CADTH

pan-Canadian Oncology Drug Review
Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation
(Patient Advocacy Group)

Avelumab (Bavencio) for Urothelial Carcinoma

Bladder Cancer Canada

March 23, 2021

CADTH

Template for Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Avelumab for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma whose disease has not progressed with first-line platinum-based induction chemotherapy
Eligible Stakeholder Role	Patient group that has provided input on the drug submission
Organization Providing Feedback	Bladder Cancer Canada

** CADTH may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by CADTH.*

3.1 Comments on the Initial Recommendation

a) Please indicate if the stakeholder agrees, agrees in part, or disagrees with the initial recommendation:

Agrees ☒ Agrees in part ☐ Disagrees

Please explain why the stakeholder agrees, agrees in part or disagrees with the initial recommendation. If the stakeholder agrees in part or disagrees with the initial recommendation, please provide specific text from the recommendation and rationale. Please also highlight the applicable pERC deliberative quadrants for each point of disagreement. The points are to be numbered in order of significance.

Bladder Cancer Canada agrees in part with the final recommendation and supports early conversion of this treatment for use in patients as soon as possible due to a significant unmet need.

1) First and foremost, pERC deliberated and stated “that avelumab aligns with patient values because it is a treatment that can be used to prevent recurrence, control disease, and maintain quality of life.” We felt this should be highlighted as the most important aspect of pERC’s decision that Bladder Cancer Canada agrees with. This is a positive phase 3 trial, and the new standard of care in the disease so needs to be approved and funded as soon as possible so the Canadian health care system is not practicing medicine below the recognized standard of care.

2) In the economic evaluation “pERC concluded it is highly unlikely that avelumab would be considered cost-effective at a willingness-to-pay threshold of $50,000 per quality-adjusted life-year (QALY) and substantial price reductions would be required.” Bladder Cancer Canada is concerned about use of the value of $50,000 for the QALY

and would like to clearly understand how this number is derived. We felt it is fair to say this number represents a shift from previous levels that were in the range of $100,000/QALY for review of oncology drugs and places less value on new therapies for cancer treatment in Canada.

b) Please provide editorial feedback on the initial recommendation to aid in clarity. Is the initial recommendation or are the components of the recommendation (e.g., clinical and economic evidence) clearly worded? Is the intent clear? Are the reasons clear?

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
4	Summary of pERC Deliberations	Paragraph 5, line 4-6	pERC is asked to explain how the value of $50,000 for QALY was determined and justify the shift down from higher QALY values in oncology in past

3.2 Comments Related to Eligible Stakeholder Provided Information

Notwithstanding the feedback provided in part a) above, please indicate if the stakeholder would support this initial recommendation proceeding to final recommendation ("early conversion"), which would occur two business days after the end of the feedback deadline date.

☒ Support conversion to final recommendation.

Recommendation does not require reconsideration by pERC.

☐ Do not support conversion to final recommendation.

Recommendation should be reconsidered by pERC.

If the eligible stakeholder does not support conversion to a final recommendation, please provide feedback on any issues not adequately addressed in the initial recommendation based on any information provided by the stakeholder during the review.

Please note that new evidence will be not considered at this part of the review process, however, it may be eligible for a resubmission.

Additionally, if the eligible stakeholder supports early conversion to a final recommendation; however, the stakeholder has included substantive comments that requires further interpretation of the evidence, the criteria for early conversion will be deemed to have not been met and the initial recommendation will be returned to pERC for further deliberation and reconsideration at the next possible pERC meeting.

Page Number	Section Title	Paragraph, Line Number	Comments related to Stakeholder Information