

Clinical Policy Title:	galcanezumab-gnlm
Policy Number:	RxA.595
Drug(s) Applied:	Emgality®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Migraine Prophylaxis (120 mg/ml dose) (must meet all):

1. Diagnosis of the following (a or b):
 - a. Episodic migraine: between 4 to 14 migraine days per month;
 - b. Chronic migraine: more than 15 migraine days per month for ≥ 3 months;
2. Trial of at least 2 months of two (2) of the following preventative therapies from different mechanisms of action, unless contraindicated or adverse effects are experienced:
 - a. Candesartan;
 - b. Antiepileptics: divalproex sodium, valproic acid, topiramate;
 - c. Beta-blockers: atenolol, metoprolol, nadolol, propranolol, timolol;
 - d. Antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine;
3. For members currently treated with Botox (a, b, and c):
 - a. Diagnosis of chronic migraine;
 - b. Member has been treated with a minimum of two (2) Botox injections in the past 6 months;
 - c. Member has experienced and maintained a positive response to Botox;
4. Trial of 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.

All lines of Business (except Medicare)

CGRP monotherapy initial approval duration: 12 months

CGRP and Botox dual therapy initial approval duration: 3 months

B. Episodic Cluster Headaches (100 mg/ml) (must meet all):

1. Diagnosis of episodic cluster headaches;
2. Member meets the following (a, b, and c):
 - a. Member has experienced ≥ 2 cluster periods;
 - b. Cluster periods last from 7 days to 365 days each;
 - c. Cluster periods are separated by pain free periods lasting ≥ 3 months;
3. Medication is not prescribed in combination with Botox;
4. Medication is not prescribed with other CGRP inhibitors used for migraine prophylaxis*.

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

Approval Duration

All lines of Business (except Medicare): 12 months

II. Continued Therapy Approval (must meet all):

A. Migraine Prophylaxis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Members treated with Emgality AND Botox for chronic migraine prophylaxis have achieved > 50% reduction in the frequency of days with headache or migraine;
3. 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.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Episodic Cluster Headaches (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Medication is not prescribed in combination with Botox;
3. Medication is not prescribed with other CGRP inhibitors used for migraine prophylaxis*;
*Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Beck E, Sieber W, Trejo R. Management of cluster headache. AFP. 2005;71(4):717-724. Available at: <https://www.aafp.org/afp/2005/0215/p717.html>. Accessed August 12, 2024.
2. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024. Available at: <https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.14692>. Accessed August 12, 2024.
3. Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults. Available at: <https://www.aan.com/Guidelines/home/GuidelineDetail/536>. Accessed August 14, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020

<ol style="list-style-type: none"> 1. Policy was reviewed: 2. Clinical policy title was updated as “galcanezumab-gnlm”. 3. Lines of business policy applies to all lines of business. 4. Continued therapy criteria II.A.1. was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance...”. 5. References were reviewed and updated. 	<p>11/23/2020</p>	<p>12/07/2020</p>
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<ul style="list-style-type: none"> 6. Continued Therapy approval duration for commercial plan was updated from 6 months to 12 months. 7. Removed specialist requirement from the Initial Approval Criteria for both indications. 8. Removed the trial/failure of Aimovig or Ajovy criteria from the Initial Approval Criteria for Migraine. 		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Initial Approval Criteria I.B.1.a was updated from “≥ 1 cluster headache attack every other day and ≤ 8 cluster headache attacks per day with a total of ≥ 5 previous attacks” to “Cluster headache frequency between 1 every other day and 8 per day” 2. Initial Approval Criteria I.B.1.b was updated from “≥ 2 cluster periods lasting ≤ 1 year each and separated by ≥ 3 months” to “Total of ≥ 5 previous attacks” 3. Initial Approval Criteria I.B.1 was updated to include criteria c (I.B.1.c) “≥ 2 cluster periods lasting from 7 days to 1 year each and separated by ≥ 3 months.” 4. Continued Therapy Approval II.A.1 and II.B.1 were rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated. 	10/12/2021	12/7/2021
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 1. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Failure of an 8 week trial of at least two (2) of the following oral migraine preventative therapies, each from a different class, unless contraindicated or clinically significant adverse effects are experienced (a, b, or c): <ul style="list-style-type: none"> a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate); b. beta-blockers (e.g., metoprolol, propranolol, timolol); c. antidepressants (e.g., amitriptyline, venlafaxine) to Trial and failure of Aimovig® and Ajovy® unless contraindicated or clinically significant adverse effects are experienced; 	09/02/2022	10/19/2022

