CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Emgality (galcanezumab-gnlm)
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 Migraine Headache Prophylaxis

For **initial** authorization, provider attests to the following (documentation not required):

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 ≥ 15 headache days per month
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. **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. Attestation 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 Migraine Headache Prophylaxis

For **initial** authorization, provider attests to the following (documentation not required):

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 4 or more migraine days per month; 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. **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. Attestation 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 or is unable to tolerate at least 2 of the following prophylactic medications for at least 2 weeks each, one of which must be verapamil unless contraindicated:
   a) Verapamil (titrate up to 360 – 960 mg per day)
   b) Lithium
   c) Topiramate
   d) Melatonin; 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. Attestation 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.

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.
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.
12/21/2022	Removed botox trial and the following: Member does not have ANY of the following: Medication overuse headache;History of hemiplegic headache, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine); Member was older than 50 years of age at migraine onset. Updated headache day requirements to at least 4 for episodic migraine and 15 for chronic migraine.
4/6/2023	Removed chart note requirement from reauthorization criteria.

References:

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