pan-Canadian Oncology Drug Review Submitter or Manufacturer Feedback on a pCODR Expert Review Committee Initial Recommendation

Nivolumab (Opdivo) with Ipilimumab (Yervoy) for Metastatic Melanoma

November 30, 2017

FEEDBACK ON pERC INITIAL RECOMMENDATION

Name of the Drug and Indication:	Combination of OPDIVO (nivolumab) plus YERVOY (ipilimumab) for the treatment of patients with unresectable or metastatic melanoma
Role in Review:	Manufacturer and Submitter
Organization Providing Feedback:	Bristol-Myers Squibb Canada

1. COMMENTS ON THE INITIAL RECOMMENDATION

a) Indicate if the Submitter (or the Manufacturer of the drug under review, if not the Submitter) agrees or disagrees with the initial recommendation:

___X___ agrees _____ agrees in part _____ disagree

Bristol-Myers Squibb Canada agrees with the pERC initial recommendation for reimbursement of the combination of nivolumab plus ipilimumab for the treatment of patients with unresectable or metastatic melanoma regardless of BRAF status who are treatment-naive, with good performance status and with stable brain metastases, if present.

We agree with the pERC conclusion that there is a net clinical benefit for the combination of nivolumab plus ipilimumab in the target patient population in terms of clinically meaningful improvement in progression-free survival (PFS), overall survival (OS) and no appreciable detrimental effect on quality of life (QoL), which are consistent with patient values. We also agree that the combination of nivolumab plus ipilimumab appears to be cost effective in patients with unresectable or metastatic melanoma when compared with ipilimumab or nivolumab monotherapy.

Bristol-Myers Squibb Canada is committed to collaborating with the provincial public drug plans to facilitate patient access to the combination of nivolumab plus ipilimumab for the treatment of patients with unresectable or metastatic melanoma.

b) Indicate if the Submitter (or the Manufacturer of the drug under review, if not the Submitter) would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

___X___ 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.

c) Please provide feedback on the initial recommendation.

Page number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity

2. ADDITIONAL COMMENTS ABOUT THE INITIAL RECOMMENDATION DOCUMENT

Page number	Section Title	Paragraph, Line Number	Additional Comments

About Completing This Template

pCODR invites the Submitter, or the Manufacturer of the drug under review if they were not the Submitter, to provide feedback and comments on the initial recommendation made by pERC. (See www.cadth.ca/pcodr for information regarding review status and feedback deadlines.)
As part of the pCODR review process, the pCODR Expert Review Committee makes an initial recommendation based on its review of the clinical, economic and patient evidence for a drug. (See www.cadth.ca/pcodr for a description of the pCODR process.) The initial recommendation is then posted for feedback and comments from various stakeholders. The pCODR Expert Review Committee welcomes comments and feedback that will help the members understand why the Submitter (or the Manufacturer of the drug under review, if not the Submitter), agrees or disagrees with the initial recommendation. In addition, the members of pERC would like to know if there is any lack of clarity in the document and if so, what could be done to improve the clarity of the information in the initial recommendation. Other comments are welcome as well.
All stakeholders have 10 (ten) business days within which to provide their feedback on the initial recommendation and rationale. If all invited stakeholders agree with the recommended clinical population described in the initial recommendation, it will proceed to a final pERC recommendation by 2 (two) business days after the end of the consultation (feedback) period. This is called an "early conversion" of an initial recommendation to a final recommendation.
If any one of the invited stakeholders does not support the initial recommendation proceeding to final pERC recommendation, pERC will review all feedback and comments received at the next possible pERC meeting. Based on the feedback received, pERC will consider revising the recommendation document as appropriate. It should be noted that the initial recommendation and rationale for it may or may not change following consultation with stakeholders.
The final pERC recommendation will be made available to the participating provincial and territorial ministries of health and cancer agencies for their use in guiding their funding decisions and will also be made publicly available once it has been finalized.

Instructions for Providing Feedback

a) Only the group making the pCODR Submission, or the Manufacturer of the drug under review can provide feedback on the initial recommendation.

b) Feedback or comments must be based on the evidence that was considered by pERC in making the initial recommendation. No new evidence will be considered at this part of the review process, however, it may be eligible for a Resubmission.

c) The template for providing *Submitter or Manufacturer Feedback on pERC Initial Recommendation* can be downloaded from the pCODR website. (See www.cadth.ca/pcodr for a description of the pCODR process and supporting materials and templates.)

d) At this time, the template must be completed in English. The Submitter (or the Manufacturer of the drug under review, if not the Submitter) should complete those sections of the template where they have substantive comments and should not feel obligated to complete every section, if that section does not apply. Similarly, the Submitter (or the Manufacturer of the drug under review, if not the Submitter) should not feel restricted by the space allotted on the form and can expand the tables in the template as required.

e) Feedback on the pERC Initial Recommendation should not exceed three (3) pages in length, using a minimum 11 point font on 8 ½" by 11" paper. If comments submitted exceed three pages, only the first three pages of feedback will be forwarded to the pERC.

f) Feedback should be presented clearly and succinctly in point form, whenever possible. The issue(s) should be clearly stated and specific reference must be made to the section of the recommendation document under discussion (i.e., page number, section title, and paragraph). Opinions from experts and testimonials should not be provided. Comments should be restricted to the content of the initial recommendation.

g) References to support comments may be provided separately; however, these cannot be related to new evidence. New evidence is not considered at this part of the review process, however, it may be eligible for a Resubmission. If you are unclear as to whether the information you are considering to provide is eligible for a Resubmission, please contact the pCODR Secretariat.

h) The comments must be submitted via a Microsoft Word (not PDF) document to the pCODR Secretariat by the posted deadline date.

i) If you have any questions about the feedback process, please e-mail submissions@pcodr.ca.

Note: Submitted feedback may be used in documents available to the public. The confidentiality of any submitted information cannot be protected.