MVP Health Care Medical Policy

Medicare Part B: Calcitonin Gene-Related Peptide (CGRP) Antagonists

Type of Policy:	Drug Therapy
Prior Approval Date:	11/01/2023
Approval Date:	08/01/2024
Effective Date:	10/01/2024
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.

Codes Requiring Prior Authorization (covered under the medical benefit)

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

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.

Cluster headaches is a debilitating primary headache disorder defined as a severe attack that can last weeks or months (also known as "cluster periods"). Cluster headaches are categorized as episodic (having pain free remission periods) and chronic (do not have pain free remission periods). Currently, Emgality is the only CGRP Antagonist indicated for the treatment of episodic cluster headache.

Medication overuse headache is not an approved indication for calcitonin gene-related peptide antagonists and providers should assess their patients and rule out prior to initiating therapy.

Calcitonin Gene-Related Peptides (CGRP) receptor antagonists are a group of medications indicated in either the prophylaxis or acute treatment of migraine headaches. Aimovig, Emgality, Vyepti, Nurtec and Ajovy are FDA approved for migraine prophylaxis while Nurtec and Ubrelvy are FDA approved for acute migraine treatment.

Indications/Criteria for prophylaxis for Vyepti

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

- Confirmed diagnosis of chronic or episodic migraine

For chronic migraine:

- 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, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses.

For episodic migraine:

- 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, propranolol, metoprolol, timolol, amitriptyline, verapamil, venlafaxine) at maximally tolerated doses.

For Vyepti:

- All applicable criteria listed above **AND**
- Documentation identifying medical necessity why the member is unable to use a self-administered product (such as a 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 product.
    - 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.

Exclusions

- Off-label diagnosis
- 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)

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, 3rd edition. Cephalagia. 2018; 38(1):1-211.
3. https://americanmigrationfoundation.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
7. Olesen J, Bes A, Kunkel R, et al. The International Classification of Headache Disorders. 3rd edition. *Cephalalgia*. 2018; 38(1): 41-42.
8. Robbins M.S, Starling A.J, et al (2016). Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache: The Journal of Head and Face Pain*. 56 (7): 1093-1106. DOI: 10.1111/head.12866
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.
11. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039. doi:10.1111/head.14153.

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