Pharmacy Management Drug Policy

SUBJECT: Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists
POLICY NUMBER: PHARMACY-74
EFFECTIVE DATE: 6/19/2018
LAST REVIEW DATE: 8/19/2019

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

The Calcitonin Gene-Related Peptide (CGRP) antagonists are a novel class of medications used for the prevention of migraine headaches. Migraine headaches are thought to be caused by the activation of the trigeminal system. CGRP is a vasodilating neuropeptide that is released upon activation of the trigeminal system and plays a key role in the pathophysiology of migraine headaches. The level of CGRP is increased during the activation of the trigeminal system causing vasodilation, pro-inflammatory effects, and pain signaling which ultimately results in a migraine attack. The circulating level of CGRP results in increased pain, phonophobia, photophobia, and nausea. CGRP inhibitors bind to either the CGRP receptor or ligand thereby preventing receptor stimulation and, ultimately, a migraine attack[1-3].
The American Academy of Neurology (AAN) and the American Headache society (AHS) have clinical practice guidelines published with regard to the management of patients with migraine headache. The following medications are recommended for the treatment of migraine prevention by both guidelines as these medications have been established as effective treatments: antiepileptic drugs (AEDs): divalproex sodium, sodium valproate, topiramate and beta-blockers: metoprolol, propranolol, timolol. In addition, the AAN guideline recommends botulinum neurotoxin for the treatment of migraine prevention for patients with chronic migraine[4-5].

Please note: For migraine treatment medications not contained in this pharmacy management drug policy (e.g. Trokendi, Cambia, etc.) please refer to The Clinical Review Prior Authorizations (CRPA) Rx Drug Policy, The Step Therapy Policy (specific to the member's plan), or the Quantity Limit Policy for drug specific information.

POLICY:

Chronic or Episodic Migraine Headache
Aimovig (erenumab-aooe) (Rx benefit); Ajovy (fremanezumab-vfrm) (Rx or Medical benefit); Emgality 120 mg (galcanezumab-gnlm) (Rx benefit)

1. The member must be 18 years of age or older.

2. The provider must attest that the medication is being used for migraine headache prevention for a diagnosis of either episodic or chronic migraine headache.

3. The provider must attest that the patient experiences 4 or more migraine headache days per month.

4. The provider must attest that the patient has had serious side effects or drug failure to at least 3 months of **TWO** different medications from **TWO** different medication classes that are used for the prevention of migraine headaches (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). If the patient is unable to tolerate a medication, a 3-month trial of that medication is not required.

5. Initial approval will be for 6 months. Recertification after the initial 6-month approval will require provider attestation of a clinical response to treatment. A clinical response to treatment is defined as a decrease in the number of migraine headache days experienced each month. If the recertification requirements are met, the request will be approved for 1 year. Yearly recertification thereafter will require provider attestation that the patient has maintained a clinical response to treatment.
6. Approved dosing:

Aimovig (erenumab-aooe): 70 mg or 140 mg subcutaneously once monthly.

Ajovy (fremanezumab-vfrm): 225 mg subcutaneously once monthly or 675 mg every three months (quarterly). The 675 mg quarterly dosage is administered as three consecutive injections of 225 mg each.

Emgality (galcanezumab-gnlm): A loading dose of 240 mg subcutaneously followed by a 120 mg subcutaneously once monthly. The 240 mg loading dose is administered as two consecutive injections of 120 mg each.
Maintenance dosing above 120 mg once monthly will be considered not medically necessary as clinical studies do not show any additional clinical benefit when given at doses exceeding this.

7. Administration:

Aimovig (erenumab-aooe): Self-administered.

Ajovy (fremanezumab-vfrm): Self-administered or administered by a health care professional.

a. For administration by a health care professional (coverage under the medical benefit), the member must have a documented inability to self-inject.

Emgality (galcanezumab-gnlm): Self-administered.

8. Quantity limit:

Aimovig (erenumab-aooe):

a. 70 mg single-dose package is 1 mL per 30 days (1-70 mg prefilled SureClick autoinjector)
b. 140 mg single-dose package is 1 mL per 30 days (1-140 mg prefilled SureClick autoinjector)
c. 140 mg two-dose package is 2 mL per 30 days (2-70 mg prefilled SureClick autoinjector)

Ajovy (fremanezumab-vfrm):

a. 1.5 mL per 30 days (1-225 mg prefilled syringe) OR 4.5 mL per 90 days (3-225 mg prefilled syringe)

Emgality (galcanezumab-gnlm):

a. 2 mL (2-120 mg single-dose prefilled pens/syringes) for 30 days for a **1 time loading dose** followed by 1 mL per 30 days (1-120 mg single-dose prefilled pen/syringe) thereafter.

Episodic Cluster Headache
Emgality 100 mg (galcanezumab-gnlm) (Rx benefit)

1. The patient must be 18 years of age or older.

2. The provider must attest that the patient has a documented diagnosis of episodic cluster headache per the International Classification of Headache Disorders (ICHD) diagnostic criteria with cluster periods lasting from seven days to one year.

3. The provider must attest that the patient has had serious side effects or drug failure of **TWO** *preferred* preventative medications used for episodic cluster headaches (including, but not limited to verapamil, oral steroids, and lithium).

4. Initial approval will be for 6 months. Recertification after the initial 6-month approval will require provider attestation of a clinical response to treatment and that the patient is still actively in a cluster period. A clinical response to treatment is defined as a decrease in the frequency of cluster headache attacks. If the recertification requirements are met, the request will be approved for 6-months. Subsequent 6-month approvals will require provider attestation that the patient has maintained a clinical response to treatment and that the patient is still actively in a cluster period. Cluster periods lasting beyond 1-year will be considered chronic cluster headaches and denied off-label.

6. Approved dosing:

Emgality (galcanezumab-gnlm): 300 mg subcutaneously at onset for cluster period followed by once monthly injections until the end of the cluster period. Given as three consecutive subcutaneous injections of 100 mg each.

7. Administration:

Emgality (galcanezumab-gnlm): Self-administered.

8. Quantity limit:

Emgality (galcanezumab-gnlm):

a. 3 mL (3-100 mg single-dose prefilled syringes) for 30 days

POLICY GUIDELINES:

1. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
2. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
     The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
3. Non-FDA approved indications for CGRP inhibitors will not be approved. Emgality 120 mg once monthly is only FDA approved for the prevention of Chronic or Episodic Migraine Headache. Emgality 100 mg (300 mg once monthly) is only FDA approved for the treatment for Episodic Cluster Headache.
4. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
5. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
6. Prior-authorization is contract dependent.
7. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.

HCPCS: **Ajovy (J3031)**

UPDATES:

Date	Revision
07/2019	Revised
11/2018	Revised
10/2018	Revised
09/2018	P&T Approval
06/2018	Created

REFERENCES:

1. Aimovig™ (erenumab-aooe) Injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen. May 2018

2. Ajovy™ (fremanezumab-vfrm) Injection for subcutaneous use [prescribing information]. North Wales, PA: Teva. September 2018

3. Emgality™ (galcanezumab-gnlm) Injection for subcutaneous use [prescribing information]. Indianapolis, IN: Eli Lilly. June 2019

4. Demaagd G. The pharmacological management of migraine, part 1: overview and abortive therapy. P T. 2008;33(7):404-16

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6. Ashina M, Dodick D, Goadsby PJ, et al. Erenumab (AMG 334) in episodic migraine: Interim analysis of an ongoing open-label study. Neurology. 2017;89(12):1237-1243.

7. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(19):1818-26.

8. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1.