<ol style="list-style-type: none"> 2. Initial Approval Criteria, I.A.3: Updated to remove prior trial and failure criteria "Failure of verapamil at a dose of 360 mg per day, unless contraindicated or clinically significant adverse effects are experienced". 3. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical Policy Title, Lines of Business Policy Applies to: Updated from All line of Business to All lines of business (except Medicare). 2. Initial Approval Criteria, I.A.2: Updated to remove prior criteria pertaining to indication Migraine Prophylaxis, "Member experiences ≥ 4 migraine days per month for at least 3 months". 3. Initial Approval Criteria, I.A.2: Updated to include new trial and failure criteria Trial of at least 2 months of two (2) of the following preventative therapies, unless contraindicated or adverse effects are experienced: <ol style="list-style-type: none"> a. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate); b. beta-blockers (e.g., metoprolol, propranolol, timolol); c. antidepressants (e.g., amitriptyline, venlafaxine); 4. Initial Approval Criteria, I.A.3: Updated to remove prior age criteria "Age ≥ 18 years". 5. 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"> 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. 6. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Trial and failure of Ajovy® and Aimovig® unless contraindicated or clinically significant adverse effects are experienced to Trial of Ajovy® and Aimovig® unless contraindicated or adverse effects are experienced. 7. Initial Approval Criteria, I.A.5: Updated 	<p>07/10/2023</p>	<p>07/13/2023</p>

<p>combination therapy criteria from Emgality® is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Ajovy®, Ajovy®) to 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.</p> <p>8. Initial Approval Criteria, I.A: Updated CGRP monotherapy initial approval duration from 3 to 12 months for Commercial and Medicaid.</p> <p>9. Initial Approval Criteria, I.A: Update to include new duration criteria CGRP and Botox dual therapy initial approval duration 3 months for both Commercial and Medicaid.</p> <p>10. Initial Approval Criteria, I.B.1: Updated diagnosis criteria from Diagnosis of episodic cluster headaches as evidenced by both of the following (a, b, and c):</p> <ol style="list-style-type: none"> Cluster headache frequency between 1 every other day and 8 per day; Total of ≥ 5 previous attacks; ≥ 2 cluster periods lasting from 7 days to 1 year each and separated by ≥ 3 months of episodic cluster headaches. <p>11. Initial Approval Criteria, I.B.2: Updated to remove prior age criteria "Age ≥ 18 years".</p> <p>12. Initial Approval Criteria, I.B.2: Updated to include criteria pertaining to indication Migraine Prophylaxis, Member experiences ≥ 2 cluster periods lasting from 7 days to 1 year each and separated by ≥ 3 months.</p> <p>13. Initial Approval Criteria, I.B.3: Updated combination therapy criteria from Emgality® is not prescribed concurrently with other injectable CGRP inhibitors (e.g., Aimovig®, Ajovy®) to Medication is not prescribed in combination with Botox.</p> <p>14. Initial Approval Criteria, I.B.4: Updated concurrent therapy criteria from Emgality® is not prescribed concurrently with other injectable CGRP inhibitors (e.g., Ajovy®, Ajovy®) to Medication is not prescribed with other CGRP inhibitors used for migraine</p>		
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<p>prophylaxis*. *Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.</p> <p>15. Continued Therapy Approval Criteria II.A.1 was updated from Member is currently receiving medication that has been authorized by RxAdvance or the member has previously met initial approval criteria listed in this policy to Member is currently receiving medication, excluding manufacturer samples.</p> <p>16. Continued Therapy Approval, Criteria II.A.2: Updated response to therapy 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>17. Continued Therapy Approval, Criteria II.A.3: Updated to remove concurrently therapy criteria "Emgality® is not prescribed concurrently with Botox or other injectable CGRP inhibitors (e.g., Aimovig®, Ajovy®)".</p> <p>18. Continued Therapy Approval, Criteria II.A.3: Updated to include new criteria pertaining to indication Migraine Prophylaxis Members who are treated with Emgality® AND Botox for chronic migraine prophylaxis, member has achieved > 50% reduction in the frequency of days with headache or migraine.</p> <p>19. 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 concurrently with other CGRP inhibitors used for acute migraine".</p> <p>20. Continued Therapy Approval Criteria, II.A: Updated Approval duration from 6 to 12 months for Medicaid.</p> <p>21. Continued Therapy Approval Criteria II.B.1 was updated from Member is currently receiving medication that has been authorized by RxAdvance or the member has previously met initial approval criteria listed</p>		
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<p>in this policy to Member is currently receiving medication, excluding manufacturer samples.</p> <p>22. Continued Therapy Approval, Criteria II.B.2: Updated response to therapy criteria from Member is responding positively to therapy as evidenced by a reduction in cluster headache attack frequency to Member has experienced and maintained positive response to therapy.</p> <p>23. Continued Therapy Approval, Criteria II.B.3: Updated to remove concurrently therapy criteria "Emgality® is not prescribed concurrently with other injectable CGRP inhibitors (e.g., Aimovig®, Ajovy®)".</p> <p>24. Continued Therapy Approval, Criteria II.B.3: Updated to include new combination therapy criteria "Medication is not prescribed in combination with Botox".</p> <p>25. Continued Therapy Approval, Criteria II.B.4: Updated to include new concurrent therapy criteria "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.</p> <p>26. Continued Therapy Approval Criteria, II.B: Updated Approval duration from 6 to 12 months for Medicaid.</p> <p>27. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy reviewed: 1. Clean up</p>	<p>3/1/2024</p>	<p>2/28/2024</p>
<p>Policy was reviewed: 1. Updated trial and failure medications. 2. References were reviewed and updated. 3. Updated continuation criteria</p>	<p>12/05/2024</p>	<p>12/05/2024</p>
<p>Policy reviewed: 1. Ajovy removed from policy</p>	<p>12/11/2025</p>	<p>12/11/2025</p>