# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| Eptinezumab-jjmr (Vyepti) | MP-RX-FP-103-23 | ☒ MMM MA ☒ MMM Multihealth |

## Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

## Service Description

This document addresses the use of eptinezumab-jjmr (Vyepti) , a drug approved by the Food and Drug Administration (FDA) for the treatment of migraine prophylaxis.

**Background Information**

This document addresses the use of Vyepti (eptinezumab), a calcitonin gene-related peptide (CGRP) inhibitor agent for migraine prophylaxis. The CGRP system is involved with vascular homeostasis. During a migraine, CGRP levels increase resulting in vasodilation, pro-inflammatory effects and pain signaling. Vyepti is FDA approved for the prophylaxis of migraine headaches. Please refer to the following clinical criteria for additional information: • Self-Injected Calcitonin Gene-Related Peptide (CGRP) Agents • Calcitonin Gene-Related Peptide (CGRP) Step Therapy Vyepti is an infused agent that requires administration via healthcare professional every 3 months. The dose recommendation per label for Vyepti is 100 mg every 3 months. However, the label indicates that some patients may benefit from a dosage of 300 mg.

**Approved Indications**

A. Migraine Prophylaxis

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J3032 | Injection, eptinezumab-jjmr, 1 mg (Effective 10/1/2020) |

| ICD-10 | Description |
|---|---|
| G43.001-G43.919 | Migraine, unspecified |

## Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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

eptinezumab-jjmr (Vyepti)

**A. Criteria For Initial Approval**

I. Individual has a diagnosis of one of the following: A. Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3-month period; OR B. Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3);

AND

II. Individual is using Vyepti for migraine prophylaxis;

AND

III. Individual has had a trial of and inadequate response to a 2-month trial at target or usual effective dose or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence, AHS 2021): A. The following antidepressants: amitriptyline, venlafaxine, nortriptyline, duloxetine; OR B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; OR C. The following calcium channel blocker: verapamil; OR D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin; OR E. Botox (for chronic migraine);

AND

IV. If individual is also currently using botulinum toxin for prophylaxis and is going to be using Vyepti and botulinum toxin together (i.e., not switching from one agent to another), the following must apply: A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with the initial agent; AND 2 B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention

i.

**B. Criteria For Continuation of Therapy**

I. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month;

AND

II. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):

A. 50% reduction in frequency of days with headache or migraine; OR

B. Significant decrease in attack duration; OR

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C. Significant decrease in attack severity; OR
D. Improved response to acute treatment; OR
E. Reduction in migraine-related disability and improvements in functioning in important areas of life; OR
F. Improvements in health-related quality of life and reduction in psychological stress due to migraine;
AND
III. If individual is using concurrently with botulinum toxin, the following must apply:
A. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or Vyepti).

Vyepti (eptinezumab) may not be approved for the following:

I. Individual is using in combination with another prophylactic CGRP agent (Ajovy, Aimovig, Emgality, Qulipta or prophylactic use of Nurtec ODT).

**C. Authorization Duration**

i. Approval duration:
   a. Initial Approval Duration: 6 months (two injection cycles)
   b. Reauthorization Approval Duration: 1 year

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## Step Therapy

**Note**: When a calcitonin gene-related peptide (CGRP) inhibitor is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred agent or agents.

**Calcitonin gene-related peptide (CGRP) Inhibitor Step Therapy**

Requests for a non-preferred calcitonin gene-related peptide (CGRP) inhibitor may be approved when the following criteria are met:

I. Individual has had a trial of and inadequate response or intolerance to one preferred CGRP agent;

## Limits or Restrictions

A. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

| Drug | Limit |
|---|---|
| Vyepti (eptinezumab) 100 mg/mL vial | 1 vial (100 mg) |
| **Exceptions** | |
| Individuals who do not respond to 100 mg dose may be approved for 3 vials (300 mg) every 3 months. | |

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## Reference Information

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## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |

Revised: 5/19/2023