

<b>Clinical Policy Title:</b>	eptinezumab-jjmr
<b>Policy Number:</b>	RxA.664
<b>Drug(s) Applied:</b>	Vyepti®
<b>Original Policy Date:</b>	12/07/2020
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Migraine Prophylaxis (must meet all):

1. Diagnosis of the following (must meet a or b):
  - a. Episodic: between 4 to 14 migraine days per month;
  - b. Chronic migraine: more than 15 headache days per month for  $\geq 3$  months;
2. Trial of at least 2 months of two (2) of the following preventative therapies, unless contraindicated or adverse effects are experienced:
  - a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);
  - b. beta-blockers (e.g., metoprolol, propranolol, timolol);
  - c. antidepressants (e.g., amitriptyline, venlafaxine);
3. For members currently treated with Botox for migraine (must meet a, b, and c):
  - a. Diagnosis of chronic migraine;
  - b. Member has tried a minimum of 2 quarterly injections (6 months) of Botox;
  - c. Member has experienced and maintained a positive response.
4. Trial of Ajoovy® and Aimovig® unless contraindicated or adverse effects are experienced;
5. Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis\*;
 

\*Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.

#### **CGRP monotherapy initial approval duration**

**Commercial:** 12 months

**Medicaid:** 12 months

#### **CGRP and Botox dual therapy initial approval duration**

**Commercial:** 3 months

**Medicaid:** 3 months

### II. Continued Therapy Approval

#### A. Migraine Prophylaxis (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples;
2. Member has experienced and maintained positive response to therapy;
3. Members who are treated with Aimovig AND Botox for chronic migraine prophylaxis, member has achieved > 50% reduction in the frequency of days with headache or migraine.
4. Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis\*;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

\*Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.

**Approval Duration**

**Commercial:** 12 months

**Medicaid:** 12 months

**References**

Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	11/23/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.8 was updated to include "Member shouldn't have any history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease".	10/21/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.6: Updated trial and failure criteria from Failure of at least 1-month trial of one of the following unless member is allergic to any inactive ingredient of these drugs: Ajovy®, Aimovig®, or Emgality® to Trial and failure of Ajovy® and Aimovig® unless contraindicated or clinically significant adverse effects are experienced. 2. Initial Approval Criteria, I.A.7: Updated combination therapy criteria from Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable CGRP inhibitors (e.g., (erenumab) Aimovig®, (fremanezumab) Ajovy®, (galcanezumab-gnlm) Emgality®) to Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™). 3. Initial Approval Criteria, I.A.8: Updated to remove prior diagnostic criteria "Member shouldn't have any history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, or cerebrovascular disease". 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Continued Therapy Approval, II.A.3: Updated	09/02/2022	10/19/2022

<p>combination therapy criteria from Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable CGRP inhibitors (e.g., (erenumab) Aimovig®, (fremanezumab) Ajovy®, (galcanezumab-gnlm) Emgality®) to Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™).</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Clinical Policy Title, Lines of business Policy Applies to: Updated from All line of business to All lines of business (except Medicare).</li> <li>2. Initial Approval Criteria, I.A.1: Updated diagnosis criteria from Diagnosis of episodic or chronic migraine to diagnosis of the following (must meet a or b):             <ol style="list-style-type: none"> <li>a. Episodic: between 4 to 14 migraine days per month;</li> <li>b. Chronic migraine: more than 15 headache days per month for ≥ 3 months.</li> </ol> </li> <li>3. Initial Approval Criteria, I.A.2: Updated to remove prior diagnostic criteria "Member experiences ≥ 4 migraine days per months for at least 3 months."</li> <li>4. Initial Approval Criteria, I.A.2: Rephrased prior trial and failure criteria to "Trial of at least 2 months of two (2) of the following preventative therapies, unless contraindicated or adverse effects are experienced..".</li> <li>5. Initial Approval Criteria, I.A.3: Updated to remove prior prescriber criteria "Prescribed by or in consultation with a neurologist, headache, or pain specialist".</li> <li>6. Initial Approval Criteria, I.A.3: Updated to include new criteria pertaining to indication Migraine Prophylaxis, For members currently treated with Botox for migraine (must meet a, b, and c):             <ol style="list-style-type: none"> <li>a. Diagnosis of chronic migraine;</li> <li>b. Member has tried a minimum of 2 quarterly injections (6 months) of Botox;</li> <li>c. Member has experienced and maintained a positive response.</li> </ol> </li> <li>7. Initial Approval Criteria, I.A.4: Updated to remove prior age criteria "Age ≥ 18 years".</li> <li>8. Initial Approval Criteria, I.A.5: Updated to include new combination therapy criteria Medication is not</li> </ol>	<p>07/10/2023</p>	<p>07/13/2023</p>

<p>prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*; *Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.</p> <p>9. Initial Approval Criteria, I.A.7: Updated to remove prior concurrent therapy criteria "Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™)."</p> <p>10. Initial Approval Criteria, I.A: Updated approval duration criteria from 6 months to 12 months for both Commercial and Medicaid.</p> <p>11. Initial Approval Criteria, I.A: Update to include new approval duration criteria, CGRP and Botox dual therapy initial approval duration 3 months for both Commercial and Medicaid.</p> <p>12. Continued Therapy Approval Criteria, II.A.1: Updated authorization criteria from Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy to Member is currently receiving medication, excluding manufacturer samples.</p> <p>13. Continued Therapy Approval Criteria, II.A.2: Updated response criteria from Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline to Member has experienced and maintained positive response to therapy.</p> <p>14. Continued Therapy Approval Criteria, II.A.3: Updated to remove prior concurrent therapy criteria "Vyepti® is not prescribed concurrently with (onabotulinumtoxin A) Botox® or other injectable or oral CGRP inhibitors (e.g., Aimovig®, Ajovy®, Emgality®, Nurtec®, Qulipta™, Ubrelvy™)".</p> <p>15. Continued Therapy Approval Criteria, II.A.3: Updated to include new criteria pertaining to indication Migraine Prophylaxis, Members who are treated with Aimovig AND Botox for chronic migraine prophylaxis, member has achieved &gt; 50% reduction in the frequency of days with headache or migraine.</p> <p>16. Continued Therapy Approval Criteria, II.A.4: Updated to include new combination therapy criteria Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*; *Medication may be prescribed</p>		
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concurrently with other CGRP inhibitors used for acute migraine treatment.		
Policy was reviewed.	10/19/2023	10/19/2023