pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Patient Advocacy Group Feedback on a pCODR Expert Review Committee Initial Recommendation

Colorectal Cancer Association of Canada (CCAC)

Cetuximab (Erbitux) for metastatic Colorectal Carcinoma

January 10, 2014

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s):	Cetuximab + FOLFIRI in 1st Line Treatment of mCRC
Name of registered patient advocacy	Colorectal Cancer Association of Canada (CCAC)

**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 advocacy group agrees or disagrees with the initial recommendation:

____ agrees ____ agrees in part __**X**__ disagree

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

- It is in the best interest of patients to be permitted to choose the most appropriate therapeutic option based on their individual disease characteristics. Patients value the ability to choose, together with their treating oncologist, the most appropriate therapeutic option for the management of their disease.
- The mCRC population, who is intolerant to, or has a contraindication to Bevacizumab, would be better served if permitted access to Cetuximab + FOLFIRI in the first line treatment of mCRC.
- In some jurisdictions, the issue of access to Bevacizumab in second line therapy due to funding restrictions would be resolved if Cetuximab + FOLFIRI were approved in the first line treatment of mCRC.
- Special consideration should be given to RAS WT potentially resectable and conversion patients.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient advocacy group 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.	__**X**__ Do not support conversion to final recommendation.
Recommendation does not require reconsideration by pERC.	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
2	Summary of pERC Deliberations	2, 5-7	Although the CRYSTAL study was not designed to evaluate conversion to resectability, it nevertheless demonstrated an improvement in resection rates in the Cetuximab + FOLFIRI group and should, therefore, be given greater consideration when evaluating the therapy's clinical benefit.
2	Summary of pERC Deliberations	3, 6-7	Regarding the patients who have intolerance or a contraindication to Bevacizumab: How will their unmet need be addressed? Perhaps a resolution may be offered for this relatively small subset of the mCRC population pending further clinical trial results.
3	Summary of pERC Deliberations	1, 1-4	When comparing the cost-effectiveness of Cetuximab + FOLFIRI to Bevacizumab + FOLFIRI/FOLFOX: was the reduced size of the Cetuximab + FOLFIRI population taken into account? True eligibility would be based on RAS status, thereby reducing the total number of patients receiving the therapy.
3	Summary of pERC Deliberations	3, 7-8	Performing RAS testing prior to first line mCRC therapy may increase the burden and costs of testing, but it would clearly identify the patients who would benefit from Cetuximab + FOLFIRI therapy. Total cost would, therefore, be reduced by refining cetuximab candidacy.

1.2 Comments Related to Patient Advocacy Group Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient advocacy 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 Secretariat.

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 advocacy group input
5	Need: more effective and tolerable…	6, 8-10	There is an unmet clinical need for the subset of the mCRC population who is ineligible for Bevacizumab in first line therapy. There is also an unmet need for the potentially resectable and conversion patients who would benefit from Cetuximab as a first line therapy. Funding consideration of the therapy is required to align with patient values.

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
4	Key Efficacy Results…..	5, 5-7	As stipulated, the PFS in KRAS WT patients observed in the FIRE-3 study was not statistically significant for the Cetuximab arm when compared to the Bevacizumab arm. However, OS was prolonged in the Cetuximab + FOLFIRI arm of RAS wild type patients demonstrating a clinical benefit.
4	Key Efficacy Results….	6, 11-13	FOLFIRI alone does not reflect the current first-line standard of care in Canada, **but** anecdotal evidence provided suggests that it is being considered and administered in first line therapy to the subset of the mCRC population who are ineligible for Bevacizumab therapy. This once again highlights an unmet need for this patient population that could be addressed through the funding of Cetuximab + FOLFIRI in the first line treatment of mCRC.

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.pcodr.ca 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.pcodr.ca 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.

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 info@pcodr.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 Advocacy Group Feedback on a pERC Initial Recommendation* can be downloaded from the pCODR website. (See www.pcodr.ca 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.pcodr.ca 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 info@pocr.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 info@pcodr.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.