

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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 30 days*
Emgality (galcanezumab) 100 mg/mL prefilled syringe	3 prefilled syringes (1 box of 3 syringes) per 30 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 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):

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- A. The following antidepressants: amitriptyline, venlafaxine; **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

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.

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

- I. Individual is using concomitantly with botulinum toxin for migraine prophylaxis.

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**

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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 Beta)

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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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