Vyepti® (eptinezumab-jjmr)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 300 billable units every 84 days

III. Initial Approval Criteria [1,4-10,14-17]

Prior authorization validity is provided in the following conditions:

- Patient must have a contraindication, intolerance, or failure to **Ajovy®, Aimovig®,** OR **Emgality®** prior to consideration of Vyepti®; **AND**

- Member is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Headache Impact Test [HIT-6]; monthly headache day [MHD]; Migraine Disability Assessment [MIDAS]; Migraine Physical Function Impact Diary [MPFID]); **AND**

Universal Criteria

- Other causes of headaches have been ruled out; **AND**
- Not used in combination with prophylactic calcitonin gene-related peptide (CGRP) inhibitors *(Note*: *This does not apply to CGRP inhibitors that are being used for acute treatment only);* **AND**
- Member is utilizing prophylactic intervention modalities (e.g., avoiding migraine triggers, pharmacotherapy, behavioral therapy, neuromodulation, physical therapy, etc.); **AND**

Preventative Treatment of Migraines †

- Member has a diagnosis of chronic migraines defined as 15 or more headache (tension-type-like and/or migraine-like) days per month for > 3 months**; **AND**
  - On at least 8 days per month for > 3 months, headaches have one of the following features consistent with migraine**:**
    - Headache is relieved by triptans or ergot derivatives; **OR**

        - Headache is presenting as migraine with aura; **OR**
        - Headache is without aura but has characteristics of a migraine as determined by the provider (e.g., unilateral, pulsating, nausea/vomiting, photophobia/phonophobia, etc.); **OR**
- Member has a diagnosis of frequent episodic migraines defined as 4-14 monthly headache days per month**; **AND**
    - On at least 4 days per month, headaches have one of the following features consistent with migraine:
        - Headache is relieved by triptans or ergot derivatives; **OR**
        - Headache is presenting as migraine with aura; **OR**
        - Headache is without aura but has characteristics of a migraine as determined by the provider (e.g., unilateral, pulsating, nausea/vomiting, photophobia/phonophobia, etc.)

***NOTE: Members new to therapy must initiate treatment at the lower dosing regimen of the 100 mg dose before increasing to the 300 mg dose, if required.*

† FDA Approved Indication; ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,10,16,17]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, severe constipation, uncontrolled hypertension, development of Raynaud's phenomenon, etc.; **AND**
- Disease response as evidenced by the following:
    - A ≥50%♦ decrease in monthly migraine days or moderate-to-severe headache days, relative to the pretreatment baseline (diary documentation or medical professional attestation); **OR**
    - A clinically meaningful improvement in ANY of the following validated migraine-specific member-reported outcome measures:
        - Reduction of ≥5 points when baseline score is 11–20 OR Reduction of ≥30% when baseline score is >20 in the MIDAS scores; **OR**
        - Reduction of ≥5 points in the MPFID score; **OR**
        - Reduction of ≥5 points in the HIT-6 score; **AND**
    - Dose escalation** (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the member has:
        - Had an initial and then subsequent loss of response to the 100 mg dose; **OR**
        - Had an inadequate response (e.g., no net decrease in frequency of headaches) to the 100 mg dose

♦ *NOTE: A ≥ 30% decrease in monthly migraine days or moderate-to-severe headache days is acceptable for members with chronic migraine who have failed prior therapies.*

V. Dosage/Administration [1,11,12]

Indication	Dose
Preventative Treatment of Migraines	The recommended dosage is 100 mg** administered by intravenous infusion every 3 months. ***Note:** Some members may benefit from a dosage of 300 mg administered by intravenous infusion every 3 months *(Refer to criteria in section IV).*

VI. Billing Code/Availability Information

HCPCS Code:

- J3032 – Injection, eptinezumab-jjmr, 1 mg; 1 billable unit = 1 mg

NDC:

