Emgality (galcanezumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial request: 3 months Renewal requests: 1 year

Medications	Quantity Limit
Emgality (galcanezumab) 120 mg/ mL prefilled pen, 120 mg/ mL prefilled syringe/autoinjector	1 prefilled pen/syringe/autoinjector per 28 days*
Emgality (galcanezumab) 100 mg/mL prefilled syringe	3 prefilled syringes (1 box of 3 syringes) per 28 days

*Initiation of therapy for prevention of migraine headaches: May approve one additional 120 mg/mL prefilled pen/syringe/autoinjector in the first month of therapy.

APPROVAL CRITERIA

Initial requests for Emgality (galcanezumab) for the prevention of migraine headaches may be approved when the following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period; **OR**
   B. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3);

AND

II. Individual is using for migraine prophylaxis ;

AND

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response to a 2 month trial or usual effective dose or intolerance to two agents for migraine prophylaxis* (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence, AHS 2021):
   A. The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine; **OR**
   B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; **OR**
   C. The following calcium channel blocker: verapamil; **OR**

D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin; **OR**
E. Botox (for chronic migraine);

*Agents for migraine prophylaxis – May require Prior Authorization

AND

IV. If individual is also currently using botulinum toxin for prophylaxis and is going to be using Emgality and botulinum toxin together (i.e., not switching from one agent to another), the following must apply:
   A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent; **AND**
   B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention.

Renewal requests for Emgality (galcanezumab) for the prevention of migraine headaches may be approved when the following criteria are met:

I. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
II. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):
   A. 50% reduction in frequency of days with headache or migraine; **OR**
   B. Significant decrease in attack duration; **OR**
   C. Significant decrease in attack severity; **OR**
   D. Improved response to acute treatment; **OR**
   E. Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR**
   F. Improvements in health related quality of life and reduction in psychological stress due to migraine;

AND

III. If individual is using concurrently with botulinum toxin for migraine prophylaxis, the following must apply:
   A. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or Emgality).

Requests for Emgality (galcanezumab) for the prevention of migraine headaches may **not** be approved for the following:

I. Individual is using in combination with another prophylactic CGRP agent (Ajovy, Vyepti, Aimovig, Qulipta, or prophylactic use of Nurtec ODT).

Initial requests for Emgality (galcanezumab) for the treatment of episodic cluster headaches may be approved when the following criteria are met:

I. Individual has a diagnosis of cluster headaches meeting the following IHS diagnostic criteria (ICHD-3):
   A. Individual has 5 or more headache attacks; **AND**
   B. Individual has severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated; **AND**
   C. Individual's headache is accompanied by 1 or both of the following:
      1. 1 or more of the following symptoms or signs, ipsilateral to the headache:
         a. Conjunctival injection and/or lacrimation; **OR**
         b. Nasal congestion and/or rhinorrhea; **OR**
         c. Eyelid edema; **OR**
         d. Forehead and facial sweating; **OR**
         e. Miosis and/or ptosis; **OR**
      2. A sense of restlessness or agitation; **AND**
   D. Attacks have a frequency from 1 every other day to 8 per day; **AND**
   E. Individual's headache is not attributed to another headache disorder;

AND

II. Individual's cluster headaches are episodic per the following diagnostic criteria (ICHD-3)
   A. Individual has cluster headache attacks that occur in bouts (cluster periods); **AND**
   B. Individual has at least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of greater than or equal to 3 months;

AND

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to one of the following agents for treatment of cluster headaches* (AHS 2016):
   A. Sumatriptan (subcutaneous or nasal spray); **OR**
   B. Zolmitriptan (nasal spray or oral).

*Agents for cluster headaches – May require Prior Authorization

Renewal requests for Emgality (galcanezumab) for the treatment of episodic cluster headaches may be approved when the following criteria are met:

I. Individual has a reduction in the overall number of cluster headache periods; **AND**
II. Individual has obtained clinical benefit deemed significant by individual or prescriber.

Key References:

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.