HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

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 or 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 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 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) OnabotulinumtoxinA (Botox for migraine).
4. **Dosage allowed:** 70 mg subcutaneous injection once a month. Some patients may benefit from a dosage of 140 mg once monthly. The 140 mg dose is administered once monthly as two consecutive injections of 70 mg each. Quantity Limit: 1 syringe or autoinjecter (70 mg/1 ml or 140 mg/1 ml) per 30 days.

Note: Aimovig is considered experimental and investigational as combination therapy with Botox, Vyepti, Ajovy or Emgality 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:** 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.

HAP 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.

HAP CareSource™

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.
07/16/2024	Added reference (May 2023); removed trial and failure of a second drug for cluster headache.

References:

1. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March, 2021.
2. Stauffer VL, Dodick DW, Zhang Q, Carter JN, Ailani J, Conley RR. Evaluation of Galcanezumab for the Prevention of Episodic Migraine: The EVOLVE-1 Randomized Clinical Trial [published correction appears in JAMA Neurol. 2019 Jul 1;76(7):872]. *JAMA Neurol*. 2018;75(9):1080-1088. doi:10.1001/jamaneurol.2018.1212
3. Skljarevski V, Matharu M, Millen BA, Ossipov MH, Kim BK, Yang JY. Efficacy and safety of galcanezumab for the prevention of episodic migraine: Results of the EVOLVE-2 Phase 3 randomized controlled clinical trial. *Cephalalgia*. 2018;38(8):1442-1454. doi:10.1177/0333102418779543
4. Detke HC, et al. Galcanezumab in chronic migraine: The randomized, double-blind, placebo-controlled REGAIN study. *Neurology*. 2018;91(24):e2211-e2221.
5. Goadsby PJ, Dodick DW, Leone M, et al. Trial of Galcanezumab in Prevention of Episodic Cluster Headache. *N Engl J Med*. 2019;381(2):132-141. doi:10.1056/NEJMoa1813440
6. 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.
7. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016;56(7):1093-1106. doi:10.1111/head.12866
8. Diener HC, May A. Drug Treatment of Cluster Headache. *Drugs*. 2022;82(1):33-42. doi:10.1007/s40265-021-01658-z
9. 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
10. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211. doi:10.1177/0333102417738202
11. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341. doi:10.1111/head.14692

Effective date: 01/01/2025
Revised date: 04/29/2024

MI-EXC-P-3321474