

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

abemaciclib (Verzenio)

Eli Lilly Canada Inc.

Indication: In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of disease recurrence based on clinicopathological features.

September 19, 2024

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CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

Stakeholder information						
CADTH project number	PC0345-000					
Brand name (generic)	(Verzenio) abemaciclib					
Indication(s)	In combination with endocrine therapy for the adjuvant treatm	ent of				
	adult patients with hormone receptor (HR)-positive, human ep	oiderma	al			
	growth factor receptor 2 (HER2)-negative, node-positive, early	y brea	st			
	cancer at high risk of disease recurrence based on clinicopath	nologic	al			
	features.					
Organization	Canadian Breast Cancer Network					
Contact information ^a	Name: JK Harris					
Stakeholder agreement with the draft recommendation						
1. Deep the stellaholder of		Yes	\boxtimes			
1. Does the stakeholder ag	gree with the committee's recommendation.	N.L.				

CBCN agrees with the recommendation to reimburse abemaciclib with conditions because of the unmet need for more treatments in this setting, as discussed in our patient submission. We also recognize the importance of evidence-based recommendations, and therefore reiterate that needing a Ki-67 score of greater than or equal to 20% to access abemaciclib has been highlighted as a barrier to accessing treatment funding in the past. As noted in our submission, a patient interviewed for our patient submission states:

"Verzenio is \$7000 per month; too expensive. I cannot afford to pay that and my insurance doesn't cover the medication because it's not approved in Canada. But I don't understand why it can be approved in United States or UK and not approved here. That's what's very sad."

"This is strange. Why some women in US, not some women, all of them, like stage I to IV, are using this medication, and here in Canada it's approved just for stage IV. For me, because I'm stage III and so many lymph nodes involved, my oncologist said that medication would be

No

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beneficial. For all the criteria for the drug plan and whatever the rules are, the tumour is big, the lymph nodes, there are lots of them, stage III. The only thing I didn't meet was the Ki 67. At the moment for Verzenio, you have to have a Ki67 higher than 20%, and mine is 18%. The US drug plan, this Ki67 criteria, they took it out. So I'm hoping Canada will do that sooner than later. Because all the trials, this medication is working and it's helping. It's helping us. I don't want to get to stage IV and then be offered this medication. Why not be proactive and do the treatment before?"

Further, Quebec has notified stakeholders of the intention to remove the criteria for Ki-67 score from eligibility criteria for abemaciclib. While this <u>recommendation is still under consideration</u>, should the recommendation be finalized, there would be a divergence between eligibility in Quebec, and that of the rest of the country. This raises concerns about equitable access nationally.

While we recognize that needing a Ki-67 score that is more than or equal to 20% to access abemaciclib is just one condition that needs to be met, meaning that those with a score less than 20% may still be able to access it if they fit other conditions, having this requirement still risks unequal access across Canada (Quebec versus the rest of Canada) and as compared to other jurisdictions around the world.

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	
We note that the recommendation demonstrates that individuals with a Ki-67 score of less t	han 20	0⁄

We note that the recommendation demonstrates that individuals with a Ki-67 score of less than 20% may be able to access abemaciclib, but not in all circumstances. In line with what INESSS is considering, we welcome a CDA recommendation that takes into account the need for patients to

access this treatment without restrictive criteria related to Ki-67 scores. CBCN advocates for	or equit	able			
treatment access nationally, and seeks a final recommendation that reflects this call for equi	table				
access nationally.					
Clarity of the draft recommendation					
2 Are the reasons for the recommendation clearly stated?	Yes	\boxtimes			
3. Are the reasons for the recommendation clearly stated?	No				
If not, please provide details regarding the information that requires clarification.					
4. Have the implementation issues been clearly articulated and adequately	Yes				
addressed in the recommendation?	No	\boxtimes			
We note that given the benefit to patients, we welcomed a final recommendation that more firmly recommends access to Ki-67 testing across all jurisdictions.					
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.					

