CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Qulipta (atogepant)

AbbVie

Indication: Migraine, prevention

June 02, 2023

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0724
Name of the drug and Indication(s)	Atogepant (Qulipta) for the prevention of episodic migraine
Organization Providing Feedback	FWG

1. Recommendation 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	X☐
	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

Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

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.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	
Brand name (generic)	Atogepant (Qulipta)
Indication(s)	
Organization	Migraine Canada
Contact information[a]	Name: Wendy Gerhart

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

If not, what aspects are missing from the draft recommendation?

In our submission we rationale on how accessing new treatment options was important to the community. The current options available are not optimal. They have intolerable side effects and are simply not effective for many. Patients and clinicians should have access to new, innovative medications approved by Health Canada to be safe and effective. It is essential patient's and clinicians have multiple options to help manage migraine.

We believe patient input submissions should have more weight and consideration. The content that feeds into our submissions is what Canadians experience daily and how they are impacted. Migraine negatively impacts almost all aspects of people's live including ability to work, cognitive functioning and more.

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

We strongly believe that with the current medications available, patient needs continue to NOT be met and there is a need for more options, including options in mode of delivery.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

If not, please provide details regarding the information that requires clarification.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒

If not, please provide details regarding the information that requires clarification.

It is clear that the recommendation from the committee is to reimburse Atogepant with some conditions. We are extremely appreciative.

In response to the reimbursement conditions and reasons we have the following comments:

Table 1: Reimbursement Conditions & Reasons

1. No Comments

2. It is our opinion that clinicians should have the ability, based on patient assessment and medical history to manage migraine with combination therapy if appropriate.

3. No Comments

Table 2: Responses to questions from the Drug Programs

Considerations for initiation of therapy

4. No Comments
5. No Comments
6. Asking patients to track both headache days and migraine days is challenging. For some people, the difference between a headache day and a migraine day isn't clear and could be captured incorrectly. Intensity is important for the assessment in response. For some, a less intense migraine attack makes a significant impact on quality of life. We feel strongly the recommendations incorporate intensity as a consideration.
7. Initial authorization for 6 months is reasonable with subsequent authorizations to be every 12 or 18 months. Asking physicians to do excessive paperwork every 6 months is inefficient use of their time. Migraine is chronic. There is no cure. When patients respond and do well to a CGRP, its essential they continue to take it without breaks. We have heard from patients that when they have taken and are well managed with a CGRP and then come off, their migraine attacks come back.
8. If the treating clinician feels atogepant would benefit a patient over the age of 65 years (with medical history considered), it should be permitted.
9. No Comments
10. No comments.

Considerations for continuation or renewal of therapy

1. The 30% improvement + HIT6 is reasonable clinically but some patients may see mostly an improvement in intensity and still not reach the 30% of frequency. Reduction in intensity can greatly impact quality of life and improve ability to work, function, improve mood, sleep, mental health, etc. For some patients severely affected and who have tried multiple treatments, modest improvements are very relevant. There is also evidence suggesting that patients who do not respond to, or do not tolerate, a CGRP antibody have around 30% chance of responding another. It is important to allow patients to try different CGRPs.
2. Initial authorization for 6 months is reasonable with subsequent authorizations to be every 12 or 18 months. Asking physicians to do excessive paperwork every 6 months is inefficient use of their time. Migraine is chronic. There is no cure. When patients respond and do well to a CGRP, its essential they continue to take it without breaks. We have heard from patients that

when they have taken and are well managed with a CGRP and then come off, their migraine attacks come back. Additionally, having physicians needing to complete paperwork every 6 months is inefficient use of their time and an unnecessary burden on the healthcare system.

Considerations for discontinuation of therapy

1. We disagree with this recommendation. The 30% improvement + HIT6 is reasonable clinically but some patients may see mostly an improvement in intensity and still not reach the 30% of frequency. Reduction in intensity can greatly impact quality of life and improve ability to work, function, improve mood, sleep, mental health, etc. For some patients severely affected and who have tried multiple treatments, modest improvements are very relevant. There is also evidence suggesting that patients who do not respond to, or do not tolerate, a CGRP antibody have around 30% chance of responding another. It is important to allow patients to try different CGRPs.

Considerations for prescribing of therapy

1. No comments
2. While we agree an accurate diagnosis of migraine is important, due to the shortage of headache specialists and access to neurologists in general, prescriptions by primary care providers is essential. Due to the prevalence of the migraine, the majority of patients are treated by a primary care clinician. There are simply not enough headache specialists / neurologists in Canada to treat everyone who has a migraine diagnosis. Making this mandatory is not efficient or responsible use of healthcare resources (human and financial).

Generalizability

1. Atogepant is a first in class medication. It provides a completely different mode of administration that may be better for a particular patient population. It provides choice.
2. It is positive that 2 trials of oral preventives are required vs patients needing to try and fail on 3. We will be advocating to all provinces to follow these recommendations to ensure Canadians have equitable access to medications regardless of the jurisdiction they reside. Consideration should also be given to medication being intolerable due to side effects as a reason to discontinue therapy. Lastly, for a significant number of severe patients, the combination of a CGRP + Botox is effective and should be considered. There are no safety issues with this combination. Patients also share that the newer medications, like CGRP antibodies, are better tolerated and more effective than the oral preventives.

   We question why a response of more than 30% is sufficient for oral preventives when a 50% improvement is required for CGRP antibodies in general. If a patient has a 30% response, this can be significant to the patient and his/her quality of life. Patients strive for reduction in frequency and/or intensity.

Care provision issues

1. No comments.

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Wendy Gerhart*
Position	*Executive Director, Migraine Canada*
Date	*Please add the date form was completed (02-06-2023)*
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

Appendix 2. Conflict of Interest Declarations for Clinician Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.
- For conflict of interest declarations:
  - Please list any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.
  - Please note that declarations are required for each clinician that contributed to the input.
  - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
  - Please add more tables as needed (copy and paste).
  - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☐
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☐
	Yes	☐
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☐
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.
Conflict of Interest Declaration	

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 3	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☒	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration				
List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.				
Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 4	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 5	
Name	*Please state full name*
Position	*Please state currently held position*
Date	*Please add the date form was completed (DD-MM-YYYY)*
☐	**I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.

Conflict of Interest Declaration

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