

**pan-Canadian Oncology Drug Review
Patient Group Feedback on a pCODR Expert
Review Committee Initial Recommendation**

**Nivolumab (Opdivo) with Ipilimumab (Yevroy) for
Metastatic Melanoma**

Melanoma Network of Canada

November 30, 2017

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Nivolumab (Opdivo) in combination with Ipilimumab for Metastatic Melanoma

Name of registered patient group: Melanoma Network of Canada

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

1.1 Comments on the Initial Recommendation

a) Please indicate if the patient group agrees or disagrees with the initial recommendation:

X agrees _____ agrees in part _____ disagree

Please explain why the patient group agrees, agrees in part or disagrees with the initial recommendation.
 We agree that there is sufficient evidence to demonstrate the net clinical benefit of the combination therapy for metastatic melanoma patients in first line. It is a much improved and important treatment option for patients that have few other options.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient group 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.

<p><input checked="" type="checkbox"/> Support conversion to final recommendation. Recommendation does not require reconsideration by pERC.</p>	<p><input type="checkbox"/> Do not support conversion to final recommendation. Recommendation should be reconsidered by pERC.</p>
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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

1.2 Comments Related to Patient Group Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient group input provided at the outset of the review on outcomes or issues important to patients that were identified in the submitted patient input. Please note that new evidence will be not considered during 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 program.

Examples of issues to consider include: what are the impacts of the condition on patients' daily living? Are the needs of patients being met by existing therapies? Are there unmet needs? Will the agents included in this recommendation affect the lives of patients? Do they have any disadvantages? Stakeholders may also consider other factors not listed here.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient group input

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
			The combination therapy should be considered in second line as well as first line, for patients that have failed targeted therapies. Until such time as researchers can more clearly identify which therapy works for which patient most effectively, it is inhumane to restrict patients to a 'one-shot' opportunity. This is not the case in other cancers or life-threatening illness.

pCODR Patient Group Feedback on a pERC Initial Recommendation

About Completing This Template

pCODR invites those registered patient groups that provided input on the drug under review **prior** to deliberation by the pCODR Expert Review Committee (pERC), to also 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 patient groups agree or disagree 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, including registered patient groups, agree with the recommended clinical population described in the initial recommendation, it will proceed to a final pERC recommendation two (2) Business Days after the end of the feedback deadline date. 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 registered patient groups that provided input at the beginning of the review of the drug can provide feedback on the initial recommendation.
 - Please note that only one submission per patient group is permitted. This applies to those groups with both national and provincial / territorial offices; only one submission for the entire patient group will be accepted. If more than one submission is made, only the first submission will be considered.
 - Individual patients should contact a patient group that is representative of their condition to have their input added to that of the group. If there is no patient group for the particular tumour, patients should contact pCODR for direction at pcodrinfo@cadth.ca.

- 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 during this part of the review process; however, it may be eligible for a Resubmission.
- c) The template for providing *pCODR Patient Group Feedback on a 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. Patient groups 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 to their group. Similarly, groups 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 initial pERC recommendations **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 new references. New evidence is not considered during 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 by logging into www.cadth.ca/pcodr and selecting "Submit Feedback" by the posted deadline date.
- i) Patient group feedback must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.
- j) If you have any questions about the feedback process, please e-mail pcodrinform@cadth.ca. For more information regarding patient input into the pCODR drug review process, see the *pCODR Patient Engagement Guide*. Should you have any questions about completing this form, please email pcodrinform@cadth.ca

Note: Submitted feedback is publicly posted and also may be used in other documents available to the public. The confidentiality of any submitted information at this stage of the review cannot be guaranteed.