

Vyepti® (eptinezumab-jjmr)

When requesting Vyepti® (eptinezumab-jjmr), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Vyepti is indicated for the preventive treatment of migraine in adults.

Coverage Guidelines

Migraine Headache Prevention

An individual must meet **all** of the following criteria for approval:

- Is 18 years of age or older;
- Has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication);
- Is not using another calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headache (e.g., Qulipta, Ajovy, Aimovig, Emgality);
- For the request of continuation of Vyepti, the individual must have a significant clinical benefit (e.g., a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time Vyepti was initiated).

Approval duration (initial and renewal): 12 months

Dosing Recommendations

The recommended dosage is 100 mg administered by intravenous infusion every 3 months.

References

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4. Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;52:103-122.
5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.

6. Ailani J, Burch RC, Robbins MS, on behalf of the 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;00:1–19.
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8. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020;40(3):241-254.
9. Data on file. Eptinezumab-jjmr Pre-Approval Dossier, version 1.7. Lundbeck, Inc.; Deerfield, IL; received on March 2, 2020.
10. Aimovig® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; May 2023.
11. Ajovy® injection for subcutaneous use [prescribing information]. North Wales, PA: Teva; October 2022.
12. Emgality® injection for subcutaneous use [prescribing information]. Indianapolis, IN: Lilly; May 2021.
13. Qulipta™ tablets [prescribing information]. Madison, NJ: AbbVie; April 2023.
14. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2023.