CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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

Emgality is a calcitonin gene-related peptide receptor antagonist initially approved by the FDA in 2018. It is the third CGRP indicated for the preventive treatment of migraine in adults. Emgality is also indicated for abortive headache treatment of cluster headaches for adults. Emgality is a humanized immunoglobulin G (IgG)-4 monoclonal antibody that works by specifically binding to the calcitonin gene-related peptide (CGRP) ligand and blocking its binding to the CGRP receptor.

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

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. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
4. 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
5. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti); AND
6. 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.
7. **Dosage allowed:** Subcutaneously, 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg. Quantity limit: 3ml (3 syringes or autoinjectors) per 30 days

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 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 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. 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. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti); AND
5. 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.

   Dosage allowed: Subcutaneously, 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg. Quantity limit: 3mL (3 syringes or autoinjectors) per 30 days

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. 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
4. Medication is not being used in combination with any other prophylactic CGRP product (e.g. Aimovig, Ajovy, or Vyepti).
5. **Dosage allowed:** Administer 300mg (3 injections of 100mg) subcutaneously once per month until cluster period ends. Quantity limit: 3mL (3 syringes or autoinjectors) per 30 days.

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 all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Emgality (galcanezumab-gnlm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
05/05/2022	Transferred to new policy. Updated references. Removed prescriber specialty and abortive trial. Added quantity limit.

References:

1. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March, 2021.
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.
9. Ailani J, Burch R, et al. Consensus Statement: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.

Effective date: 10/01/2022
Revised date: 05/05/2022