PHARMACY POLICY STATEMENT
Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Vyepti (eptinezumab-jjmr)</th>
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<tbody>
<tr>
<td>BILLING CODE</td>
<td>J3032</td>
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<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
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<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient</td>
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<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Non-Preferred Product)</td>
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<tr>
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<td>QUANTITY LIMIT— 300mg (3 vials) per 90 days</td>
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<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
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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) ≥ 15 headache days per month for at least 3 months;  
   b) ≥ 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. ≤ 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., lopiramate 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.**

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/22/2020</td>
<td>New policy for Vyepti created.</td>
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References:


Effective date: 07/20/2020
Revised date: 05/22/2020