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 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 the treatment of episodic cluster headache in 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 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 (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

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or headache specialist; AND
3. Member has a documented diagnosis of 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) Attack frequency typically between one every other day and eight per day; AND
4. Member has tried and failed verapamil at a dose of at least 360 mg per day for at least 2 weeks; AND
5. Medication is not being used in combination with any other prophylactic CGRP product (e.g., Aimovig, Ajovy, Vyepti).
6. **Dosage allowed/Quantity limit:** 300mg (3 injections of 100mg) subQ at onset of cluster period, then once per month until cluster period ends. QL: 3mL (3 syringes or autoinjectors) per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must include documentation of a reduction in the frequency of cluster headache attacks compared to baseline.

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 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.
08/10/2022	Updated section for cluster headaches: Removed “abortive” from the title and summary. Added/updated references. Added specialist requirement. Removed steroid/prednisone from prophylactic trial (should only be used as bridge). Added lithium as option. Changed anticonvulsants to only topiramate (listed valproate has negative evidence per guidelines). Specified 1 of 2 trials must be verapamil. Added verapamil dosing note. Added melatonin (alternative option). Changed trial durations

	from 2 months to 2 weeks. Reworded renewal criteria.
03/06/2023	Removed chart note requirement from migraine prophylaxis re-auth criteria. Corrected update history to remove duplicate records.
07/16/2024	Added reference (May 2023); removed trial and failure of a second drug for cluster headache.

References:

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11. Brandt RB, Doesborg PGG, Haan J, Ferrari MD, Fronczek R. Pharmacotherapy for Cluster Headache. *CNS Drugs*. 2020;34(2):171-184. doi:10.1007/s40263-019-00696-2
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