

## Medical Policy

Vyepiti™ (eptinezumab-jjmr)	
<b>MEDICAL POLICY NUMBER</b>	Med_Clin_Ops-063
<b>CURRENT VERSION EFFECTIVE DATE</b>	January 1, 2024
<b>APPLICABLE PRODUCT AND MARKET</b>	<i>Individual Family Plan: All Plans</i> <i>Small Group: All Plans</i> <i>Medicare Advantage: All Plans</i>

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## PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Vyepiti™ (eptinezumab-jjmr) therapy.

## POLICY/CRITERIA

### Prior Authorization and Medical Review is required.

Coverage for Vyepiti will be provided for 3 months and may be renewed.

### Initial Therapy

#### Migraine Prophylaxis

1. Patient is 18 years of age or older; **AND**
2. Patient has a documented diagnosed of **chronic** migraines defined as:
  - a. 8 migraine days per month **AND** 15 headache days per month; **OR**
3. Patient has a documented diagnosed of **episodic** migraines defined as:

### Vyepiti

Med\_Clin\_Ops\_063

## Medical Policy

- a. Less than 15 headache days per month **AND** Patient has 4 to 14 migraine days per month; **AND**
4. Patient has had a documented trial and therapeutic failure, contraindication, or intolerance (after a trial of at least two months) to at least TWO of the following prophylactic therapies from the list below:
  - a. Beta-blockers (i.e., propranolol, metoprolol, atenolol);
  - b. Calcium Channel blockers (i.e., verapamil);
  - c. Anti-epileptics (i.e., as topiramate or divalproex sodium);
  - d. Antidepressants (venlafaxine OR a tricyclic antidepressant such as amitriptyline or nortriptyline); **AND**
5. The patient has had inadequate therapeutic response to **BOTH** standard prophylactic pharmacologic therapies; **OR**
6. The patient has experienced adverse event(s) severe enough to warrant discontinuation of **BOTH** standard prophylactic pharmacologic therapies; **AND**
7. Patient has had a documented trial and failure, contraindication, or intolerance to a self-injectable CGRP antagonist [e.g., Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab)].

## Continuation Therapy

### Migraine Prophylaxis

1. Positive response to therapy demonstrated by a 50% reduction in monthly migraine days; **AND**
2. Patient has an overall improvement in function with therapy

## LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Concurrent use with other calcitonin gene-related peptide (CGRP) antagonists (e.g., erenumab, galcanezumab, fremanezumab, etc.)

## Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 300 billable units per 90 days

## BACKGROUND

Vyepti is indicated for the preventive treatment of migraine in adults. Vyepti is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.

## DEFINITIONS

1. VYEPTI (eptinezumab-jjmr) injection, for intravenous use. Initial U.S. Approval: 2020
  - a. VYEPTI (eptinezumab-jjmr) injection is a clear to slightly opalescent, colorless to brownish-yellow solution supplied as:
    - i. Carton containing one 100 mg/mL single-dose vial

## Vyepti

Med\_Clin\_Ops\_063

## Medical Policy

### CODING

Applicable NDC Codes	
67386-0130-51	VYEPTI 100 MG/ML SINGLE-DOSE VIAL

Applicable Procedure Code	
J3032	Injection, eptinezumab-jjmr, 1 mg (Vyepti)

Applicable ICD-10 Codes	
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus

### EVIDENCE BASED REFERENCES

1. VYEPTI (eptinezumab-jjmr) [Prescribing Information] Bothell, WA: Lundbeck Seattle Biopharmaceuticals, Inc.; Feb 2020. Accessed May 2021

### POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	<p>November 1, 2021: Annual review – no changes made.</p> <p>February 2, 2022: Annual review – no changes made.</p> <p>February 28, 2023 – Annual Review and approval (no policy revisions made)</p> <p>March 1, 2023 – Adopted by MA UM Committee (no policy revisions made)</p> <p>January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)</p>

**Medical Policy**

Approved by Pharmacy and Therapeutics Committee on 2/28/2023