JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS113
		Effective Date	07/18/2018
		Review Date	04/19/2023
	Subject **Self-administered CGRP Inhibitors: Aimovig, Ajovy, Emgality**	*Revision Date*	02/22/2023
		Page	1 of 4

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Aimovig, Ajovy, CGRP inhibitors, Emgality

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Ajovy	**1**
	B. Aimovig	**2**
	C. Emgality	**2**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**3**
IV.	**EXCLUSIONS**	**3**
V.	**REFERENCES**	**3**
VI.	**APPROVALS**	**4**

I. POLICY

Aimovig (Erenumab-aooe), **Ajovy** (fremanezumab-vfrm), and **Emgality** (galcanezumab-gnlm) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Ajovy** (fremanezumab-vfrm) may be approved for the following:
   1. **Preventative chronic migraine management** in patients who meet all the following:
      a. Patient is 18 years of age or older
      b. Documentation showing a diagnosis of chronic migraine (greater than or equal to 15 headache days per month with 8 being migraine days with symptoms lasting 4 hours a day or longer)
      c. Documentation that the patient does not have medication-induced headaches from overuse of acute treatment agents (analgesics, triptans, ergots)
      d. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants
      e. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists
   2. **Preventative episodic migraine management** in patients who meet all the following:
      a. Patient is 18 years of age or older
      b. Documentation showing a diagnosis of episodic migraine (<15 days per month)
      c. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants

d. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists

B. **Aimovig** (erenumab-aooe) may be approved for the following:

1. **Preventative chronic migraine management** in patients who meet all the following:
   a. Patient is 18 years of age or older
   b. Documentation showing a diagnosis of chronic migraine (greater than or equal to 15 headache days per month with 8 being migraine days with symptoms lasting 4 hours a day or longer)
   c. Documentation that the patient does not have medication-induced headaches from overuse of acute treatment agents (analgesics, triptans, ergots)
   d. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants
   e. Documentation that the patient has had trial and failure with Ajovy
   f. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists
2. **Preventative episodic migraine management** in patients who meet all the following:
   a. Patient is 18 years of age or older
   b. Documentation showing a diagnosis of episodic migraine (<15 days per month)
   c. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants
   d. Documentation that the patient has had trial and failure with Ajovy
   e. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists

C. **Emgality** (galcanezumab-gnlm) may be approved for the following:

1. **Preventative chronic migraine management** in patients who meet all the following:
   a. Patient is 18 years of age or older
   b. Documentation showing a diagnosis of chronic migraine (greater than or equal to 15 headache days per month with 8 being migraine days with symptoms lasting 4 hours a day or longer)
   c. Documentation that the patient does not have medication-induced headaches from overuse of acute treatment agents (analgesics, triptans, ergots)
   d. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants
   e. Documentation that the patient has had trial and failure with Ajovy
   f. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists
2. **Preventative episodic migraine management** in patients who meet all the following:
   a. Patient is 18 years of age or older
   b. Documentation showing a diagnosis of episodic migraine (<15 days per month)
   c. Trial and failure of medications from at least two of the following therapeutic classes used in standard therapy for migraine prophylaxis: beta antagonists, anticonvulsants, and antidepressants
   d. Documentation that the patient has had trial and failure with Ajovy
   e. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists
3. **Treatment of episodic cluster headache** in patients who meet all the following:
   a. Patient is 18 years of age or older
   b. Documentation showing a diagnosis of episodic cluster headache (cluster headache attacks in periods lasting from 7 days to one year, separated by pain-free periods lasting at least 3 months)
   c. Documentation that the patient has a maximum of 8 attacks per day, and a minimum of one attack every other day

d. Trial and failure of at least two medications used in standard therapy for cluster headache preventative treatment: verapamil, and prednisone or dexamethasone
e. The prescriber is a neurologist or pain specialist, or has consulted with one of these specialists

III. AUTHORIZATION PERIOD/LIMITATIONS

1. Initial approval will be restricted to 6 months of therapy
2. Approval for continuation of therapy can be extended in 12-month intervals with evidence of clinical improvement as evidenced by documentation of at least one of the following:
   A. The patient's mean monthly headache days have been reduced by 50% or greater relative to the patient's baseline prior to treatment
   B. The patient has had a reduction in any of the following validated migraine-specific patient-reported outcome measures, as described below:
      i. Migraine Disability Assessment (MIDAS):
         a. Reduction of 5 points or greater when baseline score is 11–20
         b. Reduction of 30% or greater when baseline scores >20
      ii. Migraine Physical Function Impact Diary (MPFID):
         a. Reduction of 5 points or greater
      iii. HIT-6 (Headache Impact Test):
         a. Reduction of 5 points or greater
3. Quantity limitations:
   A. Aimovig: The requested dose is not greater than 140 mg once monthly
   B. Ajovy: The requested dose is not greater than 225 mg once monthly, or 675 mg every 3 months (three consecutive injections of 225 mg)
   C. Emgality for Migraine:The requested dose is not greater than 240 mg (two consecutive injections of 120 mg) as a one-time loading dose, and 120 mg once monthly
   D. Emgality for episodic cluster headache: The requested dose is not greater than 300 mg (three consecutive injections of 100 mg) at the onset of the cluster period, and 300 mg monthly until the end of the cluster period

IV. EXCLUSIONS

A. **Aimovig, Ajovy, and Emgality** will not be approved for the following:
   1. Concurrent use with medical botulinum toxin injection
   2. Concurrent use with another injectable CGRP inhibitor
   3. Patients under the age of 18 years of age
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen Inc. May 2018
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3. Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. June 2019
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VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/18/2018	Policy Creation for Aimovig
11/09/2018	Addition of clinical criteria for Ajovy and Emgality.
07/17/2019	Updated Emgality criteria for new indication of episodic cluster headache; Clarified clinical criteria for continuation of therapy; updated criteria to reflect Ajovy as the preferred CGRP inhibitor product
12/16/2020	Clarified exclusions
05/13/2021	Updated authorization guidance
12/08/2021	Updated Exclusions section regarding physician samples
02/22/2023	Updated authorization guidance

Review Date:07/18/2018, 11/09/2018, 07/17/2019

Revision Date: 07/18/2018, 11/09/2018, 07/17/2019, 12/16/2020, 05/13/2021, 12/08/2021, 02/22/2023