pan-Canadian Oncology Drug Review

Patient Advocacy Group Feedback on a Drug Review

Panitumumab (Vectibix) for Left Sided metastatic Colorectal Carcinoma

Colorectal Cancer Canada

March 29, 2018

Feedback on pERC Initial Recommendation

Name of the drug indication(s):	Panitumumab (Vectibix®) for Left Sided Metastatic Colorectal Cancer (mCRC)
Name of registered patient group:	Colorectal Cancer Canada (CCC)

**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:

____ agrees ____ agrees in part __X__ disagree

Please explain why the patient group agrees, agrees in part or disagrees with the initial recommendation.

- It is in the best interest of mCRC patients to be permitted to choose, together with their treating oncologist, the most appropriate therapeutic option based on their individual disease characteristics (for example consideration of primary tumour location).
- The survey results, previously submitted, clearly highlight the fact that patients value the ability to choose the most appropriate therapeutic option for the management of their disease; and the focus should be on identifying treatment options for patients that are based on their cancer's genetic makeup. These genetically targeted therapies should be administered in the first line setting, when a patient's cancer is most vulnerable.
- Patients have also repeatedly expressed how important it is they be provided with new and effective therapies for the management of their mCRC that have been proven to extend patient survival. As per the survey results, less favorable drug toxicity profiles will be endured provided improved survival benefits are experienced.
- Patients who were interviewed (in great detail) and whose drug-related experiences were captured entirely in TABLE 1 (previously submitted) were quite supportive of the therapy under review and interviewed patients made every effort to relay the benefits of the therapy including any survival benefit.
- Based on the above noted points, pERC's recommendation does not align with our patients' values.

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.

____	Support conversion to final recommendation. Recommendation does not require reconsideration by pERC.	__X__	Do not support conversion to final recommendation. Recommendation should be reconsidered by pERC.

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
4	Summary of pERC Deliberation	3; 9-10	The turnaround time for RAS testing results should not factor into the decision to negatively recommend the reimbursement of the therapy under review and every effort should be made to reduce delays in access to RAS testing, independent of this issue.
8	Need & Burden of Illness	6; 16-17	The use of the word "urgent" is relative. Based on our patients' input and from the patient's perspective, the need to reimburse an anti-egfr therapy in first line in the management of mCRC that effectively targets a patient's personal disease characteristics and their tumour's genetic makeup, is quite urgent.
10	Adoption Feasibility	6; 7-11	According to the literature, patients with RAS wild type right-sided tumours do not stand to benefit from anti-egfr therapies in the first line setting. Instead, the combination of bevacizumab plus standard chemotherapy remains the standard of care for these patients. Therefore, there would be no loss of provincially reimbursed access to panitumumab for any subset of the patient population. Please see recommendations issued: Current Oncology. 2017 Dec; 24(6): 390-400 **DOI:** https://doi.org/10.3747/co.24.3757
11	Adoption Feasibility	1;6-9	Upfront extended RAS testing in the first line setting should be standardized and performed upon presentation of metastatic disease. Yes, the number of patients requiring RAS testing would be larger in the first line setting. The benefits to patients, however, would far exceed the challenges of the increased financial burden resulting from a larger population to be tested.

1.2 Comments Related to Patient Group Input

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient group input
4	Summary of pERC Deliberation	3; 6-8	**TABLE 1**, (appearing in the patient submission) contains the patient experiences with respect to the therapy under review and is clearly labelled in the header "…..**LEFT SIDED mCRC.**" All patients had direct

			experience with the therapy under review and were confirmed to have **left sided tumours** at the start of their interview.
9	Patient-Based Values	3;3-4	Yes, patients did report that the therapy under review helped shrink their disease, but it should be duly noted as per **TABLE 1**, two patients achieved an NED status and another two patients achieved surgical candidacy at the time of their interview. Furthermore, the balance of interviewed patients achieved significant disease regression with Panitumumab.

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments

About Completing This Template

pCODR invites those registered patient advocacy 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 advocacy 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 advocacy groups, 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.

1

2 Instructions for Providing Feedback

a) Only registered patient advocacy 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 advocacy group is permitted. This applies to those groups with both national and provincial / territorial offices; only one submission for the entire patient advocacy group will be accepted. If more than one submission is made, only the first submission will be considered.
- Individual patients should contact a patient advocacy group that is representative of their condition to have their input added to that of the group. If there is no patient advocacy group for the particular tumour, patients should contact pCODR for direction at www.cadth.ca/pcodr.

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 Advocacy 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 advocacy 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 advocacy 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 pcodrinfo@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 pcodrinfo@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.