

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Vyepti (eptinezumab-jjmr)
BILLING CODE	J3032
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 300mg (3 vials) per 90 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Vyepti (eptinezumab-jjmr) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CHRONIC MIGRAINE HEADACHE PROPHYLAXIS

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by a neurologist or a headache specialist; AND
3. Medication is being prescribed for the prevention of chronic migraine, defined as **both** of the following and must be documented in chart notes:
 - a) \geq 15 headache days per month for at least 3 months;
 - b) \geq 8 migraine days per month for at least 3 months; AND
4. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
5. 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
6. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month);
7. 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 Ajoovy (fremanezumab) AND a 3-month trial of the 100mg Vyepti dose; AND
8. 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., Ajoovy, Aimovig, Emgality).
9. **Dosage allowed:** 100mg administered intravenously every 3 months. A dose of 300mg may also be used. No evidence is established for any other dosages.

Note: Vyepti is considered experimental and investigational as combination therapy with Botox, Aimovig, Ajovy, or Emgality because the safety and effectiveness of these combinations has not been established.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member is in compliance with all other initial criteria; AND
2. 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
3. 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 member meets all the reauthorization requirements above, 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 must be prescribed by a neurologist or a headache specialist; AND
3. 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
4. Member has tried and failed or unable to tolerate **three** 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. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month);
6. 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
7. 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).
8. **Dosage allowed:** 100mg administered intravenously every 3 months. A dose of 300mg may also be used. No evidence is established for any other dosages.

Note: Vyepti is considered experimental and investigational as combination therapy with Botox, Aimovig, Ajovy, or Emgality because the safety and effectiveness of these combinations has not been established.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member is in compliance with all other initial criteria; AND
2. 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
3. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Vyepti (eptinezumab-jjmr) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/22/2020	New policy for Vyepti created.

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. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2018.
8. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; January 2019.
9. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; September, 2018.
10. 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.

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