

Vyepti (eptinezumab)

Override(s)	Approval Duration
Prior Authorization	Initial request: 6 months (two injection cycles)
Quantity Limit	Renewal requests: 1 year

Medications	Quantity Limit
Vyepti (eptinezumab) 100 mg/mL vial	1 vial (100 mg)* per 3 months

*Individuals have had an inadequate response to 100 mg dose may be approved for 3 vials (300 mg) every 3 months

APPROVAL CRITERIA

Initial requests for Vyepti (eptinezumab) may be approved when the following criteria are met:

- I. Individual has a diagnosis of one of the following:
 - A. Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period; **OR**
 - B. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3);

AND

- II. Individual is using Vyepti for migraine prophylaxis;

AND

- III. Individual has had a trial of and inadequate response to a 2 month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis* (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence, AHS 2021). Medication samples/coupons/discount cards are excluded from consideration as a trial.:
 - A. The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine; **OR**
 - B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; **OR**
 - C. The following calcium channel blocker: verapamil; **OR**
 - D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin.

*Agents for migraine prophylaxis – May require Prior Authorization

AND

- IV. Individual has had a trial of and inadequate response or intolerance to Emgality. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

- V. If individual is also currently using botulinum toxin for prophylaxis and is going to be using Vyepti and botulinum toxin together (i.e., not switching from one agent to another), the following must apply:
 - A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent;
AND
 - B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention.

Renewal requests for Vyepti (eptinezumab) may be approved when the following criteria are met:

- I. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
- II. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):
 - A. 50% reduction in frequency of days with headache or migraine; **OR**
 - B. Significant decrease in attack duration; **OR**
 - C. Significant decrease in attack severity; **OR**
 - D. Improved response to acute treatment; **OR**
 - E. Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR**
 - F. Improvements in health related quality of life and reduction in psychological stress due to migraine.

AND

- III. If individual is using concurrently with botulinum toxin for migraine prophylaxis, the following must apply:
 - A. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or Vyepti).

Vyepti (eptinezumab) may **not** be approved for the following:

- I. Individual is using in combination with another prophylactic CGRP agent (Ajovy, Aimovig, Emgality, Qulipta, or prophylactic use of Nurtec ODT).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. Available from: [icsi.org/wp-content/uploads/2019/01/Headache.pdf](https://www.icsi.org/wp-content/uploads/2019/01/Headache.pdf). Updated January 2013.

6. The International Classification of Headache Disorders 3rd Edition. Available from: <https://www.ichd-3.org/>. Accessed April 22, 2023. 5
7. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A summary and comparison with other recent clinical practice guidelines. *Headache*. 2018; 52:930-945.
8. Rapoport AM. How to choose a preventative medication for migraine. American Headache Society. Available from: https://americanheadachesociety.org/wp-content/uploads/2018/05/Alan_Rapoport_-_Migraine_Prevention_Medications.pdf.
9. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. 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; 78:1337–1345.
10. The American Headache Society Consensus statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61:1021-1039.
11. Dodick DW, Lipton RB, Silberstein S, et.al. Eptinezumab for prevention of chronic migraine: A randomized phase 2b clinical trial. *Cephalgia*. 2019; 39(9):1075-1085.
12. Ashina M, Saper J, Cady R et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 2020; 0(0): 1-14. Doi: 10.1177/0333102420905132.
13. Blumenfeld AM, Frisberg BM, Schim JD, et.al. Real-world evidence for control of chronic migraine patients receiving CGRP monoclonal antibody therapy added to onabotulinumtoxinA: A retrospective chart review. *Pain Ther*. 21 April 2021. <https://doi.org/10.1007/s40122-021-00264-x>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.