Clinical Policy Title:	eptinezumab-jjmr
Policy Number:	RxA.664
Drug(s) Applied:	Vyepti™
Original Policy Date:	11/25/2020
Last Review Date:	11/25/2020
Line of Business Policy Applies to:	All lines of business

Background

Vyepti™ is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
eptinezumab-jjmr (Vyepti™)	Migraine prophylaxis	100 mg IV every 3 months. Some patients may benefit from a dose of 300 mg IV every 3 months	300 mg IV every 3 months

Dosage Forms

- Injection: 100 mg/mL solution in a single-dose vial.

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of episodic or chronic migraine;
2. Member experiences ≥ 4 migraine days per months for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache or pain specialist;
4. Age of 18 years or older;
5. Failure of at least one of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Failure of at least 1-month trial of one of the following unless member is allergic to any inactive ingredient of these drugs: Ajovy, Aimovig, or Emgality;
7. Vyepti™ is not prescribed concurrently with Botox® (onabotulinumtoxin A) or other injectable CGRP inhibitors (e.g., Aimovig®(erenumab), Ajovy® (fremanezumab), Emgality® (galcanezumab-gnlm));
8. Dose does not exceed 300 mg (3 injections) every 3 months.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Migraine Prophylaxis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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® (onabotulinumtoxin A) or other injectable CGRP inhibitors (e.g., Aimovig®(erenumab), Ajovy® (fremanezumab), Emgality® (galcanezumab-gnlm));
4. If request is for a dose increase, new dose not exceed 300 mg (3 injections) every 3 months.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®)	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information
Beta-blockers such as: propranolol, metoprolol (Lopressor®)*, timolol	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information
Antidepressants/tricyclic antidepressants* such as: amitriptyline, venlafaxine	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Vyepti™ is contraindicated in patients with serious hypersensitivity to eptinezumab-jjmr or to any of the excipients.

- Boxed Warning(s):
  - None

APPENDIX D: General Information

International Classification of Headache Disorders (ICHD-3) diagnostic criteria for chronic migraine headache include the following:

- Headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days
- per month, has the features of migraine headache.
- Episodic migraine is described as migraine with or without aura occurring in a headache pattern or <14 days per month.
- Features of migraine headache:
  - Headache lasts 4 to 72 hours (when untreated or unsuccessfully treated);
  - Headache has at least 2 of the following 4 characteristics:
    - Unilateral location
    - Pulsating quality
    - Moderate or severe pain intensity
    - Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
  - During headache, at least one of the following:
    - Nausea and/or vomiting
    - Photophobia and phonophobia

References

1. Vyepti™ Prescribing Information. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc; February 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761119s000lbl.pdf. Accessed November 25, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 25, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology.com. Accessed November 25, 2020.
4. Headache Classification Committee of the International Headache Society (HIS). The International Classification of Headache Disorders; 3rd edition. Cephalalgia. 2018 Jan;38(1):1- 211. Available at: https://journals.sagepub.com/doi/pdf/10.1177/0333102417738202. Accessed November 25, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/23/2020	12/07/2020