CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Faricimab (Vabysmo)

(Hoffmann-La Roche Canada)

Indication: Diabetic Macular Edema

September 29, 2022

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0729
Name of the drug and Indication(s)	Faricimab (Vabysmo) for the treatment of Diabetic macular edema (DME)
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	☐
	No requested revisions	X

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

Version: 1.0
Publication Date: TBC
Report Length: 2 Pages

Single Technology

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.

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CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0729-000
Brand name (generic)	Faricimab
Indication(s)	Diabetic Macular Edema
Organization	Fighting Blindness Canada, Canadian Council of the Blind, CNIB, Diabetes Canada, Vision Loss Rehabilitation Canada
Contact information[a]	[redacted]

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.

The recommendation to reimburse faricimab for DME is welcomed as it provides another treatment option to patients. Importantly, faricimab may allow patients to reduce the number of treatments, which would have large impacts of their quality of life as well as reducing the risk of treatment related side effects. This is to be commended.

Reducing the treatment burden is important in any patient population, but perhaps even more so in the case of DME. Individuals with DME are often dealing with multiple health conditions and co-morbidities. There is also less access and uptake of diabetic eye care among some of the most vulnerable and underserved populations. This has been demonstrated in the case of diabetic eye screening, where lower income, recent immigration status, mental health history or those without a primary care provider were at higher risk of not accessing eye screening (https://pubmed.ncbi.nlm.nih.gov/35577027/). These trends are likely to also impact treatment adherence and outcomes.

These demographic factors make having an effective treatment that required less visits even more crucial for the target population and could dramatically reduce patients stopping or missing treatments thus improving health outcomes.

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?

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.

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.		

[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	*Larissa Moniz*
Position	*Director, Research and Mission Programs*
Date	*21-09-2022*
☒	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	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0729
Brand name (generic)	Faricimab (VABYSMO)
Indication(s)	Diabetic Macular Edema (DME)
Organization	Canadian Retina Society (CRS)
Contact information[a]	[redacted]

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?		

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.		
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.		

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

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- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
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 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	☐	☐	☐	☐

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CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0729-000
Brand name (generic)	VABYSMO (faricimab)
Indication(s)	For the treatment of Diabetic Macular Edema (DME)
Organization	Hoffmann-La Roche Ltd. (Roche)
Contact information[a]	[redacted]

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

Roche Canada agrees that the committee's recommendation is aligned with the evidence from the YOSEMITE and RHINE clinical trials. The population identified in the recommendation is reflective of the populations included in the trials and that of clinical practice.

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	☐

The recommendation reflects that the clinical and economic data submitted were considered as part of the assessment.

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

The reasons for the recommendation are clearly stated and are based on the clinical trial data.

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

The implementation issues have been clearly articulated and adequately addressed in the recommendation.

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

Overall, Roche recognizes that the rationale provided in the reimbursement conditions and associated reasons are clearly stated.

While Roche acknowledges that there is limited direct comparative evidence versus other treatments currently available for DME, the pivotal studies for faricimab (YOSEMITE and RHINE) were conducted versus the most relevant comparator (aflibercept) and demonstrated non-inferiority with respect to change from baseline in best-corrected visual acuity (BCVA) averaged over weeks 92, 96 and 100. In both YOSEMITE and RHINE, mean vision gains at and over 2 years were comparable between patients receiving faricimab Q8W (n=632) or faricimab personalized treatment interval (PTI) up to Q16W (n=632), and those receiving aflibercept Q8W (n=627).

Roche agrees with the CDEC that frequency of injection is considered to be an important outcome of interest by both patient and clinician groups. Therefore, Roche would like to highlight that in the faricimab PTI arm durable vision gains were achieved with extended dosing, with more than 60% of patients on Q16W dosing at week 96 and almost 80% on Q12W dosing or longer (The sum of Q12W and Q16W percentages which is the calculated proportion of patients who achieved Q12W or Q16W dosing at week 96 is 78%). The majority of patients who achieved Q12W or Q16W dosing at 52 weeks were able to maintain these extended intervals through week 96. Patients in the faricimab PTI arms received a median of 3 injections during year 2 of the trials. This accounts for a 40% reduction from the 5 injections received by each of the fixed Q8W treatment arms.

Table 1. At Week 96, ≥60% of Faricimab-treated Patients in the PTI Arms achieved Q16W Dosing

	YOSEMITE (n=270)	RHINE (n=287)
Q4W	7.0 %	10.1%
Q8W	14.8%	11.8%
Q12W	18.1%	13.6%
Q16W	60.0%	64.5%

[a] Analyses included patients in the faricimab PTI arms who had not discontinued the study at the week 96 visit. Treatment interval at week 96 was defined as the treatment interval decision made at that visit.

In addition, when viewing the anatomic outcomes, a numerically greater proportion of patients receiving faricimab Q8W or faricimab PTI achieved absence of DME (defined as CST less than 325 µm) through year 2 compared with aflibercept Q8W. In a post hoc analysis, presented at the American Society of Retina Specialists Annual Meeting in July 2022, first absence of DME was achieved earlier and in more patients treated with faricimab Q8W and PTI versus aflibercept Q8W. By week 100, almost 100% of faricimab-treated patients had achieved first absence of DME, compared with approximately 90% of aflibercept-treated patients. The time point at which the cumulative incidence of absence of DME reached 75% was week 20–24 in the faricimab Q8W and PTI arms, after an average of 4–6 injections. In the aflibercept Q8W arms, the 75th percentile was reached at week 44 in YOSEMITE and week 28 in RHINE, after an average of 7.5 and 6 injections, respectively.

Similarly, absence of intraretinal fluid (IRF) through year 2 was achieved by more patients treated with faricimab Q8W or faricimab PTI up to Q16W versus aflibercept Q8W. Noting that superiority analyses for absence of DME and absence of IRF through year 2 were not pre-specified and not powered. Furthermore, safety results were consistent across study arms, with no reported cases of retinal vasculitis or retinal occlusive events.

Thus, the funding of faricimab is expected to result in fewer injections while maintaining vision and anatomic outcomes for people with DME and substantial cost savings to the publicly funded health care system, compared to currently available and approved anti-VEGF treatments. Roche looks forward to working with pCPA and the jurisdictions to make faricimab accessible to all Canadians in a timely manner.

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