

PHARMACY POLICY STATEMENT

Ohio 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) Alternative preferred product includes Botox QUANTITY LIMIT— see Dosage Allowed below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Emgality (galcanezumab-gnlm) is a **non-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 HEADACHE PROPHYLAXIS

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 documented history of ≥ 15 headache days per month for more than 3 months, of which ≥ 8 days were migraine days characterized as ≥ 5 attacks lasting 4-72 hours with **both** of the following:
 - a) **Two** or more of the following:
 - i) Aggravation by or causing avoidance of routine physical activity;
 - ii) Moderate or severe pain intensity;
 - iii) Pulsating quality;
 - iv) Unilateral location;
 - b) **One** or more of the following:
 - i) Nausea or vomiting;
 - ii) Photophobia and phonophobia; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Other prophylactic therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by **two** or more of the following:
 - a) Beta-blockers;
 - b) Antidepressants such as amitriptyline, nortriptyline, doxepin, or protriptyline;
 - c) Anticonvulsant medications such as topiramate or valproic acid;
 - d) Calcium channel blockers; AND
5. Abortive therapeutic options (i.e., ergotamine, triptans, combination analgesics, or simple analgesics) have been ineffective or not tolerated for at least 3 months (for a minimum of 8 or more days per month); AND
6. Medication is not being used in combination with botulinum toxin therapy; AND
7. Member does **not** have ANY of the following:
 - a) Medication overuse headache;
 - b) Pregnant or nursing female;
 - c) History of cluster or hemiplegic headache, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine);
 - d) Member was older than 50 years of age at migraine onset.

8. **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, Ajoovy or Aimovig 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. Member has improvement in prevention of migraines documented in chart notes (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks).

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:

- Cluster or hemiplegic migraine headache

DATE	ACTION/DESCRIPTION
03/05/2019	New policy for Emgality created.

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 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.

Effective date: 07/01/2019

Revised date: 03/05/2019