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

Bevacizumab (Avastin) Capecitabine (AVEX) for mCRC

Colorectal Cancer Association of Canada

July 21, 2015
Feedback on pERC Initial Recommendation

Name of the drug indication(s): Bevacizumab + Capecitabine in 1st line for mCRC
Name of registered patient advocacy Colorectal Cancer Association 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 advocacy group agrees or disagrees with the initial recommendation:
   ____ agrees  X agrees in part  ____ disagree

   Please explain why the patient advocacy group agrees, agrees in part or disagrees with the initial recommendation.
   We support the positive funding recommendation for Bevacizumab + Capecitabine in the first line treatment of advanced or metastatic colorectal cancer for patients who are not suitable for oxaliplatin or irinotecan based therapy. We do not, however, agree with funding being conditional upon cost effectiveness being improved to an acceptable level. The therapy should be funded regardless.

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.
   X Support conversion to final recommendation.  ____ 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?

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<td>7</td>
<td>Economic Evaluation</td>
<td>7,6-7</td>
<td>pERC determined that BEV + CAP was not cost-effective when compared with CAP alone. Perhaps the more appropriate therapeutic comparison could have been BEV + FOLFOX or BEV + FOLFIRI (not CAP alone) for these are therapies which are readily administered in the first line treatment of metastatic colorectal cancer.</td>
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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.

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1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

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About Completing This Template

- This Patient Advocacy Group Input on a Drug Review template should be used by patient advocacy groups to submit input at the beginning of a drug review. The input template starts after these instructions. Please note that there is a different template for providing feedback on an initial recommendation.

- Patient advocacy groups must also complete the pCODR Patient Advocacy Group Conflict of Interest Declarations template when providing input at the beginning of a drug review, located in Appendix A of this document and available on the pCODR website (www.cadth.ca/pcodr).

- Patient advocacy groups must be registered with pCODR to provide input on a drug review. To register with pCODR please go to “Submit and Contribute” on the pCODR website, complete the online registration request form and submit the completed form to pCODR (See the pCODR Patient Engagement Guide for information on eligibility and registration.)

- Please note that only one submission per patient advocacy group is permitted. This applies to those groups with 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.

- Please ensure that the input is in English, and that it is succinct and clear. Please use a minimum 11-point font and do not exceed eight (8) typed, 8 ½” by 11” pages. If a submission exceeds eight pages, only the first eight pages will be considered. Patient advocacy group input must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.

- Patient advocacy groups should complete those sections of this input 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 / contract the tables in the template as required. The page limit of eight (8) typed pages remains.

- You may delete the instructions, questions and examples under each heading on the Patient Advocacy Group Input on a Drug Review template for more space. Appendix A is NOT included in the eight (8) typed page limit for the Patient Advocacy Group Input on a Drug Review template.

- In sections 2 and 3 of the Patient Advocacy Group Input on a Drug Review template, guidance or examples are provided to help identify the type of information that pCODR will find most helpful to understand the needs and preferences of the majority of patients. Objective, experiential information that is representative of the majority of the patient advocacy group is preferred.
• Patient advocacy groups are encouraged to address the questions posed in the input template as succinctly as possible and to communicate key messages.

• Scientific, published references are not required, as pCODR has access to current scientific literature through the manufacturer’s submission and a rigorous, independent literature search. Published studies are reviewed by the clinical guidance panel and summarized in the Clinical Guidance Report.

• The patient advocacy group input must be submitted by the deadline date for this drug, posted on the pCODR website under “Find a Review” so that it can be available in time to be fully used in the pCODR review process.

• In addition to its use in the pCODR process, the information provided in your submission may be shared with the provincial and territorial ministries of health and provincial cancer agencies that participate in pCODR, to use in their decision-making. Any patient-specific personal information will be removed.

• Information about pCODR may be found at www.cadth.ca/pcodr. 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.