Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Feedback on Draft Recommendation

trametinib

(non-sponsored review)

Indication: For recurrent low-grade serous ovarian cancer

Mar 6, 2025

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CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PX0372
Brand name (generic)	Trametinib
Indication(s)	For the treatment of recurrent low-grade serous ovarian cancer
Organization	Ontario Health (Cancer Care Ontario) Gynecological Cancers Drug Advisory Committee ("OH(CCO) Gyne DAC")
Contact information[a]	Name: Dr. Rachel Kupets

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.

Trametinib should be available to all comers in view of limited treatment options. Objective response rate of course greater in mutation positive cohort but the difference was not stat. significant. HR for PFS similar in both groups and crossed 1.

Measurable disease should be a requirement based on the study.

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	☒
OH-CCO provided secretariat function to the group.		
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. Orit Freedman • Dr. Tiffany Zigras • Dr. Josee-Lyne Ethier • Dr. Julie Nguyen • Dr. Julie Ann Francis		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Rachel Kupets*
Position	*Lead, Ontario Health (Cancer Care Ontario) Gynecologic Cancer Drug Advisory Committee*
Date	*21-02-2025*
☒	**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 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**			
	$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 Reimbursement Review
Drug Program Input on Implementation Issues

Section 1: General Information

1.1 Drug Product Information:	
Drug name (generic): trametinib	**Sponsor:** BC Gynecology Tumour Group
Indication: Recurrent low grade serous ovarian cancer following initial diagnosis of ovarian or peritoneal low grade serous carcinoma or serous borderline tumour.	
Reimbursement Request: Recurrent low grade serous ovarian cancer	

1.2 Lead Jurisdiction
Jurisdiction: BC

Section 2: Jurisdictional Implementation Issues

Table 1: Jurisdictional Context

2.1 RELEVANT COMPARATORS Check (type "X") whether you have identified potential or current **issues** and provide brief details	
x	**a) Issues with the choice of comparator in the submitted trial(s)** GOG 281/LOGS study compared trametinib to standard of care options (paclitaxel, pegylated liposomal doxorubicin, topotecan, letrozole or tamoxifen).

Table 2: Policy Considerations for Reimbursing the Drug

2.2 CONSIDERATIONS FOR INITIATION OF THERAPY Check any category where you have identified potential or current **issues** and provide brief details	
x	**a) Disease diagnosis, scoring or staging for eligibility** Clinical trial requires measurable disease, as defined by RECIST criteria. Should this be a requirement for initiation of therapy if trametinib is recommended for reimbursement?
2.3 CONSIDERATIONS FOR CONTINUATION OR RENEWAL OF THERAPY Check any category where you have identified potential or current **issues** and provide brief details	
x	**a) Challenges related to assessment and monitoring of therapeutic response** Clinical trial measured efficacy by contrast CT or MRI lesion assessment every 8 weeks for 15 months and then every 3 months thereafter. Access to that frequency may be a concern.
2.4 CONSIDERATIONS FOR DISCONTINUATION OF THERAPY Check any category where you have identified potential or current **issues** and provide brief details	
2.5 CONSIDERATIONS FOR PRESCRIBING OF THERAPY	

Check any category where you have identified potential or current **issues** and provide brief details

Table 3: Special Implementation Issues

2.6 GENERALIZABILITY Check any category where you have identified potential or current **issues** and provide brief details	
x	**b) Patients on active treatment with a time-limited opportunity to switch to the drug(s) under review** Example: Potential need to allow switching patients currently receiving a comparator, if the drug under review is recommended and deemed superior. Should patient receiving treatment with existing options be eligible to switch to trametinib?
2.7 FUNDING ALGORITHM (ONCOLOGY ONLY) Check any aspect that may require the development of a provisional funding algorithm by CADTH Refer to the CADTH Drug Reimbursement Review Procedures.pdf (cda-amc.ca) for the explanation of rapid versus panel provisional funding algorithm. In general, we aim to deliver a rapid provisional funding algorithm shortly after the final posting of the reimbursement recommendations. For panel provisional funding algorithm, timelines may be extended due to coordination of panel members. All timelines will be posted on the website. **May refer to the sponsor's submission for Place in Therapy to support the discussion**	
2.8 CARE PROVISION ISSUES Check any category where you have identified potential or current **issues** and provide brief details	
2.9 SYSTEM AND ECONOMIC ISSUES Check any category where you have identified potential or current **issues** and provide brief details	