CareSource Rxinnovations

# PHARMACY POLICY STATEMENT
## North Carolina Marketplace

| DRUG NAME | Vyepti (eptinezumab-jjmr) |
|---|---|
| BENEFIT TYPE | Medical |
| STATUS | Prior Authorization Required |

Vyepti is a calcitonin gene-related peptide receptor antagonist initially approved by the FDA in 2020. It is indicated for the preventive treatment of migraine in adults. Vyepti works as a humanized immunoglobulin G1 (IgG1) monoclonal antibody that binds to the calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor.
The efficacy of Vyepti was evaluated as a preventive treatment of episodic and chronic migraine in two randomized, multicenter, placebo-controlled studies, both with 6-month double-blind periods: one study in patients with episodic migraine (Study 1) and one study in patients with chronic migraine (Study 2). Patients treated with Vyepti in both trials had greater decreases from baseline in mean monthly migraine days over Months 1-3 compared to placebo-treated patients.

Vyepti (eptinezumab-jjmr) will be considered for coverage when the following criteria are met:

## Chronic Migraine Headache Prophylaxis

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication is being prescribed for prevention of chronic migraine, defined as **both** of the following:
   a) ≥ 15 headache days per month for at least 3 months
   b) ≥ 8 migraine days per month for at least 3 months; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
   a) Beta blocker (e.g., metoprolol, timolol, or propranolol)
   b) Calcium channel blocker (e.g., verapamil)
   c) Antidepressant (e.g., amitriptyline or venlafaxine)
   d) Anticonvulsant (e.g., topiramate or valproic acid)
   e) Candesartan; AND
4. Member has tried and failed a preferred CGRP; AND
5. If the dosage requested is 300mg, member must have a 3-month trial of the 100mg Vyepti dose; AND
6. **Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g., Aimovig, Ajovy, or Emgality).**
7. **Dosage allowed:** 100mg administered intravenously every 3 months. A dose of 300mg may also be used. Quantity Limit: 300mg (3 vials) per 84 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:
1. Chart notes have been provided showing improvement in migraine frequency and severity (e.g., reduced migraine days, reduced use of medications for acute migraines attacks).

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Episodic Migraine Headache Prophylaxis

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication is being prescribed for prevention of episodic migraine, defined as **both** of the following:
    a. ≤ 14 headache days per month for at least 3 months
    b. 4 or more migraine days per month for at least 3 months **that cause significant impairment to quality of life (i.e., requiring bed rest, missed school/work)**; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
    a. Beta blocker (e.g., metoprolol, timolol, or propranolol)
    b. Calcium channel blocker (e.g., verapamil)
    c. Antidepressant (e.g., amitriptyline or venlafaxine)
    d. Anticonvulsant (e.g., topiramate or valproic acid)
    e. Candesartan; AND
4. Member has tried and failed a preferred CGRP; AND
5. If the dosage requested is 300mg, member must have a 3-month trial of the 100mg Vyepti dose; AND
6. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g., Aimovig, Ajovy, or Emgality**).**
7. **Dosage allowed:** 100mg (1 vial) administered intravenously every 3 months. A dose of 300mg may also be used. Quantity Limit: 300mg (3 vials) per 84 days.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided showing improvement in migraine frequency and severity (e.g., reduced migraine days, reduced use of medications for acute migraines attacks).

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## CareSource considers Vyepti (eptinezumab-jjmr) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **05/22/2020** | New policy for **Vyepti** created. |
| **05/05/2022** | Transferred to new template. Updated references. Removed prescriber specialty and abortive trials. Added quantity limit. |
| **06/30/2023** | Removed Botox trial and the following: Member does not have ANY of the following: Medication overuse headache; History of hemiplegic headache, ophthalmoplegic migraine, and migraine with brainstem aura (basilar-type migraine); Member was older than 50 years of age at migraine onset. Removed CGRP trial from the 300 mg dosage request for initial and reauthorization criteria. Added preferred CGRP trial. |
| **04/29/2024** | Updated references. Changed from 2 prior prophylactic trials to 1 and added candesartan to list of trial options (per AHS 2024 statement). |

References:


1. Vyepti [package insert]. Deerfield, IL: Lundbeck Seattle BioPharmaceuticals, Inc.; 2022.
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3. Lipton RB, Goadsby PJ, Smith J, Schaeffler BA, Biondi DM, Hirman J, Pederson S, Allan B, Cady R. Efficacy and safety of eptinezumab in patients with chronic migraine. PROMISE-2. *Neurology*. 2020 Mar 31; 94(13):e31364-e1377
4. Buse D, Manack A, Serrano D, et al. Headache impact of chronic and episodic migraine: results from the American Migraine Prevalence and Prevention study. Headache. 2012;52(1):3-17. doi:10.1111/j.1526-4610.2011.02046.x
5. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders. *Cephalalgia*. 2018 Jan;38(1):1-211.
6. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019;59: 1-18.
7. Ailani J, Burch R, et al. Consensus Statement: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.
8. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341. doi:10.1111/head.14692

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