pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Submitter or Manufacturer Feedback on a pCODR Expert Review Committee Initial Recommendation

December 22, 2014

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	Yervoy® (ipilimumab) for the first-line treatment of adult patients with advanced melanoma
Role in Review (Submitter and/or Manufacturer):	Submitter and Manufacturer
Organization Providing Feedback	Bristol-Myers Squibb Canada

3.1 Comments on the Initial Recommendation

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

✓	agrees	___	agrees in part	___	disagree

Please explain why the Submitter (or the Manufacturer of the drug under review, if not the Submitter) *agrees, agrees in part or disagrees with the initial recommendation.*

BMS recognizes that a thorough assessment of the clinical, economic and patient evidence supporting the value of ipilimumab in the first line setting for the treatment of advanced melanoma has been conducted by the pCODR Expert Review Committee. The net clinical benefit of treating patients upfront was well balanced with issues surrounding dosing and the lack of randomized studies at a dose of 3mg/kg. As pointed out in the clinical guidance report, sequencing of BRAF therapy with ipilimumab will continue to be debated, however BMS firmly agrees that ipilimumab should be available for all patients with appropriate clinical characteristics regardless of their mutational status to increase their chance of achieving a long term response from treatment with ipilimumab.
BMS is committed to working with provinces to improve cost-effectiveness of ipilimumab to an acceptable level.

b) Notwithstanding the feedback provided in part a) above, please 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 within 2(two) business days of the end of the consultation period.

✓	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.

The wording and intent of both the clinical and economic guidances are considered clear. BMS has no further comments or suggestions to make.

c) Please provide feedback on the initial recommendation. 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
NO COMMENTS			

3.2 Comments Related to Submitter or Manufacturer-Provided Information

Please provide feedback on any issues not adequately addressed in the initial recommendation based on any information provided by the Submitter (or the Manufacturer of the drug under review, if not the Submitter) in the submission or as additional information 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. If you are unclear as to whether the information you are providing is eligible for a Resubmission, please contact the pCODR Secretariat.

Page Number	Section Title	Paragraph, Line Number	Comments related to Submitter or Manufacturer-Provided Information
NO COMMENTS			

3.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
NO COMMENTS			