CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vyepti (eptinezumab-jjmr)
BILLING CODE	J3032
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home
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 the prevention of chronic migraine, defined as **both** of the following and must be documented in chart notes:
   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 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
4. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   a) Beta-blockers (e.g., metoprolol, timolol, or propranolol);
   b) Calcium channel blockers (e.g., verapamil);
   c) Antidepressants (e.g., amitriptyline or venlafaxine);
   d) Anticonvulsant medications (e.g., topiramate or valproic acid); AND
5. If the dosage requested is 300mg, member must have a 3-month trial and failure for each of **two** of the following drugs: Aimovig (erenumab), Emgality (galcanezumab), or Ajovy (fremanezumab) AND a 3-month trial of the 100mg Vyepti dose; AND
6. Member does not have ANY of the following:
   a) Member was older than 50 years of age when first diagnosed with migraines;
   b) Active medication-overuse headache, cluster headache, or hemiplegic migraine;
   c) Concurrent use with botulinum toxin injection or any other prophylactic CGRP products (e.g., Ajovy, Aimovig, Emgality).
7. **Dosage allowed:** 100mg administered intravenously every 3 months. A dose of 300mg may also be used. No evidence is established for any other dosages. 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. If the request is for a dosage increase to 300mg, member must have a 3-month trial and failure for each of **two** of the following drugs: Aimovig (erenumab), Emgality (galcanezumab), or Ajovy (fremanezumab), unless not tolerated or contraindicated; AND
2. 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 and must be documented in chart notes:
    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 or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
    a. Beta-blockers (e.g., metoprolol, timolol, or propranolol);
    b. Calcium channel blockers (e.g., verapamil);
    c. Antidepressants (e.g., amitriptyline or venlafaxine);
    d. Anticonvulsant medications (e.g., topiramate or valproic acid); AND
4. If the dosage requested is 300mg, member must have a 3-month trial and failure for each of **two** of the following drugs: Aimovig (erenumab), Emgality (galcanezumab), or Ajovy (fremanezumab) AND a 3-month trial of the 100mg Vyepti dose; AND
5. Member does not have ANY of the following:
    a. Member was older than 50 years of age when first diagnosed with migraines;
    b. Active medication-overuse headache, cluster headache, or hemiplegic migraine;
    c. Concurrent use with botulinum toxin injection or any other prophylactic CGRP products (e.g., Ajovy, Aimovig, Emgality).
6. **Dosage allowed:** 100mg (1 vial) administered intravenously every 3 months. A dose of 300mg may also be used. No evidence is established for any other dosages. 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. If the request is for a dosage increase to 300mg, member must have a 3-month trial and failure for each of **two** of the following drugs: Aimovig (erenumab), Emgality (galcanezumab), or Ajovy (fremanezumab), unless not tolerated or contraindicated; AND
2. 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.

References:

1. Vyepti [package insert]. Deerfield, IL: Lundbeck Seattle BioPharmaceuticals, Inc.
2. Ashina M, Saper J, Cady R, Schaeffler B, Biondi D, Hirman J, Pederson S, Allan B, Smith J. Eptinezumab in episodic migraine: the randomized, double-blind, placebo-controlled PROMISE-1 study. *Cephalalgia*. 2020 Mar; 40(3):241-254.
3. 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
4. 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.
5. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology Apr 2012, 78 (17) 1337-1345.
6. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders. *Cephalalgia*. 2018 Jan;38(1):1-211.
7. 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.
8. 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.

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