

Clinical Policy: Eptinezumab-jjmr (Vyepsti)

Reference Number: ERX.SPA.403

Effective Date: 09.01.20

Last Review Date: 02.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

Eptinezumab-jjmr (Vyepsti[™]) a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Vyepsti 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. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Age ≥ 18 years;
5. 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);
6. Failure of two of the following formulary injectable CGRP inhibitors, unless clinically significant adverse effects are experienced or all are contraindicated: Aimovig[®], Ajovy[®], Emgality[®];
7. Vyepsti is not prescribed concurrently with Botox[®] or other injectable and oral CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality, Nurtec[®], Ubrelvy[™]);
8. Dose does not exceed 100 mg (1 vial) once every 3 months.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Migraine Prophylaxis (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member has experienced and maintained positive response to therapy as evidenced by 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, 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®), valproate sodium	Migraine Prophylaxis <i>Refer to prescribing information or Micromedex</i>	<i>Refer to prescribing information or Micromedex</i>
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	Migraine Prophylaxis <i>Refer to prescribing information or Micromedex</i>	<i>Refer to prescribing information or Micromedex</i>
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	<i>Refer to prescribing information or Micromedex</i>
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
Ajovy (fremanezumab-vfrm)	Migraine Prophylaxis 225 mg SC once monthly or 675 mg SC every three months	675 mg every 3 months
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 November 18, 2020.
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. ClinicalTrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US). Identifier NCT02974153, Evaluation of ALD403 (Eptinezumab) in the Prevention of Chronic Migraine (PROMISE 2). Available at: <https://clinicaltrials.gov/ct2/show/NCT02974153>. Accessed March 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.14.20	08.20
1Q 2021 annual review: added redirection to two of the following formulary injectable CGRP inhibitors: Aimovig, Ajovy, Emgality; 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	

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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