

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

- Prevention of migraine headaches 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; AND
- Has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication); AND
- Has tried at least two standard prophylactic (preventive) 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:
 - Has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies; OR
 - Has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies; OR
 - Has had inadequate efficacy to one standard prophylactic pharmacologic therapy and has experienced adverse event(s) severe enough to warrant discontinuation to another standard prophylactic pharmacologic therapy; AND
- The patient meets one of the following:
 - Is not taking a calcitonin gene-related peptide (CGRP) inhibitor (e.g., Aimovig (erenumab-aooe injection), Ajovy (fremanezumab-vfrm injection), Emgality (galcanezumab-gnlm injection), and Vyepti.) and meets one the following (a or b):
 - a. Has tried at least one triptan therapy; OR
 - b. Has a contraindication to triptan(s) (e.g., a history of coronary artery disease; cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; or severe hepatic impairment); OR

- Is currently taking Vyepti and has had a significant clinical benefit (e.g., reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Vyepti was initiated.); OR
- Is switching from a different CGRP inhibitor

Approval duration (initial and renewal): 12 months

Dosing Recommendations

- Up to 300 mg administered by intravenous infusion once 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.
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7. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020 Feb 19. [Epub ahead of print].
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 Pharmaceuticals USA, Inc.; January 2020.
11. Emgality® injection for subcutaneous use [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2019.
12. Nurtec™ ODT [prescribing information]. New Haven, CT: Biohaven Pharmaceuticals; May 2021.

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