CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0341-000 Stakeholder Feedback on Draft Recommendation
Brand name (generic)	capivasertib
Indication(s)	HR-positive, HER2-negative locally advanced or metastatic breast cancer
Organization	REAL Canadian Breast Cancer Alliance (clinician group)
Contact information[a]	Name: Dr. Mita Manna

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.

REAL Alliance clinical recommendation is regarding a change to the eligibility of capivasertib as stated in the draft recommendation for HR-positive metastatic breast cancer having had no prior treatment with fulvestrant. *Reference in draft recommendation: Table 1. Reimbursement Conditions and Reasons; #2 Initiation / Reason "The CAPItello-291 trial excluded patients who had received prior therapy with fulvestrant…"*

Our members would recommend the CDA eligibity be changed to "no prior severe toxicity to or progression on fulvestrant" to reflect a clinical aspect of care outside of the study eligibility.

Rationale: In rare occasions where patients may have had prior fulvestrant exposure but discontinued due to reasons other than severe toxicity to or progression on fulvestrant. For example, HR- positive, HER2-negative metastatic patients could receive CDK4/6 inhibitor with fulvestrant in frontline MBC, where only the CDK4/6 inhibitor was discontinued due to toxicity. Patients should be eligible for second line therapy with fulvestrant, in which they are still sensitive, plus capivasertib.

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.

	Yes	☒

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	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. REAL Alliance recommends clarification and revision for the access of fulvestrant with capivasertib if a HR-positive, HER2-negative MBC patient has been initiated on frontline fulvestrant with a CDK4/6 inhibitor and remains sensitive / responsive to fulvestrant.		

[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	☐
If yes, please detail the help and who provided it.		
2. 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		
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. Mita Manna • Dr. Jan-Willem Henning • Dr. Sandeep Sehdev • Dr. Karen Gelmon		