

### CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

Faricimab (Vabysmo) (Hoffmann-La Roche Canada)

Indication: Diabetic Macular Edema

September 29, 2022

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## CADTH

## **CADTH Reimbursement Review**

### **Feedback on Draft Recommendation**

Stakeholder information	
CADTH project number	SR0729
Name of the drug and	Faricimab (Vabysmo) for the treatment of Diabetic macular edema
Indication(s)	(DME)
Organization Providing	FWG
Feedback	

<b>1. Recommendat</b> Please indicate if the recommendation.	<b>ion revisions</b> ne stakeholder requires the expert review committee to reconsider or clari	fy its
Request for	Major revisions: A change in recommendation category or patient	
Reconsideration	Minor revisions: A change in reimbursement conditions is requested	
<b>Editorial revisions:</b> Clarifications in recommendation text are requested		
Reconsideration	No requested revisions	х

#### 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

## CADTH

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.



## 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, C	NIB,	
	Diabetes Canada, Vision Loss Rehabilitation Canada		
Contact information <sup>a</sup>			
Stakeholder agreement w	ith the draft recommendation		
1. Does the stakeholder ag	gree with the committee's recommendation.	Yes No	
	e specific text from the recommendation and rationale.	/heneve	r
option to patients. Important	mburse faricimab for DME is welcomed as it provides another t tly, faricimab may allow patients to reduce the number of treatm acts of their quality of life as well as reducing the risk of treatm ommended.	nents,	
the case of DME. Individual morbidities. There is also le vulnerable and underserved screening, where lower inco primary care provider were	den is important in any patient population, but perhaps even m s with DME are often dealing with multiple health conditions an ss access and uptake of diabetic eye care among some of the d populations. This has been demonstrated in the case of diabe- ome, recent immigration status, mental health history or those v at higher risk of not accessing eye screening <u>h.gov/35577027/</u> ). These trends are likely to also impact treatm	id co- most etic eye vithout a	
	make having an effective treatment that required less visits ev tion and could dramatically reduce patients stopping or missing health outcomes.		;
Expert committee conside	eration of the stakeholder input		
	on demonstrate that the committee has considered the	Yes	
stakeholder input that y	our organization provided to CADTH?		$\boxtimes$
If not, what aspects are mis		No	
	sing from the draft recommendation?	NO	
Clarity of the draft recomm		No	
		Yes No	
3. Are the reasons for the	nendation	Yes	
3. Are the reasons for the If not, please provide details	nendation recommendation clearly stated?	Yes	

If not, please provide details regarding the information that requires clarification.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes	$\boxtimes$
for the conditions provided in the recommendation?	No	
If not, please provide details regarding the information that requires clarification.		

<sup>a</sup> 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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> 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 a matter involving this patient gro patient group in a real, potentia	up with a comp	any, organizatio	n, or entity that n		
B. Assista	nce with Providing Feedback					
					No	$\boxtimes$
1. Did yo	ou receive help from outside you	ir patient grou	p to complete y	our feedback?	Yes	
2. Did vo	u receive help from outside vou	r patient grou	p to collect or a	analyze any	No	$\boxtimes$
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## 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 <sup>a</sup>			
Stakeholder agreement wi	th the draft recommendation		
1 Does the stakeholder an	ree with the committee's recommendation.	Yes	$\boxtimes$
		No	
	eholder agrees or disagrees with the draft recommendation. W specific text from the recommendation and rationale.	henevo	er
Expert committee conside	ration of the stakeholder input		
2. Does the recommendati	on demonstrate that the committee has considered the	Yes	$\boxtimes$
stakeholder input that y	our organization provided to CADTH?	No	
If not, what aspects are miss	sing from the draft recommendation?		
Clarity of the draft recomm	nendation		
3 Are the reasons for the	recommendation clearly stated?	Yes	$\boxtimes$
	-	No	
If not, please provide details	regarding the information that requires clarification.		
	n issues been clearly articulated and adequately	Yes	$\boxtimes$
addressed in the recom		No	
If not, please provide details	regarding the information that requires clarification.		
	nbursement conditions clearly stated and the rationale	Yes	$\boxtimes$
•	ded in the recommendation?	No	
If not, please provide details	regarding the information that requires clarification.		

<sup>a</sup> CADTH may contact this person if comments require clarification.

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- CADTH may contact your group with further questions, as needed.
- Please see the <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.

