JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP029
		Effective Date	07/17/2019
		Review Date	07/15/2020
	Subject **Provider-administered CGRP Inhibitors: Ajovy, Vyepti**	*Revision Date*	11/10/2021
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Ajovy, CGRP inhibitors, Vyepti

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I. POLICY

Ajovy (fremanezumab-vfrm) and **Vyepti** (eptinezumab-jjmr) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. **Ajovy** 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. 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. Prescriber is a neurologist or pain specialist, or has consulted with one of these specialists

B. **Vyepti** may be approved for the following
   1. **Preventative chronic migraine management** in patients who meet all the following:
      1. Patient is 18 years of age or older

2. Documentation showing a diagnosis of chronic migraine (15 to 26 headache days per month with at least 8 being migraine days)
3. Documentation that the patient does not have medication-induced headaches from overuse of acute treatment agents (analgesics, triptans, ergots)
4. 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
5. 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:
   1. Patient is 18 years of age or older
   2. Documentation showing a diagnosis of episodic migraine (4 to 14 headache days per month with at least 4 being migraine days)
   3. 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
   4. 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 6-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. Ajovy: The requested dose is not greater than 225 mg once monthly, or 675 mg every 3 months (three consecutive injections of 225 mg)
   B. Vyepti: The requested dose is not greater than 300mg every 3 months (100mg every 3 months is recommended for initial dosing)

IV. EXCLUSIONS

A. **Ajovy and Vyepti** 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

V. RECOMMENDED DOSAGE

All FDA approved dosage(s) and dosing interval(s) for the FDA approved indication(s).

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
AJOVY 225MG/1.5ML Solution Prefilled Syringe Injection, fremanezumab-vfrm, 1 mg	J3031
VYEPTI 100MG/ML Solution Injection, eptinezumab-jjmr, 1 mg	C9063

VII. REFERENCES

1. Ajovy [Prescribing Information]. North Wales, PA; Teva Pharmaceuticals. September 2018
2. Vyepti [Prescribing Information]. Bothell, WA; Lundbeck Seattle BioPharmaceuticals, Inc. February 2020
3. Institute for Clinical and Economic Review. Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventive Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value. Final Evidence Report. July 3, 2018. Available at: https://icer-review.org/wp-content/uploads/2017/11/ICER_Migraine_Final_Evidence_Report_070318.pdf Accessed 11/9/2018.
4. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18. Available at: https://onlinelibrary.wiley.com/doi/pdf/10.1111/head.13456 Accessed 6/19/2019.
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VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2019	Policy Creation for provider-administered Ajovy (clinical criteria adapted from MEDS113: Aimovig, Ajovy, Emgality)

01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
07/15/2020	Added clinical criteria for Vyepti
12/16/2020	Clarified exclusions
05/13/2021	Updated authorization guidance
11/10/2021	Removed Priority Partners as an applicable LOB

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