraine attacks with or without aura; AND
2. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
3. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   a) Beta-blockers (e.g., metoprolol, timolol, or propranolol);
   b) Calcium channel blockers (e.g., verapamil);
   c) Antidepressants (e.g., amitriptyline or venlafaxine);
   d) Anticonvulsant medications (e.g., topiramate or valproic acid); AND
4. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); AND
5. **Dosage allowed:** Subcutaneously, 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg.

Note: Emgality is considered experimental and investigational as combination therapy with Botox, Ajovy, Aimovig, or Vyepti because the safety and effectiveness of these combinations has not been established.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. History of the requested agent within the past 90 days
2. Dose requested does not exceed 120mg per month

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

EPISODIC CLUSTER HEADACHE TREATMENT (ABORTIVE)

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. **Dosage allowed:** Administer 300mg (3 injections of 100mg) subcutaneously once per month until cluster period ends.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. History of the requested agent within the past 90 days
2. Dose requested does not exceed 300mg per month

If member meets all the reauthorization requirements above, 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:

- Chronic cluster headache
- 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. Prescriber requirement removed.
07/20/2020	Prescriber requirement removed per state mandate.
11/17/2021	Combined prophylactic diagnoses' criteria, removed headache days and migraine days requirement. For episodic cluster headache: removed all criteria except for age requirement and dose limit. Updated reauthorization criteria.

References:

1. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; September, 2018.
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 Efficay & 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. Beck E, Sieber WJ, Trejo R. Management of cluster headache. Am Fam Physician. 2005 Feb 15;71(4):717-724.
8. ClinicalTrials.gov. Identifier: NCT02397473. A Study of Galcanezumab in Participants with Episodic Cluster Headache. Available at: https://clinicaltrials.gov/ct2/show/NCT02397473.