



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;
- 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 The patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies; OR
 - o The patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies; OR
 - o The patient 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:
 - o Has tried at least one triptan therapy; OR
 - o Has a contraindication to triptan(s).

Approval duration (initial and renewal): One year

Dosing Recommendations

- Up to 300 mg administered by intravenous infusion once every 3 months

References

1. Vyepti™ injection for intravenous use [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition (beta version). *Cephalalgia*. 2013;33:629-808.
3. MacGregor EA. In the clinic. Migraine. *Ann Intern Med*. 2017;166(7):ITC49-ITC64.
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 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.
9. Aimovig® injection for subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen; October 2019.
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.

Vyepti® (eptinezumab-jjmr)