	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					
	I hereby certify that I have the matter involving this patient gi patient group in a real, potent	roup with a comp	oany, organizatio	on, or entity that r		
B. Assista	nce with Providing Feedback					
4 B' I				<b>6</b> H 10	No	
1. Did yo	u receive help from outside yo	our patient grou	p to complete	your feedback?	Yes	
2. Did yo	u receive help from outside yo	our patient grou	p to collect or	analyze any	No	
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## CADTH Reimbursement Review Feedback on Draft Recommendation

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 <sup>a</sup>			
Stakeholder agreement wi	ith the draft recommendation		
1 Does the stakeholder ac	gree with the committee's recommendation.	Yes	$\boxtimes$
		No	
YOSEMITE and RHINE clin the populations included in t	the committee's recommendation is aligned with the evidence f ical trials. The population identified in the recommendation is re the trials and that of clinical practice.		of
· · ·		Maa	
	on demonstrate that the committee has considered the	Yes	
	our organization provided to CADTH?	No	
of the assessment.	ts that the clinical and economic data submitted were considere	eo as pa	π
Clarity of the draft recomm	nondation		
	nenuauon		
		Yes	
3. Are the reasons for the	recommendation clearly stated?	No	
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<ul> <li>3. Are the reasons for the The reasons for the recomm</li> <li>4. Have the implementation addressed in the recommondation issues recommendation.</li> <li>5. If applicable, are the rein for the conditions provide Overall, Roche recognizes the reasons are clearly stated.</li> <li>While Roche acknowledges currently available for DME, versus the most relevant change from baseline in best set of the condition of the condition of the condition of the condition of the conditions provide of the conditions provided the conditions of the condition of the conditions provided the conditions of the conditions provided the conditions of the condition of the conditions provided the conditions of the conditions</li></ul>	recommendation clearly stated? mendation are clearly stated and are based on the clinical trial d in issues been clearly articulated and adequately mendation? have been clearly articulated and adequately addressed in the mbursement conditions clearly stated and the rationale ded in the recommendation? hat the rationale provided in the reimbursement conditions and is that there is limited direct comparative evidence versus other the pivotal studies for faricimab (YOSEMITE and RHINE) were omparator (aflibercept) and demonstrated non-inferiority with st-corrected visual acuity (BCVA) averaged over weeks 92, 96 a	No ata. Yes No Yes associat treatme conduct respect and 100	□ ⊠ □ Ed nts te to . In
<ul> <li>3. Are the reasons for the recommodation</li> <li>4. Have the implementation addressed in the recommodation issues recommendation.</li> <li>5. If applicable, are the rein for the conditions provid</li> <li>Overall, Roche recognizes to reasons are clearly stated.</li> <li>While Roche acknowledges currently available for DME, versus the most relevant co change from baseline in best both YOSEMITE and RHIN</li> </ul>	recommendation clearly stated? mendation are clearly stated and are based on the clinical trial d in issues been clearly articulated and adequately mendation? have been clearly articulated and adequately addressed in the mbursement conditions clearly stated and the rationale ded in the recommendation? hat the rationale provided in the reimbursement conditions and is that there is limited direct comparative evidence versus other the pivotal studies for faricimab (YOSEMITE and RHINE) were omparator (aflibercept) and demonstrated non-inferiority with st-corrected visual acuity (BCVA) averaged over weeks 92, 96 and NE, mean vision gains at and over 2 years were comparable	No ata. Yes No Yes No associat treatme conduct respect and 100 e betwe	
<ul> <li>3. Are the reasons for the recommodation</li> <li>4. Have the implementation addressed in the recommodation issues recommendation.</li> <li>5. If applicable, are the rein for the conditions provide Overall, Roche recognizes to reasons are clearly stated.</li> <li>While Roche acknowledges currently available for DME, versus the most relevant conditions provide the provide the provide the term of the conditions provided by the most relevant conditions of the conditions provided by the most relevant conditions provided by the conditions provided by the most relevant conditions provided by the most</li></ul>	recommendation clearly stated? mendation are clearly stated and are based on the clinical trial d in issues been clearly articulated and adequately mendation? have been clearly articulated and adequately addressed in the mbursement conditions clearly stated and the rationale ded in the recommendation? hat the rationale provided in the reimbursement conditions and is that there is limited direct comparative evidence versus other the pivotal studies for faricimab (YOSEMITE and RHINE) were omparator (aflibercept) and demonstrated non-inferiority with st-corrected visual acuity (BCVA) averaged over weeks 92, 96 a	No ata. Yes No Yes No associat treatme conduct respect and 100 e betwe	

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 Dosing	6, ≥60% of Faricimab-treated Patients in th	e PTI Arms achieved Q16W
	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%

<sup>a</sup> 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.

<sup>a</sup> CADTH may contact this person if comments require clarification.

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