CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

pembrolizumab (Keytruda mTNBC)

(Merck Canada Inc.)

Indication: Triple-negative breast cancer

December 15, 2022

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0295-000
Brand name (generic)	pembrolizumab (Keytruda)
Indication(s)	Pembrolizumab in combination with chemotherapy for the treatment of adult patients with locally recurrent unresectable or metastatic TNBC who have not received prior chemotherapy for metastatic disease and whose tumors express PDL1 (CPS 10) as determined by a validated test
Organization	Ontario Health (Cancer Care Ontario) Breast Cancer Drug Advisory Committee ("Breast DAC")
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. 1. Re: weight-based dosing. The Breast DAC wants to highlight issues related to drug wastage in Ontario. As drug wastage isn't reimbursed in Ontario, some smaller sites may face challenges with administering weight-based dosing and this can lead to inequitable patient access to immunotherapy. 2.		

If a patient starts with chemotherapy first, can pembrolizumab be added after, provided all other eligibility criteria are met and no disease progression has occurred?

Please answer this question for two scenarios:

- In the event of delays obtaining PD-L1 results or any other delay in accessing pembrolizumab, but where chemotherapy needs to be initiated before this information is available.

Re: "Delays in obtaining PD-L1 results. The Breast DAC recommends to remove the suggested "6 weeks" window of time for adding pembrolizumab after initiation of chemotherapy. Ontario is currently facing significant delays in testing turnaround time and would suggest to allow flexibility around this issue.

3.

- Time-limited situation: at the time of public funding for patients who have started chemotherapy and meet all eligibility criteria, but pembrolizumab was not yet funded when chemotherapy was initiated.

Re: Time-limited situation: The Breast DAC recommends to clarity that this is related to patients who have started **"first-line"** chemotherapy and meet all eligibility criteria.

4. The Breast DAC is concerned about the definition of TNBC being ER=0, PR=0, because there are subsets of patients with ER very low (e.g., <5) who have other clinical features consistent with high grade, triple-negative disease.

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.

1. Re: #1.5 - The Breast DAC noted that for patients who received adjuvant capecitabine and relapsed within 6 months of completion, there are limited treatment options. Please clarify that the 6-month interval include adjuvant capecitabine treatment.

[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		
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 secretariat support in completing this submission.		
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: • Clinician 1 • Clinician 2 • *Add additional (as required)*		

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.

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Stakeholder information	
CADTH project number	PC0295
Name of the drug and Indication(s)	Pembrolizumab for triple-negative breast cancer (TNBC)
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	☐
	No requested revisions	X

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
None.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
None.
b) Reimbursement conditions and related reasons
None.
c) Implementation guidance
None.

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Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0295
Brand name (generic)	KEYTRUDA® (pembrolizumab)
Indication(s)	KEYTRUDA®, in combination with chemotherapy for the treatment of adult patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), who have not received prior chemotherapy for metastatic disease and whose tumours express PD-L1 (Combined Positive Score (CPS) ≥10) as determined by a validated test.
Organization	Merck Canada Inc.
Contact information[a]	[redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
We agree with the recommendation that pembrolizumab be reimbursed in combination with chemotherapy, for the treatment of adult patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), who have not received prior chemotherapy for metastatic disease and whose tumors express programmed death-ligand 1 (PD-L1) (combined positive score [CPS] ≥10) as determined by a validated test.		
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.