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	JK Harris					
Position	Health Policy and Advocacy Le	ad				
Date	September 16, 2024					
	I hereby certify that I have the a matter involving this patient gro patient group in a real, potentia	oup with a comp	any, organizatio	on, or entity that m		
B. Assista	nce with Providing Feedback					
					No	
1. Did yo	u receive help from outside you	ir patient grou	p to complete y	our feedback?	Yes	\boxtimes
2. Did yo	u receive help from outside you	ır patient grou	p to collect or a	analyze any	No	\boxtimes
inform	u receive help from outside you ation used in your feedback? se detail the help and who provide		p to collect or a	analyze any	No Yes	
inform If yes, plea C. Previou	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interes	ed it.			Yes	
inform If yes, plea C. Previou 1. Were o submi	ation used in your feedback? se detail the help and who provide	ed it. st provided in pa review and ha	tient group inp	ut that was	Yes	
inform If yes, plea C. Previou 1. Were o submi uncha	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations tted at the outset of the CADTH	ed it. st provided in pa review and ha ection D below	tient group inp	ut that was	Yes	
inform If yes, plea C. Previou 1. Were o submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations tted at the outset of the CADTH nged? If no, please complete se	ed it. st provided in pa review and ha ection D below claration	tient group inp ve those decla ided your grou	out that was rations remained p with financial p	d No Yes	
inform If yes, plea C. Previou 1. Were o submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations t	ed it. st provided in pa review and ha ection D below claration	tient group inp ve those decla ided your grou t interest in the	out that was rations remained p with financial p	d No Yes d Yes	
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inform f yes, plea C. Previou 1. Were of submi uncha D. New or 3. List ar past tw Company	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations to vo years AND who may have dir	ed it. st provided in pa review and ha ection D below claration that have provi- rect or indirect	itient group inp ive those decla ided your grou t interest in the <u>Check Appro</u> \$5,001 to	out that was rations remained p with financial p drug under revi priate Dollar Ra \$10,001 to	d No Yes d Yes yes nge In Exces \$50,000	□ □ ⊠
inform If yes, plea C. Previou 1. Were o submi uncha D. New or 3. List ar	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations to vo years AND who may have dim	ed it. st provided in pa review and ha ection D below claration that have provi rect or indirect \$0 to 5,000	tient group inp ve those decla ided your group t interest in the <u>Check Appro</u> \$5,001 to 10,000	put that was rations remained p with financial p drug under revi priate Dollar Rat \$10,001 to 50,000	d No Yes d Yes payment of ew. In Exces \$50,000	over the

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.

	Check Appropriate Dollar Range				
Company	\$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					

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.

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.

	Check Appropriate Dollar Range				
Company	\$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 Up	dated Declaration for Clinician	<u>ع</u>			
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
\boxtimes	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.				
	Interest Declaration			· · ·	
List any cor	Interest Declaration mpanies or organizations that have who may have direct or indirect i				er the past two
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List any cor	mpanies or organizations that have		ug under review		
List any cor years AND Company	npanies or organizations that hav who may have direct or indirect i	nterest in the dr	Ug under review Check Approp \$5,001 to	priate Dollar Rang	ge In Excess of
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CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information			
CADTH project number	PC0345-000		
Brand name (generic)	Verzenio (abemaciclib)		
Indication(s)	HR-positive, HER2-negative early breast cancer		
Organization	Rethink Breast Cancer		
Contact information ^a	Name: Jenn Gordon		
Stakeholder agreement wi	th the draft recommendation		
1. Does the stakeholder ag	ree with the committee's recommendation.	Yes No	
	e recommendations made by the committee acknowledge that ases access for patients with a high risk of recurrence.	removi	ng
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 No	
If not, please provide details	regarding the information that requires clarification.		1
4. Have the implementation	n issues been clearly articulated and adequately	Yes	\boxtimes
addressed in the recom	mendation?	No	
If not, please provide details	regarding the information that requires clarification.		
5. If applicable, are the rei	nbursement conditions clearly stated and the rationale	Yes	\boxtimes
for the conditions provi	ded in the recommendation?	No	
If not, please provide details	regarding the information that requires clarification.	1.10	

