

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope								
Eptinezumab-jjmr (Vyepti)	MP-RX-FP-103-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth								
Service Category										
<input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B DRUG										
Service Description										
<p>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.</p> <p>Background Information</p> <p>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.</p> <p>Approved Indications</p> <p>A. Migraine Prophylaxis</p>										
Applicable Codes										
<p>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.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>J3032</td> <td>Injection, eptinezumab-jjmr, 1 mg (Effective 10/1/2020)</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>ICD-10</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>G43.001-G43.919</td> <td>Migraine, unspecified</td> </tr> </tbody> </table>			HCPCS	Description	J3032	Injection, eptinezumab-jjmr, 1 mg (Effective 10/1/2020)	ICD-10	Description	G43.001-G43.919	Migraine, unspecified
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**

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

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

AND

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Eptinezumab-jjmr (Vyepti)	MP-RX-FP-103-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
<p>II. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):</p> <p>A. 50% reduction in frequency of days with headache or migraine; OR</p> <p>B. Significant decrease in attack duration; OR</p> <p>C. Significant decrease in attack severity; OR</p> <p>D. Improved response to acute treatment; OR</p> <p>E. Reduction in migraine-related disability and improvements in functioning in important areas of life; OR</p> <p>F. Improvements in health-related quality of life and reduction in psychological stress due to migraine;</p> <p>AND</p> <p>III. If individual is using concurrently with botulinum toxin, the following must apply:</p> <p>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).</p> <p>Vyepti (eptinezumab) may not be approved for the following:</p> <p>I. Individual is using in combination with another prophylactic CGRP agent (Ajovy, Aimovig, Emgality, Qulipta or prophylactic use of Nurtec ODT).</p> <p>C. Authorization Duration</p> <p>i. Approval duration:</p> <p>a. Initial Approval Duration: 6 months (two injection cycles)</p> <p>b. Reauthorization Approval Duration: 1 year</p> <p>Step Therapy</p> <p>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.</p> <p>Calcitonin gene-related peptide (CGRP) Inhibitor Step Therapy</p> <p>Requests for a non-preferred calcitonin gene-related peptide (CGRP) inhibitor may be approved when the following criteria are met:</p> <p>I. Individual has had a trial of and inadequate response or intolerance to one preferred CGRP agent;</p>		

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope								
Eptinezumab-jjmr (Vyepti)	MP-RX-FP-103-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth								
Limits or Restrictions										
<p>A. Quantity Limitations</p> <p><i>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.</i></p> <table border="1"> <thead> <tr> <th>Drug</th> <th>Limit</th> </tr> </thead> <tbody> <tr> <td>Vyepti (eptinezumab) 100 mg/mL vial</td> <td>1 vial (100 mg)</td> </tr> <tr> <td colspan="2">Exceptions</td> </tr> <tr> <td colspan="2">Individuals who do not respond to 100 mg dose may be approved for 3 vials (300 mg) every 3 months.</td> </tr> </tbody> </table>			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.	
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.										

Policy Name	Policy Number	Scope
Eptinezumab-jjmr (Vyepti)	MP-RX-FP-103-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
<p>Reference Information</p> <ol style="list-style-type: none"> 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically. 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically. 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically. 5. Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. Available from: icsi.org/wpcontent/uploads/2019/01/Headache.pdf. Updated January 2013. 6. The International Classification of Headache Disorders 3rd Edition. Available from: https://www.ichd-3.org/. Accessed April 22, 2023. 7. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A summary and comparison with other recent clinical practice guidelines. Headache. 2018; 52:930-945. 8. Rapoport AM. How to choose a preventative medication for migraine. American Headache Society. Available from: https://americanheadachesociety.org/wp-content/uploads/2018/05/Alan_Rapoport_-_Migraine_Prevention_Medications.pdf. 9. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012; 78:1337–1345. 10. The American Headache Society Consensus statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021; 61:1021-1039. 11. Dodick DW, Lipton RB, Silberstein S, et.al. Eptinezumab for prevention of chronic migraine: A randomized phase 2b clinical trial. Cephalgia. 2019; 39(9):1075-1085. 12. Ashina M, Saper J, Cady R et al. Eptinezumab in episodic migraine: a randomized, double-blind, placebo-controlled study (PROMISE-1). Cephalgia. 2020; 0(0): 1-14. Doi: 10.1177/0333102420905132. 13. Blumenfeld AM, Frisberg BM, Schim JD, et.al. Real-world evidence for control of chronic migraine patients receiving CGRP monoclonal antibody therapy added to onabotulinumtoxinA: A retrospective chart review. Pain Ther. 21 April 2021. https://doi.org/10.1007/s40122-021-00264-x. <p>Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.</p> <p>No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.</p> <p>© CPT Only – American Medical Association</p>		

Medical Policy

Healthcare Services Department

Policy Name Eptinezumab-jjmr (Vyepti)	Policy Number MP-RX-FP-103-23	Scope <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth																	
Policy History <table border="1"> <thead> <tr> <th>Revision Type</th> <th>Summary of Changes</th> <th>P&T Approval Date</th> <th>MPCC Approval Date</th> </tr> </thead> <tbody> <tr> <td>Annual Review 06/02/2025</td> <td>Annual review, minimal changes; Word formatting.</td> <td>6/9/2025</td> <td>6/19/2025</td> </tr> <tr> <td>Policy Inception</td> <td>Elevance Health’s Medical Policy adoption.</td> <td>N/A</td> <td>11/30/2023</td> </tr> <tr> <td>Choose an item.</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date	Annual Review 06/02/2025	Annual review, minimal changes; Word formatting.	6/9/2025	6/19/2025	Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023	Choose an item.			
Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date																
Annual Review 06/02/2025	Annual review, minimal changes; Word formatting.	6/9/2025	6/19/2025																
Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023																
Choose an item.																			