Commercial & HealthCare Exchange PA Criteria

Effective: May 6th, 2019

Prior Authorization: Emgality

Products Affected: Emgality (galcanezumab-gnlm injection) subcutaneous injection/prefilled syringe/auto-injector

Medication Description: Emgality (galcanezumab-gnlm injection) blocks calcitonin gene-related peptide (CGRP), a receptor involved in migraine attacks.

Covered Uses:

1. Preventive treatment of migraine in adults.
2. Treatment of episodic cluster headache in adults.

Exclusion Criteria:

1. Concurrent use (for example, during the same time period) of two CGRP inhibitors indicated for the preventative treatment of migraine (for example, Aimovig, Ajovy, Nurtec ODT, Vyepti)
2. Acute treatment of migraine.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

Initial Criteria

Migraine Prophylaxis

1. Patient has clinically diagnosed episodic migraine as defined at least 4 migraine days per month; **AND**
2. Patient has prior usage of at least **TWO** standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent migraines or reduce migraine frequency including:
    a. Angiotensin receptor blockers;
    b. Angiotensin Converting Enzyme Inhibitors;
    c. Beta-blockers (i.e. propranolol, metoprolol, atenolol);
    d. Calcium Channel blockers (i.e. verapamil);
    e. Anti-epileptics (i.e. as topiramate or divalproex sodium);
    f. Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); **AND**
3. The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
4. The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescribing physician.

Episodic cluster headache (treatment)

1. Patient has a diagnosis of episodic cluster headache; **AND**
2. Patient has between one headache every other day and eight headaches per day; **AND**
3. Patient has prior usage of at least **TWO** standard prophylactic pharmacologic therapies, each from a different pharmacologic class, used to prevent cluster headaches including:
    a. Verapamil;
    b. Lithium Carbonate;
    c. Melatonin;
    d. Corticosteroids (Prednisone);
    e. Anticonvulsant (topiramate, valproate);
    f. Suboccipital steroid injection; **AND**
4. The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescribing physician; **OR**
5. The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescribing physician.

Renewal Criteria:

1. Positive response to therapy demonstrated by a 50% reduction in monthly headache days; **AND**
2. The use of acute medications (ie NSAIDs, triptans) has decreased since start therapy; **AND**
3. Patient has an overall improvement in function with therapy

References:

1. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2019.

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Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/19/2019
2	Policy Update	Addition of indication for cluster headache to match FDA Label	All	7/10/2019
3	Policy Update	Removal of Aimovig AND Ajovy as required trials for migraine prophylaxis	Other Criteria	1/1/2020

4	Update	Episodic cluster headache: Update covered use to treatment Removal of requirement of “abortive” therapy Addition of renewal criteria	Covered Uses Other Criteria	3/27/2020
5	Update	In renewal criteria updated following two sentences in criteria from: 1. “Positive response to therapy demonstrated by a 50% reduction in monthly migraine days” to “Positive response to therapy demonstrated by a 50% reduction in monthly headache days.” 2. “The use of acute migraine medications (ie NSAIDs, triptans) has decreased since start therapy;” to “The use of acute medications (ie NSAIDs, triptans) has decreased since start therapy”	Renewal Criteria	12/10/2020
3	Update	Removed the following from Migraine prophylaxis other criteria: 5.Patient has prior usage in the last 18 months of at least one triptan therapy; AND 6.Patient is intolerant to or, has a contraindication to or, inadequate response from triptan therapy. Removed Frovatriptan from preferred trial in Episodic Cluster headache treatment	Other Criteria	7/01/2021
4	Update	Updated Exclusion criteria: From: 1.Concurrent use with another (CGRP) inhibitor to: Concurrent use (for example, during the same time period) of two CGRP inhibitors indicated for the preventative treatment of migraine (for example, Aimovig, Ajovy, Emgality, Nurtec ODT, Vyepti)	Other Criteria	4/5/2022