CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
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 **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.

CHRONIC 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 migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≥ 15 headache days per month for at least 3 months;
   b) ≥ 8 migraine days per month for at least 3 months; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
5. 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
6. 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
7. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti); AND
8. Member does **not** have ANY of the following:
   a) Medication overuse headache;
   b) History of hemiplegic headache, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine);
   c) Member was older than 50 years of age at migraine onset.
9. **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. 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.

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 prevention of episodic migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≤ 14 headache days per month for at least 3 months;
   b) 4 or more migraine days per month for at least 3 months that cause significant impairment to quality of life (i.e. requiring bed rest, missed school/work); AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member has tried and failed or unable to tolerate **three** 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
5. 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
6. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti); AND
7. Member does **not** have ANY of the following:
   a) Medication overuse headache;
   b) History of hemiplegic headache, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine);
   c) 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, 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**:

2. 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.

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

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.

Effective date: 01/01/2022
Revised date: 09/16/2021