



## PHARMACY BENEFITS MANAGER

### P.262 Approval Criteria

#### Vyepti

- I. Generic Name:**
  - a. Eptinezumab
- II. Brand Name:**
  - a. Vyepti
- III. Medication Class:**
  - a. Monoclonal antibody; Calcitonin gene-related peptide (CGRP) receptor antagonist
- IV. FDA Approved Uses:**
  - a. Migraine prophylaxis: Preventive treatment of migraine in adults
- V. Application of Criteria:**
  - a. The following criteria apply to Michigan Medicaid, Illinois Medicaid, and Meridian Choice (HIX)
- VI. Criteria for Use:**
  - a. Documentation of an FDA approved indication
  - b. Member must be 18 years of age or older
  - c. Current clinical documents with plan of care recommending treatment with Vyepti
  - d. Clinical documentation of headaches on  $\geq 15$  days per month for at least three months, with the features of migraine headache present on at least eight days per month (Appendix 1)
  - e. Clinical documentation of adequate trial and failure of all of the following for at least 90 consecutive days with appropriate dose adjustments:
    - A. Beta blocker (e.g. metoprolol, propranolol, timolol)
    - B. Antidepressant (e.g. amitriptyline, venlafaxine)
    - C. Anticonvulsant (e.g. valproate, topiramate)
    - D. Botox
  - f. Dose escalation to 300mg every 3 months requires clinical documentation of mean monthly reduction of migraine days from baseline of less than 4 days after 3 months of treatment
- VII. Required Medical Information:**
  - a. Proper diagnosis and documentation of an FDA approved indication
  - b. Current progress notes detailing the diagnosis with current plan of care
  - c. Complete progress notes documenting the disease and treatment history
  - d. Documentation of dose, date ranges of therapy, and clinical outcomes for all medications previously tried and failed

## Vyepiti

- e. Chart notes showing compliance to previous therapy and office visits

**VIII. Contraindications:**

- a. Serious hypersensitivity (e.g., angioedema) to eptinezumab or any component of the formulation

**IX. Not Approved If:**

- a. Patient shows non-compliance with previous treatment
- b. Patient shows any contraindications to the use of eptinezumab
- c. Request is for a non-FDA approved indication
- d. Request to be used in combination with Botox
- e. Request to be used in combination with another CGRP antagonist

**X. Length of Authorization:**

- a. 6 months

**XI. Dosing:**

- a. 100mg every 3 months
- b. Some patients may benefit from 300mg every 3 months

**XII. Criteria for Continuation of Therapy:**

- a. Initial therapy was tolerated
- b. Demonstrated improvement in disease (documentation of mean monthly reduction of migraine days from baseline of at least 4 days)
- c. Patient must be compliant with taking the medication as prescribed
- d. Patient must not be experiencing any severe adverse reaction while taking the medication
- e. Office visit every 6 months with verified compliance and improvement or stability on drug

**XIII. Criteria for Discontinuation of Therapy:**

- a. Patient is non-compliant with pharmacologic or non-pharmacologic therapy
- b. No demonstrable clinically significant improvement after initiation and stabilization of drug therapy
- c. Patient is non-responsive to FDA-approved dosing

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**Vyepti**

**XIV. References:**

1. Facts and Comparisons. Wolters Kluwer Health. April 2020.
2. Vyepti (eptinezumab) [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals Inc: February 2020.
3. Ashina M, Saper J, Cady R, et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). *Cephalalgia* 2020; 40:241.
4. Dodick DW. Clinical practice. Chronic daily headache. *N Engl J Med* 2006; 354:158.
5. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia* 2018; 38:1.
6. Kudrow D, Lipton R, Silberstein S, et al. Eptinezumab for prevention of chronic migraine: Results of 2 infusions in the phase 3 PROMISE-2 (Prevention of migraine via intravenous eptinezumab safety and efficacy–2) trial. P2.10-006. *Neurology* 2019; 91.
7. Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine-revised report of an EFNS task force. *Eur J Neurol* 2009; 16:968.
8. Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci* 2012; 39:S1.
9. Schwedt TJ. Chronic migraine. *BMJ* 2014; 348:g1416.

Approved by: \_\_\_\_\_

CMO

Date: \_\_\_\_\_

<b>Initial Approval:</b>	
<b>Revised:</b>	
<b>Annual Review:</b>	
<b>Next Review Date:</b>	

**Appendix 1:**

## Chronic migraine diagnostic criteria:

- A. Headache (tension-type-like and/or migraine-like) on 15 or more days per month for more than three months and fulfilling criteria B and C
- B. Occurring in a patient who has had at least five attacks fulfilling the following criteria for migraine without aura (B1) and/or migraine with aura (B2)
- B1. Migraine without aura:
- B1a. Headache attacks lasting 4 to 72 hours (untreated or unsuccessfully treated)
- B1b. Headache has at least two of the following 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)
- B1c. During headache at least one of the following:
- Nausea and/or vomiting
  - Photophobia and phonophobia
- B2. Migraine with aura:
- B2a. One or more of the following fully reversible aura symptoms:
- Visual
  - Sensory
  - Speech and/or language
  - Motor
  - Brainstem
  - Retinal
- B2b. At least two of the following characteristics:
- At least one aura symptom spreads gradually over  $\geq 5$  minutes
  - Two or more aura symptoms occur in succession
  - Each individual aura symptom lasts 5 to 60 minutes
  - At least one aura symptom is unilateral
  - At least one aura symptom is positive
  - The aura is accompanied, or followed within 60 minutes, by headache
- C. On eight days or more per month for more than three months, fulfilling any of the following:
- Criteria B1b and B1c for migraine without aura
  - Criteria B2a and B2b for migraine with aura
  - Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative
- D. Not better accounted for by another ICHD-3 diagnosis