Clinical Policy: Eptinezumab-jjmr (Vyepti)

Reference Number: HIM.PA.SP64
Effective Date: 10.01.20
Last Review Date: 02.22
Line of Business: HIM

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Eptinezumab-jjmr (Vyepti™) a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)

Vyepti is indicated for the preventive treatment of migraine in adults.

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Vyepti is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine Prophylaxis (must meet all):

1. Diagnosis of episodic or chronic migraine;
2. Provider's attestation that member experiences ≥ 4 migraine days per month for at least 3 months;
3. Age ≥ 18 years;
4. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
5. Failure of Aimovig® and Emgality®, unless clinically significant adverse effects are experienced or both are contraindicated;
6. Vyepti is not prescribed concurrently with Botox® or other injectable and oral CGRP inhibitors (e.g., Aimovig, Ajovy®, Emgality, Nurtec®, Qulipta™, Ubrelvy™);
7. Dose does not exceed 100 mg (1 vial) once every 3 months.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member has experienced and maintained positive response to therapy as evidenced by provider's attestation of a reduction in migraine days per month from baseline;
3. Vyepti is not prescribed concurrently with Botox or other injectable and oral CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Ubrelvy);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 100 mg (1 vial) once every 3 months;
   b. 300 mg (3 vials) once every 3 months if medical justification for higher dose is provided.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®),valproate sodium	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** 70 mg SC once monthly Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly	*Refer to prescribing information or Micromedex*
Aimovig® (erenumab-aaoe)	**Migraine Prophylaxis** 70 mg SC once monthly Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly	140 mg/month
Emgality® (galcanezumab-gnlm)	**Migraine Prophylaxis** Loading dose: 240 mg SC once Maintenance dose: 120 mg SC once monthly	120 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): serious hypersensitivity to eptinezumab-jjmr or to any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- In the PROMISE-I clinical trial, a migraine was classified by the following characteristics: lasted 4–72 hours; with at least two of the following: unilateral location, pulsating quality, moderate or severe pain intensity, or aggravation by or causing avoidance of routine physical activity; and had one or more of the following: nausea and/or vomiting and photophobia and phonophobia. A probable migraine was a qualifying headache with two of the three preceding criteria.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine prophylaxis	The recommended dosage is 100 mg IV every 3 months. Some patients may benefit from a dosage of 300 mg IV every 3 months.	300 mg every 3 months

VI. Product Availability

Single-dose vial: 100 mg/mL

VII. References

1. Vyepti Prescribing Information. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020. Available at: https://www.vyeptihcp.com/. Accessed September 15, 2021.
2. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45.
3. Simpson DM, Hallett M, Ashman EJ, et al. American Academy of Neurology: Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86: 1818-26.
4. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). Cephalalgia 2020 March; 40(3):241-254.
5. Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine: Promise-2. Neurology. 2020 March 31; 94(13): e1365-1377.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3032	Injection, eptinezumab-jjmr, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adapted from CP.PCH.29 which will be retired and split for Commercial line of business) per September SDC and prior clinical guidance to redirect to Aimovig and Emgality (Ajovy redirection removed); removed prescriber requirements; clarified provider attestation is required to confirm migraine day requirements.	09.08.20	09.20 (ad hoc)
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.18.20	02.21
Revised requirement on concurrent use with other CGRP inhibitors to include oral products with Nurtec and Ubrelvy listed as additional examples.	06.28.21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.15.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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