CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

capivasertib (Truqap)

(AstraZeneca Canada Inc.)

Indication: For the treatment of adult females with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

August 16, 2024

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0341-000
Brand name (generic)	capivasertib
Indication(s)	Capivasertib is indicated in combination with fulvestrant for the treatment of adult females with hormone receptor-positive, human epidermal growth factor receptor 2-negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
Organization	Canadian Breast Cancer Network
Contact information[a]	Name: JK Harris

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
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	☐
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒

On page 12 of our patient submission under companion diagnostics, we state that:

> *In order for patients to enjoy equitable access to this treatment, there must be equitable access to PIK3CA/AKT/PTEN alteration testing. Currently, testing standards are varied across Canada and access issues are exacerbated when private rather than public funding and resources are relied on to fill the gaps. CBCN recognises that fully addressing this equity gap is outside the scope of both this submission, and CADTH's mandate, however a recommendation which takes into account how these implementation issues can be addressed is warranted. Having equitable access and reimbursement to companion tests in order to access capivasertib go hand in hand.*

In essence, we want to convey that guidance is needed about how to ensure access to testing is not an additional hurdle for patients to jump on their path to accessing this treatment. In table 1, numbers 7 and 8 appear to respond to this concern by concluding with conditions that state:

> (#7) *The feasibility of adoption of capivasertib plus fulvestrant must be addressed*

And

> (#8) *The organizational feasibility of conducting testing for PIK3CA/AKT1/PTEN alterations must be addressed.*

The reasons column for each point make observations about the cost and availability of companion testing, but no firm recommendations about what CDA advises for the payment and availability of these tests.

CBCN notes that condition #7 and #8 are ambiguous because stating that "feasibility of adoption… must be addressed" does not provide concrete ways of how this is to be addressed. By comparison, other conditions provide concrete ways that they are to be addressed. For example, #6, which speaks about *a reduction in price of capivasertib* provides specific instructions for this condition in the reason column and states:

> *…A price reduction of 85% would be required for capivasertib to achieve an ICER of $50,000 per QALY gained when compared to endocrine monotherapy.*

Based on the unclear condition and reasons presented in Table 1 for #7 and #8, we cannot agree that the implementation issues have been clearly articulated and adequately addressed in the recommendation.

On page 12 of our input under companion diagnostics, CBCN further notes the equity and implementation issues which arise based on the need for companion diagnostic testing for this treatment. However, the recommendation fails to stipulate how these concerns will be addressed. In fact, the recommendation acknowledges gaps in access:

- (Page 6): While most provincial laboratories in Canada include PIK3CA, AKT1 and PTEN on their NGS panels, funded testing options that target all three alterations are currently limited or not available. Furthermore, there are no publicly funded or private genetic testing facilities in the territories. Patients also identified a need for equitable access and reimbursement to companion testing in order to ensure equitable access to this treatment. pERC noted that clinical experts indicated that implementation of NGS testing for PIK3CA/AKT1/PTEN alterations will have substantial health system impact (e.g., impact on personnel and currently available testing infrastructure). pERC discussed that testing implementation will affect the budget impact of capivasertib plus fulvestrant.
- (page 26): There is inconsistent access to testing for PIK3CA/AKT1/PTEN alterations across jurisdictions. Most patients currently access testing through clinical trials, special programs, or private payment options.

While the equity gaps that can be caused due to the genomic testing requirements to access this treatment are well articulated and identified in the recommendation, CBCN notes that identification of equity gaps falls short of providing a recommendation that directly addresses these barriers to access.

With respect to preferred treatment funding, our medical advisory board notes that while the trial did not require it, the recommendation should qualify that CDK4/6i would be the preferred combination

partner for fulvestrant if patients have not received a CDK4/6i in the adjuvant, or 1st line setting. That is, relapsing on or within 12 months of an aromatase inhibiter, or progressing on aromatase inhibiter monotherapy if given as 1L treatment for metastatic breast cancer.

Finally, we would like to note that oral therapies in Ontario may not receive the same public funding as in-hospital treatments. The implementation of how capivasertib should be funded in Ontario, or among provinces with different funding structures for take home treatments was absent from this recommendation.

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

Please see our comments in question 4.

