

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

galcanezumab (Emgality)

(Eli Lilly Canada Inc.)

Indication: Prevention of migraine

December 2, 2021

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CADTH Reimbursement Review

Feedback on Draft Recommendation

| Stakeholder information | |
|-------------------------|--|
| CADTH project number | SR0693 |
| Name of the drug and | Galcanezumab (Emgality) for the prevention of migraine in adults |
| Indication(s) | who have at least four migraine days per month |
| Organization Providing | FWG |
| Feedback | |

| 1. <u>Recommendation</u> revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation. | | | |
|---|--|---|--|
| Request for Reconsideration | Major revisions: A change in recommendation category or patient population is requested | | |
| | Minor revisions: A change in reimbursement conditions is requested | | |
| No Request for Reconsideration | Editorial revisions: Clarifications in recommendation text are requested | Х | |
| | No requested revisions | | |

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested

Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation

Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

Please provide details regarding the information that requires clarification.

b) Reimbursement conditions and related reasons

Please provide details regarding the information that requires clarification.

c) Implementation guidance

• Specify acceptable oral prophylactic therapies (e.g., beta blockers, candesartan, amitriptyline, venlafaxine, sodium valproate/divalproex sodium, topiramate, gabapentin, etc.), adequacy of dosing and trial duration.

- Clarify whether consideration can be given for renewals in patients who had an initial adequate response, discontinued therapy as renewal criteria was not met subsequently, then relapsed?
- Provide additional context around the statement that 'Galcanezumab should not be used in combination with onabotulinumtoxinA.' Is it that it should not be used in combination with Botox, or that it is not cost effective to use with Botox? Or is it that there is no data supporting combination use with Botox?

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions

- 1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
- 1.
- 2.
- 2. Please specify other implementation questions or issues that should be addressed by CADTH
- 1.
- 2.

Support strategy

3. Do you have any preferences or suggestions on how CADTH should address these issues?

May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.