Appendix 1. Conflict of Interest Declarations for Patient Groups

A. Patient Group Information							
Name	Jenn Gordon						
Position	Lead Strategic Operations & Er	ngagement					
Date	09-09-2024						
	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. Assistan	ce with Providing Feedback						
	reacive help from outside you	r notiont grou	n to complete v	our foodbook?	No	\boxtimes	
1. Did you	receive help from outside you	r patient grou	p to complete y		Yes		
	e detail the help and who provide						
	receive help from outside you	r patient grou	p to collect or a	nalyze any	No	\boxtimes	
	tion used in your feedback? e detail the help and who provide				Yes		
C. Previous	ly Disclosed Conflict of Interes	it					
	onflict of interest declarations p				No		
	ed at the outset of the CADTH ged? If no, please complete se			ations remained	Yes	\boxtimes	
D. New or U	pdated Conflict of Interest Dec	laration					
	r companies or organizations t o years AND who may have dir					over the	
				priate Dollar Rai			
Company	Sompany\$0 to 5,000\$5,001 to\$10,001 toIn Excess of10,00050,000\$50,000						
Add compar	ny name				[
Add compar	ny name				[]	
Add or remo	ve rows as required				[

Stakeholder information			
CADTH project number	PC0345		
Brand name (generic)	abmaciclib		
Indication(s)	In combination with endocrine therapy for the adjuvant treatm	nent of	
	adult patients with hormone receptor (HR)-positive, human ep	biderma	al
	growth factor receptor 2 (HER2)-negative, node-positive, ear	ly breas	st
	cancer at high risk of disease recurrence based on clinicopat	hologic	al
	features		
Organization	OH (CCO) Breast Cancer Drug Advisory Committee		
Contact information ^a	Name: Dr. Andrea Eisen		
Stakeholder agreement w	ith the draft recommendation	-	
1 Does the stakeholder ar	gree with the committee's recommendation.	Yes	\boxtimes
		No	
	scholder agrees or disagrees with the draft recommendation. W	/henev	er
possible, please identity the	e specific text from the recommendation and rationale.		
Repeat radiologic staging a	fter surgery is not routine.		
•	eration of the stakeholder input	_	
	ion demonstrate that the committee has considered the	Yes	\boxtimes
	our organization provided to CADTH?	No	
If not, what aspects are mis	sing from the draft recommendation?		
Clarity of the draft recomm	nendation		
2 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes
5. Are the reasons for the	recommendation clearly stated?	No	
If not, please provide details	s regarding the information that requires clarification.		
		Vee	
4. Have the implementatio addressed in the recom	n issues been clearly articulated and adequately	Yes	
	s regarding the information that requires clarification.	No	
n not, please provide details			
In part a) of "Considerations	s for initiation of therapy", it should be reiterated, that for patient	ts with	1-3
positive nodes, not high gra	de, and not greater than 5 cm, still requires Ki-67 testing.		
F If an unline all a superficients and			\boxtimes
	mbursement conditions clearly stated and the rationale	Yes	
for the conditions provi	mbursement conditions clearly stated and the rationale ded in the recommendation? s regarding the information that requires clarification.	Yes No	

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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> 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	\boxtimes
If yes, please detail the help and who provided it.		
OH (CCO) provided a secretariat function to the group.		
2 Did you receive help from outside your elipicien group to collect or evolute only	Nia	
3. Did you receive help from outside your clinician group to collect or analyze any	No	\boxtimes
information used in this submission?	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	No	
submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	Yes	\boxtimes
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Andrea Eisen		

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.

	Check Appropriate Dollar Range				
Company	\$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					

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.

