



## **MVP Health Care Medical Policy**

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### **Medicare Part B: Vyapti**

**Type of Policy:** Drug Therapy

**Prior Approval Date:** 08/01/2024

**Approval Date:** 10/01/2025

**Effective Date:** 01/01/2026

**Related Policies:** N/A

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

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### **Codes Requiring Prior Authorization (covered under the medical benefit)**

J3032 Vyapti (injection, eptinezumab-jjmr, 1mg)

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### **Overview/Summary of Evidence**

Migraine is a common disabling primary headache disorder. In the Global Burden of Disease Study 2010 (GBD2010), it was ranked as the third most prevalent disorder in the world. In GBD2015, it was ranked the third-highest cause of disability worldwide in both males and females under the age of 50 years.

Calcitonin Gene-Related Peptides (CGRP) receptor antagonists are a group of medications indicated in either the prophylaxis or acute treatment of migraine headaches. Vyapti is a humanized monoclonal antibody that binds to the CGRP ligand and blocks its binding to the receptor.

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### **Indications/Criteria for prophylaxis for Vyapti**

Requests will be considered for coverage when all the following are met:

For chronic migraine:

- Confirmed diagnosis of chronic migraines
- Inadequate response (defined as less than a 2 day decrease per month in headache frequency) to at least a 1 (one) trial to at least 1 (one) prophylactic medication (i.e., topiramate, divalproex, beta blocker (i.e. propranolol, timolol, atenolol, nadolol), candesartan, amitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Quipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality) ) at maximally tolerated doses.

For episodic migraine:

- Confirmed diagnosis of episodic migraines
- Inadequate response (defined as less than a 2 day decrease in headache frequency) to at least a 1 (one)-month trial to at least 1 (one) prophylactic medication (i.e., topiramate, divalproex, beta blockers (i.e. propranolol, timolol, atenolol, nadolol), candesartan, amitriptyline, nortriptyline, verapamil, venlafaxine, duloxetine, rimegepant (Nurtec), atogepant (Quipta), Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality) at maximally tolerated doses.
- Documentation identifying medical necessity why the member is unable to use a self-administered CGRP product indicated for migraine prevention (such as failure, intolerance, or contraindication to self-administered products).
  - If applicable, documentation should also include why the member or caregiver is unable to administer a self-administered CGRP product indicated for migraine prevention.
  - Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

**Initial approval** will be for **3 months**.

**Extension requests** will be approved for **up to 12 months** if the member has a continued benefit to therapy.

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## **Exclusions**

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- History of hemiplegic ophthalmoplegic, migraine with brainstem aura, or persistent daily headaches
- Use of devices (i.e., nerve blocks and transcranial magnetic stimulation)

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## References

1. Aimovig (erenumab-aooe) [Package Insert]. Thousand Oaks, CA: Amgen Inc.; 20182.
2. Olesen J, Bes A, Kunkel R, et al. The international classification of headache disorders, 3<sup>rd</sup> edition. *Cephalgia*. 2018; 38(1):1-211.
3. <https://americanmigrainefoundation.org/understanding-migraine/medication-overuse-headache-2/>
4. Ajovy (fremanezumab-vfrm) [Package Insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. September 2018.
5. Emgality (galcanezumab-gnlm) [Package Insert]. Indianapolis, IN: Eli Lilly and Company. June 2019.
6. <https://clinicaltrials.gov/ct2/show/study/NCT02397473?term=NCT02397473&rank=1>
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9. Local Coverage Determination L33646; Botulinum Toxins; effective 10/31/2019
10. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache* 2018; 59:1-18.
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12. Aimovig. Study Details | Study to Evaluate the Efficacy and Safety of Erenumab (AMG 334) in Migraine Prevention | ClinicalTrials.gov. A Controlled Trial of Erenumab for Episodic Migraine | New England Journal of Medicine (nejm.org)
13. Ajovy: Efficacy and Safety of 2 Dose Regimens of TEV-48125 Versus Placebo for the Preventive Treatment of Episodic Migraine - Full Text View - ClinicalTrials.gov.

Comparing Efficacy and Safety of 2 Dose Regimens of Subcutaneous Administration of TEV-48125 Versus Placebo for the Preventive Treatment of Chronic Migraine - Full Text View - ClinicalTrials.gov

14. Emgality. Evaluation of Galcanezumab in the Prevention of Episodic Migraine- the EVOLVE-1 Study - Full Text View - ClinicalTrials.gov