

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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 Ajovy (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., Ajovy, 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.  $\leq 14$  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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