CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

abemaciclib (Verzenio)

(Eli Lilly Canada Inc.)

Indication: Adjuvant treatment of HR-positive, HER2-negative early breast cancer

September 16, 2022

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0282-000
Brand name (generic)	Abemaciclib
Indication(s)	Adjuvant treatment of HR-positive, HER2-negative early breast cancer
Organization	Ontario Health (CCO) Breast Cancer Drug Advisory Committee
Contact information[a]	Name: Dr. Andrea Eisen

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

Table 1 [Inclusion Criteria: High Ki 67 HC NOC]: The HC indication does not align with the MONARCH clinical trial. The group disagrees with the exclusion of a significant proportion of the study population that benefited from abemaciclib in the MONARCH trial. In the trial, 30% of patients had Ki 67 <20%. It is novel to the DAC to see a drug review indication based on a specific subgroup of the pivotal clinical trial rather than the full inclusion population included in the trial. The subgroups that are out of scope for this review would benefit greatly from the use of abemaciclib. The trial used Ki 67 as an additional criterion to treat patients, rather than the sole criteria to treat. Other regulatory agencies have not included Ki 67<20% in their indication for the use of abemaciclib. In Ontario, there are barriers to access Ki 67 testing. The addition of Ki 67 testing for this indication will require more demands on pathology services, which represents an additional cost to the centers when it is not necessary for clinical benefit in all potentially eligible patients.

There will be inequitable access for Canadian patients due to the inclusion of a high Ki 67.

Table 1 [Time-period]: There should be a grandfathered in time-period for patients who have already received surgery. Some patients would be a candidate for abemaciclib that would be more than 16 months post-surgery.

Implementation table 2: The DAC suggests to grandfather in any patient on ET with no signs or symptoms of metastatic disease. The DAC suggests at least a 1 year time frame that are outside of the 16 months.

Table 1 [Discontinuation]: This protocol does not reflect standard clinical practice; it is more intensive. This will require increased resources for the follow up of adjuvant breast cancer patients. In Ontario, which also includes multi-disciplinary care teams including pharmacists, and nurses also contribute to the follow up care of these patients. The standard for assessment of disease recurrence is guided by clinical signs and symptoms, and not routine imaging.

Table 1 [Follow-up]: The DAC suggests patients should be followed closely for the 6 months. ET should be continued beyond the 2 year mark listed (ABE treatment period). The DAC noted that in the trial, clinical assessment and lab tests were routine (done by any medically qualified individual) , and not imaging as stated in Table 1.
Table 1 [Prescribing 6] The DAC suggests that the wording "hospital outpatient clinics with expertise in systemic therapy" could be changed to "treatment should be given by qualified practitioners in outpatient clinics"

Table 1 [Prescribing 8] The DAC suggests that “ET should continue as monotherapy after the 2 years” instead of the current wording of “ET can continue as final therapy after the 2 years”.		
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 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		
1. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
Ontario Health provided secretariat function to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
B. Previously Disclosed Conflict of Interest		
3. 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: • Dr. Andrea Eisen • Dr. Phillip Blanchette • Dr. Orit Freedman		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0282
Name of the drug and Indication(s)	Abemaciclib for Adjuvant treatment of HR-positive, HER2-negative early BC
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 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
In Table 1 Reimbursement Conditions and Reasons, under the heading “Discontinuation” PAG is requesting the following revision to align with the text in Table 2 “*if treatment with ABE would be interrupted or delayed in the absence of disease progression, it would be reasonable to resume therapy and administer the remaining doses of ABE to complete 2 years of treatment. Determination to resume therapy should be at the discretion of the treating clinician*.”

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
In Table 2. Responses to Questions from the Drug Programs, under the section “Considerations for initiation of therapy” in the response column, PAG is requesting the following revision *“is ≥ 6 months post completion of adjuvant ABE.”*
b) Reimbursement conditions and related reasons
None.
c) Implementation guidance
None.