

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);
- Has tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, β -blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant) and meets one of the following:
 - o Had an inadequate response to both of those standard prophylactic medications; OR
 - o Has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic medications; OR
 - o Had an inadequate response to one standard prophylactic medication and has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic 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. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345.
7. 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.
8. Data on file. Eptinezumab-jjmr Pre-Approval Dossier, version 1.7. Lundbeck, Inc.; Deerfield, IL; received on March 2, 2020.
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10. Ajovy® injection for subcutaneous use [prescribing information]. North Wales, PA: Teva; September 2021.
11. Emgality® injection for subcutaneous use [prescribing information]. Indianapolis, IN: Lilly; December 2019.
12. Qulipta™ tablets [prescribing information]. Madison, NJ: AbbVie; September 2021.
13. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.