CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Emgality (galcanezumab-gnlm)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Emgality (galcanezumab-gnlm) will be considered for coverage when the following criteria are met:

CHRONIC OR EPISODIC 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. Medication is being prescribed for the prevention of chronic or episodic migraine, defined as at least 4 migraines per month, AND
3. Member has tried and failed or been unable to tolerate two prophylactic medications from the following groups:
    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);
    e. OnabotulinumtoxinA (Botox for migraine).

4. **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, Vyepti, Ajovy or Aimovig because the safety and effectiveness of these combinations has not been established.

If all the above requirements are met, 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 all the above requirements are met, 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. Member has documented episodic cluster headache defined as **all** of the following:
   a) At least two cluster periods lasting 7 days to 1 year, separated by pain-free remission periods of at least 3 months;
   b) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated);
   c) Has one headache every other day or up to 8 per day; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member has tried and failed or unable to tolerate **two** of the following prophylactic medications for 2 months per trial:
   a) Verapamil
   b) Glucocorticoids (e.g. prednisone) - trial does not need to be 2 months
   c) Anticonvulsant medications (e.g. topiramate or divalproex); AND
5. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options for 2 months per trial: ergotamine, triptans, intranasal lidocaine or capsaicin; AND
6. Medication is not being used in combination with any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti).
7. **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. Chart notes have been provided showing a reduction in the number of cluster headache attacks and its severity.

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.
09/16/2021	Annual Review, no changes
03/07/2022	Combined criterion for chronic and episodic migraines. Required number of migraines decreased to 4 per month. Provider specialty removed. Botox trial moved to be grouped with other prophylactic trials. Trial and failure of abortive therapies removed. Differential diagnosis removed.

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.

Effective date: 04/01/2022
Revised date: 03/07/2022