[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	JK Harris
Position	Health Policy and Advocacy Lead
Date	August 16, 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. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☐
	Yes	☒
Yes – CBCN sought the input of our medical advisory board in preparation for our feedback.		
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	PC0341-000
Brand name (generic)	Truqap (capivasertib)
Indication(s)	HR-positive, HER2-negative locally advanced and metastatic breast cancer
Organization	Rethink Breast Cancer
Contact information[a]	Name: Jenn Gordon

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	☒
The implementation issues have been clearly articulated; however, Rethink would like to highlight the issue around the feasibility of testing. Thankfully oncology treatments are becoming more precise, which requires additional testing to ensure that only patients who will benefit from treatments are receiving them and that we are optimizing patient care and outcomes while maximizing financial resources. A critical component to facilitate precision oncology is testing. It's imperative that provincial health systems consider implementation of this testing so that it's not creating barriers to care for Canadians.		
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

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A. Patient Group Information	
Name	*Jenn Gordon*
Position	*Lead Strategic Operations and Engagement*
Date	*06-09-2024*
☒	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. 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**
AstraZeneca	☐	☐	☐	☒

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0341-000
Brand name (generic)	Truqap (capivasertib)
Indication(s)	For the treatment of adult females with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
Organization	OH (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	☐
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. The DAC is requesting clarification on the following statements: • "The clinical experts indicated that patients receiving alternate second- or later-line of therapy who are clinically stable or responding to treatment should not be switched to capivasertib plus fulvestrant, but should be eligible to receive capivasertib plus fulvestrant if they experience disease progression or intolerance, with no prior exposure to fulvestrant." • "pERC indicated that patients that did not have capivasertib + fulvestrant available to them second- or third-line, have not had prior fulvestrant, and have had only one prior chemotherapy regimen should be eligible on a time limited basis for this therapy."		

The DAC is asking that patients who are stable on fulvestrant without progression, be eligible for capivasertib and fulvestrant. Patients who have had more than two prior lines of endocrine therapy should also be eligible for capivasertib and fulvestrant.

The DAC is also advocating for universal testing of PIK3CA/AKT1/PTEN for all metastatic ER+/HER2 negative patients at the time of diagnosis of metastatic disease given the testing is already funded and these mutations seem to be stable.

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.

The Breast DAC has concerns with access to timely results.

For condition #2, the committee wants to clarify if capivasertib and fulvestrant should not be initiated for those who received >2 lines of hormone therapy in the metastatic setting.

If an oral agent becomes available in the future, there should be allowance to use it in combination with capivasertib. The use of fulvestrant can increase the number of visits for administering injections.

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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- 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		
2. 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. OH (CCO) provided a secretariat function to the group.		
3. 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		
4. 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. Orit Freedman • Dr. Ronita Lee • Dr. Olexiy Aseyev		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	Dr. Haider Samawi
Position	Member, OH (CCO) Breast Cancer Drug Advisory Committee
Date	13-08-2023

☒	**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.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000
AstraZeneca	☒	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

New or Updated Declaration for Clinician 2	
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.

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	☐	☐	☐	☐

New or Updated 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)*
☒	**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.

Company	Check Appropriate Dollar Range

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 [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.

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 recommendation 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 to 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.

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. 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.

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  - 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		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0341-000
Name of the drug and Indication(s)	Capivasertib (Trugap) for HR+ HER2- Breast Cancer
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

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.

- For recommendation condition 1.3, PAG suggested adding "adjuvant" to the statement:
  - received a least one line of hormone therapy in the metastatic setting or progressed on adjuvant hormone therapy or within 12 months of "adjuvant" hormone therapy
- For recommendation condition #2: *Capivasertib plus fulvestrant should not be initiated in patients who have received prior therapy with fulvestrant, more than 2 lines of hormone therapy, or more than 1 line of chemotherapy in the metastatic setting.*
  - PAG suggested replacing the word "received" with something else, and provide clarity if disease progression is a requirement.

○ PAG suggested to indicate the 2 lines of hormone therapy should be in the metastatic setting (if this is the intent)
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. • Under Table 2 Generalizability 3rd question, PAG suggested adding "having had only one prior chemotherapy regimen" as another condition to be considered for treatment. PAG also seeks if this guidance is on a time-limited basis. • Under Table 2 Generalizability 4th question, PAG suggested rewording the response as follow: ○ "Provided the patient only had 1 prior chemotherapy in thee metastatic setting and has not received prior fulvestrant, then pERC indicated that time-limited funding for capivasertib+fulvestrant would be reasonable even if the patient has already 'received' more than 2 prior lines of hormone therapy in the metastatic setting."

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.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. Rapid algorithm update with SK as PAG lead 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. 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.