CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Emgality (galcanezumab-gnlm)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Emgality, approved by the FDA in 2018, is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults and for the treatment of episodic cluster headache in adults. Emgality is a humanized monoclonal antibody that binds to CGRP ligand and blocks its binding to the 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 at least 18 years of age; AND
2. Medication is being prescribed for the prevention of chronic migraine with or without aura, defined as ≥ 15 headache days per month, at least 8 of which are migraine days, for >3 months; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
   a) Beta blocker (e.g., metoprolol, timolol, or propranolol)
   b) Calcium channel blocker (e.g., verapamil)
   c) Antidepressant (e.g., amitriptyline or venlafaxine)
   d) Anticonvulsant (e.g., topiramate or valproic acid)
   e) Candesartan; 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).
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: 2 mL (2 pens/syringes) per 28 days for the first month, then 1 mL (1 pen/syringe) per 28 days thereafter.

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.

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Episodic Migraine Headache Prophylaxis

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

1. Member is at least 18 years of age; AND
2. Medication is being prescribed for prevention of episodic migraine with or without aura, defined as 4-14 migraine days per month with at least moderate disability; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
   a) Beta blocker (e.g., metoprolol, timolol, or propranolol)
   b) Calcium channel blocker (e.g., verapamil)
   c) Antidepressant (e.g., amitriptyline or venlafaxine)
   d) Anticonvulsant (e.g., topiramate or valproic acid)
   e) Candesartan; 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).
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: 2 mL (2 pens/syringes) per 28 days for the first month, then 1 mL (1 pen/syringe) per 28 days thereafter.

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 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:** 300 mg (3 injections of 100mg) subQ at onset of cluster period, then once per month until cluster period ends. QL: 3 mL (3 syringes/pens) per 28 days.

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

For **reauthorization**:
1. Chart notes must document decreased frequency of weekly cluster headache 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.
04/06/2023	Removed chart note requirement from reauthorization criteria.
04/29/2024	Migraine: Updated references. Changed from 2 prior prophylactic trials to 1 and added candesartan to list of trial options (per AHS 2024 statement). Added “at least moderate disability” to episodic section. Changed episodic definition from 4 or more days to 4-14 days. Added >3 months to chronic definition, specified at least 8 headache days as being migraine days for chronic (ICHD3). Removed note from chronic section. Corrected QL’s for migraine sections. Cluster headache: Corrected reauth section.
07/16/2024	Added reference (May 2023); removed trial and failure of a second drug for cluster headache.

References:

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Effective date: 10/01/2024
Revised date: 07/16/2024