- Vyepti 100 mg/mL solution for injection; single-dose vial: 67386-0130-xx

VII. References

1. Vyepti [package insert]. Bothell, WA; Lundbeck Seattle BioPharmaceuticals, Inc; June 2026. Accessed June 2026.
2. Modi S, Lowder DM. Medications for migraine prophylaxis. Am Fam Physician. 2006 Jan 1; 73(1):72-8.
3. Pringheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. Can Jneurol Sci. 2012 Mar; 39(2 Suppl 2):S1-S9.
4. The International Classification of Headache Disorders, 3rd edition. Headache Classification Committee of the International Headache Society (IHS) Cephalalgia. 2018; 38(1):1-211.
5. Garza I, Schwedt TJ. (2026) Chronic Migraine. In Robertson CE (Ed). *UpToDate*. Last updated: May 7, 2026. Accessed on June 15, 2026. Available from https://www.uptodate.com/contents/chronic-migraine.
6. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019 Jan;59(1):1-18. doi: 10.1111/head.13456. Epub 2018 Dec 10.
7. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). Cephalalgia. 2020 Mar;40(3):241-254. doi: 10.1177/0333102420905132. Epub 2020 Feb 19.
8. Cady R, McGill L, Hirman J, et al. Patient Global Impression of Change Related to Improvement in Most Bothersome Symptom Following Treatment With Eptinezumab (S38.009). Neurology Apr 2019, 92 (15 Supplement) S38.009;
9. Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. Neurology. 2020 Mar 31;94(13):e1365-e1377. doi:

10.1212/WNL.0000000000009169. Epub 2020 Mar 24. Erratum in: Neurology. 2023 Aug 8;101(6):283. PMID: 32209650; PMCID: PMC7274916.

10. Ailani J, Burch RC, Robbins MS; 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 Jul;61(7):1021-1039. doi: 10.1111/head.14153. Epub 2021 Jun 23. PMID: 34160823.
11. Apelian R, Boyle L, Hirman J, Asher D. Measuring dose-related efficacy of eptinezumab for migraine prevention: post hoc analysis of PROMISE-1 and PROMISE-2. J Headache Pain. 2022 Apr 18;23(1):48. Doi: 10.1186/s10194-022-01418-8. PMID: 35436857; PMCID: PMC9014586.
12. Chen H, Luo W. Efficacy and safety of eptinezumab 300mg versus 100mg for migraine patients: a meta-analysis of randomized controlled studies. Int J Neurosci. 2022 Sep 29:1-6. doi: 10.1080/00207454.2022.2115906. Epub ahead of print. PMID: 35993143.
13. Toni T, Tamanaha R, Newman B, et al. Effectiveness of dual migraine therapy with CGRP inhibitors and onabotulinumtoxinA injections: case series. Neurol Sci. 2021 Dec;42(12):5373-5376. doi: 10.1007/s10072-021-05547-x. Epub 2021 Aug 18. PMID: 34409517.
14. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024; 64: 333-341. doi:10.1111/head.14692
15. Schwedt TJ, Garza I. (2026) Preventive Treatment of Episodic Migraine in Adults. In Swanson JW (Ed). *UpToDate*. Last updated: May 5, 2026. Accessed on June 15, 2026. Available from https://www.uptodate.com/contents/preventive-treatment-of-episodic-migraine-in-adults.
16. Puledda F, Sacco S, Diener HC, et al. International Headache Society Global Practice Recommendations for Preventive Pharmacological Treatment of Migraine. *Cephalalgia*. 2024;44(9):3331024241269735. doi:10.1177/03331024241269735.
17. Sacco S, Ashina M, Diener HC, et al. Setting higher standards for migraine prevention: A position statement of the International Headache Society. *Cephalalgia*. 2025;45(2):3331024251320608. doi:10.1177/03331024251320608.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA

Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10 Code	ICD-10 Description
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migraine with aura, intractable, without status migrainosus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/ LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT,	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC