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 calcitonin gene-related peptide antagonist approved by the Food and Drug Administration (FDA) for preventive treatment of migraine in adults.

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

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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. 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**
   b. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention

B. Criteria For Continuation of Therapy

MMM Considers continuation of therapy with Vyepti (eptinezumab) medically necessary in all patients requesting reauthorization for an indication listed above (Section A), when the following criteria are met:

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**
   - 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**

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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).

C. Authorization Duration

i. Approval duration:

a. Initial Approval Duration: 6 months (two injection cycles)

b. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

II. When the above criteria are not met and for all other indications.

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Limits or Restrictions

A. 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;

B. 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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Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 06/15/2024	Remove prior trial of 2 preventative agents per updated AHS position statement. Coding Reviewed: No changes.	3/14/2025	4/2/2025
Policy Inception 09/19/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023