

Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Vyepti®	Drug Generic Name:	Eptinezumab-jjmr
J Code:	J3032	1 billable unit =	1 mg
Original Date of Review:	12/3/2025	Last Reviewed:	12/3/2025
Revision Date History			

Vyepti is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that specifically binds gene related peptide (CGRP) ligand and blocks its binding in the receptor.

Criteria:

- **Length of authorization (LOA):**
 - **Initiation:** 6 months
 - **Renewal:** 12 months
- **Age:** At least 18 years of age
- **Diagnoses:**
 - Migraine
- **Quantity Limit:**
 - Vyepti® 100 mg vial
 - Initial dose: 1 vial (100 mg) IV every 3 months
 - Max: 3 vials (300 mg) IV every 3 months
- **Maximum Units:**
 - 300 units every 84 days
- **Initial Approval Criteria**
 - **Universal Criteria**
 - Patient is at least 18 years of age
 - **Indication Specific Criteria**
 - **Prophylaxis of Chronic Migraine**
 - Patient has a diagnosis of migraine with or without aura; **AND**
 - Patient has four (4) or more migraine days per month for at least three months; **AND**
 - Clinical documentation showing trial and failure or intolerance to Aimovig®, Emgality®, and Ajovy® for three (3) continuous months each without achieving adequate reduction in migraines; **OR**
 - Clinical documentation showing FDA-recognized contraindication to Aimovig®, Emgality®, and Ajovy®; **AND**
 - Provider attests requested drug will not be used in combination with another calcitonin gene-related peptide (CGRP) inhibitors for the preventative treatment of migraines (e.g., Aimovig® [erenumab], Emgality® [galcanezumab], Ajovy® [fremanezumab], Nurtec® [rimegepant], Qulipta® [atopepant], etc.); **AND**
 - Clinical documentation showing patient has tried and failed an 8-week trial of at least one (1) medication in at least two (2) of the following medication classes:

- Antidepressants (amitriptyline, venlafaxine, or nortriptyline)
- Beta Blockers (propranolol, metoprolol, timolol, or atenolol)
- Anti-epileptics (valproate, topiramate, or divalproex)
- Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan, etc.)
- Calcium channel blockers (verapamil)
- **Renewal Criteria**
 - Coverage may be renewed based upon the following criteria:
 - Patient continues to meet universal and indication-specific criteria as identified in Initial Approval Criteria; **AND**
 - Provider attests patient has not experienced any unacceptable toxicities from the drug
 - **Prophylaxis of Chronic Migraine**
 - Provider attests patient has demonstrated significant decrease in the number, frequency, and/or intensity of migraines
- **Dosage/Administration**

Vyepti® (IV)	
Indication	Dose (Intravenous Administration)
Preventive Treatment of Migraine	<u>Adult Initial Dose:</u> - 100 mg IV every 3 months <u>Adult Max Dose:</u> - 300 mg IV every 3 months (A dose of 300 mg may be used after 3 months of 100 mg dose)

NDC:

- Vyepti® 100 mg single-dose vial (SDV): 67386-0130-51

References:

1. Vyepti [prescribing information]. Bothell, WA: Lundbeck Seattle Biopharmaceuticals, Inc.; March 2025.
2. Alder Biopharmaceuticals, Inc. Evaluation of ALD403 (Eptinezumab) in the Prevention of Chronic Migraine (PROMISE 2.) In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2020 Jan 24].
3. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia*. 19 February 2020; doi:333102420905132.
4. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018; 38:1-211.
5. 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; 61(7):1021-1039. doi:10.1111/head.14153.
6. Ashina M, Lanteri-Minet M, Pozo-Rosich P, et al. Safety and efficacy of eptinezumab for migraine prevention in patients with two-to-four previous preventive treatment failures (DELIVER): a multi-arm, randomized, double-blind, placebo-controlled, phase 3b trial. *Lancet Neurol*. 2022; 21(7):597-607. doi:10.1016/S1474-4422(22)00185-5.
7. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. April 2024; 64(4):333-341. doi:10.1111/head.14692. Epub 11 March 2024. PMID: 38466028.

8. Qaseem A, Cooney TG, Etxeandia-Ikobaltzeta I, et al. Prevention of Episodic Migraine Headache Using Pharmacologic Treatments in Outpatient Settings: A Clinical Guideline From the American College of Physicians. *Ann Intern Med.* 2025; 178(3):426-433. doi:10.7326/ANNALS-24-01052.

Appendix 1 – Covered Diagnosis Codes - Intravenous (J3032)

ICD-10	ICD-10 Description	FDA/Off Label
G43.001	Migraine without aura, not intractable, with status migrainosus	FDA
G43.009	Migraine without aura, not intractable, without status migrainosus	FDA
G43.011	Migraine without aura, intractable, with status migrainosus	FDA
G43.019	Migraine without aura, intractable, without status migrainosus	FDA
G43.101	Migraine with aura, not intractable, with status migrainosus	FDA
G43.109	Migraine with aura, not intractable, without status migrainosus	FDA
G43.111	Migraine with aura, intractable, with status migrainosus	FDA
G43.119	Migraine with aura, intractable, without status migrainosus	FDA
G43.701	Chronic migraine without aura, not intractable, with status migrainosus	FDA
G43.709	Chronic migraine without aura, not intractable, without status migrainosus	FDA
G43.711	Chronic migraine without aura, intractable, with status migrainosus	FDA
G43.719	Chronic migraine without aura, intractable, without status migrainosus	FDA
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus	FDA
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus	FDA
G43.E11	Chronic migraine with aura, intractable, with status migrainosus	FDA
G43.E19	Chronic migraine with aura, intractable, without status migrainosus	FDA
G43.801	Other migraine, not intractable, with status migrainosus	FDA
G43.809	Other migraine, not intractable, without status migrainosus	FDA
G43.811	Other migraine, intractable, with status migrainosus	FDA
G43.819	Other migraine, intractable, without status migrainosus	FDA
G43.901	Migraine, unspecified, not intractable, with status migrainosus	FDA

G43.909	Migraine, unspecified, not intractable, without status migrainosus	FDA
G43.911	Migraine, unspecified, intractable, with status migrainosus	FDA
G43.919	Migraine, unspecified, intractable, without status migrainosus	FDA