	Check Appropriate Dollar Range					
Company	\$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 up	dated 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)				
\boxtimes	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.				
List any cor	Interest Declaration mpanies or organizations that hav who may have direct or indirect i		rug under review		
List any cor years AND	mpanies or organizations that have		rug under review	priate Dollar Rang	
List any cor	mpanies or organizations that have		rug under review		
List any cor years AND Company	mpanies or organizations that hav who may have direct or indirect i	nterest in the dr	rug under review Check Approp \$5,001 to	oriate Dollar Rang \$10,001 to	ge In Excess o
List any cor years AND	mpanies or organizations that hav who may have direct or indirect i nny name	nterest in the dr \$0 to 5,000	rug under review Check Approp \$5,001 to 10,000	oriate Dollar Rang \$10,001 to	ge In Excess o

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0345
Name of the drug and Indication(s)	Abemaciclib in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of disease recurrence based on clinicopathological features
Organization Providing Feedback	PAG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.

Request for	Major revisions: A change in recommendation category or patient population is requested	
Reconsideration	Minor revisions: A change in reimbursement conditions is requested	
No Request for	Editorial revisions: Clarifications in recommendation text are requested	х
Reconsideration	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.

In table 1, under 1. Initiation, PAG suggested adding the following statement under: "For greater clarity, those with 1 to 3 positive ALN with grade 3 disease or with a primary tumor size equal to or greater than 5 cm DO NOT require ki-67 testing".

In table 1 (2.1), PAG wanted to add exclusion criteria from abemaciclib's past review if they still apply: e.g., inflammatory breast cancer, prior treatment with a CDK4/6 inhibitor.

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.

In table 2 under Relevant Comparators, PAG suggested updating the following sentence to mirror the description from the trial: "However, for patients with 1-3 positive ALN, *histologic grade 1 or 2 disease, and tumour size < 5cm*, Ki-67 >=20% (as described in Cohort 2 in the MonarchE trial and representing 10% of the included participants) is required to access abemaciclib, therefore ongoing access to Ki-67 testing is still required in this subgroup of patients".

In table 2 under Relevant Comparators, PAG asked to omit "or try to sequence the drugs" in the sentence: "The clinical experts stated that most clinicians use abemaciclib, but some use olaparib or try to sequence the drugs." PAG also suggested adding a statement regarding the lack of evidence supporting drug sequencing of abemaciclib and olaparib if this was noted by pERC.

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.

Al	gorithm and implementation questions				
1.	Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)				
1. 2.	The algorithm needs to be updated (rapid algorithm).				
(2. Please specify other implementation questions or issues that should be addressed by CADTH				
1. 2.					
Su	upport strategy				
	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.



Stakeholder information			
CADTH project number	PC0345-000		
Brand name (generic)	VERZENIO [®] (abemaciclib)		
Indication(s)	In combination with endocrine therapy for the adjuvant treatme adult patients with hormone receptor (HR)-positive, human en- growth factor receptor 2 (HER2)-negative, node-positive, earl cancer at high risk of disease recurrence based on clinicopat	oiderma y breas	st
Organization	features. Eli Lilly Canada Inc.		
Contact information ^a			
	th the draft recommendation		
1. Does the stakeholder ag	ree with the committee's recommendation.	Yes No	
possible, please identify the Eli Lilly is aligned with CDA- treatment of adult patients w receptor 2 -negative(HER2-)	eholder agrees or disagrees with the draft recommendation. We specific text from the recommendation and rationale. AMC's reimbursement recommendation for Verzenio [®] for the a with hormone receptor -positive (HR+), human epidermal growt), node-positive, early breast cancer at high risk of disease rec I features, which is consistent with the Health Canada's approv	adjuvar h facto urrence	nt r
	eration of the stakeholder input		
stakeholder input that y	on demonstrate that the committee has considered the our organization provided to CADTH? sing from the draft recommendation?	Yes No	
Clarity of the draft recomm	nendation		
	recommendation clearly stated?	Yes No	
If not, please provide details	regarding the information that requires clarification.		
4. Have the implementation addressed in the recom	n issues been clearly articulated and adequately mendation?	Yes No	
If not, please provide details	regarding the information that requires clarification.		
	mbursement conditions clearly stated and the rationale ded in the recommendation?	Yes No	
•	regarding the information that requires clarification.		