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 with another (CGRP) inhibitor
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; **AND**
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

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. Frovatriptan;
    d. Melatonin;
    e. Corticosteroids (Prednisone);
    f. Anticonvulsant (topiramate, valproate);
    g. 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 migraine days; **AND**
2. The use of acute migraine 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