Medical Drug Clinical Criteria

Subject:	Vyepti (eptinezumab)		
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Overview

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.

Clinical Criteria

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.

Vyepti (eptinezumab)

Initial requests for Vyepti (eptinezumab) may be approved when the following criteria are met:

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.

Renewal requests for Vyepti (eptinezumab) may be approved 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**
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).

Approval duration:

- Initial request: 6 months (two injection cycles)
- Renewal requests: 1 year

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[1] agent or agents.

Calcitonin gene-related peptide (CGRP) Inhibitor Step Therapy

A list of the preferred calcitonin gene-related peptide (CGRP) inhibitors is available here.

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;

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Vyepti (eptinezumab) Quantity Limit

Drug	Limit per 3 months
Vyepti (eptinezumab) 100 mg/mL vial	1 vial (100 mg)
Override Criteria	
Individuals who have had an inadequate response to 100 mg dose may be approved for 3 vials (300 mg) every 3 months	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3032	Injection, eptinezumab-jjmr, 1 mg

ICD-10 Diagnosis

G43.001-G43.919	Migraine, unspecified

Document History

Reviewed: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: Remove prior trial of 2 preventative agents per updated AHS position statement. Coding Reviewed: No changes.
- 03/15/2024 – Step therapy table update.
- 09/11/2023 – Select Review: Clarify quantity limit override. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 03/27/2023 – Step therapy table updates.
- 05/20/2022 – Annual Review: Update exclusion for combination use to include additional prophylactic agents; reformat duplication therapy with botulinum toxin criteria for clarity; update references. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Updated criteria to include specific examples of clinical benefit from prophylaxis, updated criteria to include clinical criteria for concurrent use with botulinum toxin for migraine prophylaxis, updated criteria to prevent combination therapy between prophylactic CGRP agents; updated approval duration based on AHS 2019 to 6 months due to administration frequency of every 3 months. Coding Reviewed: No changes.
- 04/26/2021 – Step therapy table update.
- 03/23/2021 – Step therapy table update.
- 10/26/2020 – Administrative update to add step therapy.
- 05/15/2020 – Annual Review: Minor wording and formatting update. Coding reviewed: Added HCPCS C9063 (Effective 7/1/2020) Effective 10/1/2020 Added HCPCS J3032, Delete 9/30/2020 HCPCS J3490, J3590, C9063
- 03/02/2020 – Selected review: New criteria document for Vyepti; Added quantity limit for Vyepti per label with override criteria for higher dose. Coding Reviewed: New policy. Added HCPCS J3490, J3490, G43.001-G43.919.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

CC-0160 Vyepti

Commercial Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
02/01/2021	Aimovig Emgality	Vyepti
04/01/2024	Aimovig Emgality Qulipta	Vyepti

Medicaid Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
04/01/2021: MD, NJ, NV, NY, SC, WNY 05/01/2021: GA, IN 04/01/2023: DC	Aimovig Emgality	Vyepti

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
N/A	N/A	N/A