PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Provincial Advisory Group (PAG) Feedback on a pCODR Expert Review Committee Initial Recommendation

Bevacizumab (Avastin) for Platinum-Resistant Ovarian Cancer

May 5, 2016

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Bevacizumab (Avastin) for Ovarian Cancer

Endorsed by: Provincial Advisory Group Chair

Feedback was provided by all nine provinces (Ministries of Health and/or provincial cancer agencies) participating in pCODR.

3.1 Comments on the Initial Recommendation

a) Please indicate if the PAG (either as individual PAG members and/or as a group) agrees or disagrees with the initial recommendation:

__X___ Agrees ____ Agrees in part ____ Disagree

All PAG members providing feedback agree with the recommendation.

b) Notwithstanding the feedback provided in part a) above, please indicate if the PAG 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. Recommendation does not require reconsideration by pERC.

_____ Do not support conversion to final recommendation. Recommendation should be reconsidered by pERC.

All PAG members support conversion of the initial recommendation to final.

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	pERC Recommendation	Paragraph 1, Lines 6 & 7	PAG suggests that the phrase "a dose equivalent to 5 mg/kg every 1 week" may be misinterpreted and be specified as in the trial (15mg/kg every 3 weeks with topotecan or 10mg/kg every 2 weeks with pegylated liposomal doxorubicin or with paclitaxel)

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
1	pERC Recommendation	Paragraph 1, Line 7-8	PAG suggests that the statement "*Treatment with bevacizumab should continue until disease progression or unacceptable toxicity*" be modified to "*Treatment with bevacizumab and chemotherapy should continue until disease progression or unacceptable toxicity*". PAG noted that the AURELIA trial did not allow for patients to drop one agent and continue with monotherapy with the other.
1	pERC Recommendation	Paragraph 1, Line 10	PAG is seeking clarification or definition of the phrase "*whose disease is not primary platimum refractory*", either in the recommendation or in the body of the document.
2		Paragraph 3, last sentence	Re: No prior use of antiangiogenic therapy - pERC was unable to make a recommendation for or against funding bevacizumab in this population. PAG noted that this appears inconsistent with prior recommendations and puts the onus on the funder which may impact the funder's ability to negotiate. Suggest removing this statement and stating that in the absence of evidence, pERC could not make a recommendation on the use of bevacizumab in patients who had received prior anti-angiogenic therapy.
2		Paragraph 5, second sentence	Re: Definition of prior anticancer regimen. PAG recognizes that the trial definition was not clear. However, the recommendation that "jurisdictions should consult with provincial tumour groups to determine an appropriate definition for prior anticancer regimen" may lead to inconsistencies with this definition and inconsistencies in implementation. Could pCODR clarify this with the trial investigator?

3.2 Comments related to PAG input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on the PAG input provided at the outset of the review on potential impacts and feasibility issues of adopting the drug within the health system.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial PAG input
Page 31	Section 5.3 of Clinical Guidance Report - Summary of PAG Input	Paragraph 2, Lines 2 & 3	Bevacizumab dose should be mg/kg

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
8	Drug Costs	Paragraph 4, Line 2	Pegylated liposomal doxorubicin (Caelyx) is available in 20mg vial. The dose of pegylated doxorubicin used in the AURELIA trial was 40 mg/m^2 but on page 8 it states 60mg/m^2.
9		3rd last paragraph	Suggest that this be added as part of the next steps for stakeholders since it may be an important follow-up and consideration during negotiations. - "pERC considered the feasibility of implementing a funding recommendation for bevacizumab plus chemotherapy. pERC noted the PAG's concern about the unknown, but potentially long duration of therapy with bevacizumab compared with chemotherapy alone and concluded that a substantial reduction in drug price would be required to improve cost effectiveness to an acceptable level."
			PAG is seeking clarity on whether the recommendation applies to the subgroup of patients with mucinous type.

About Completing This Template

pCODR invites the Provincial Advisory Group (PAG) to provide feedback and comments on the initial recommendation made by the pCODR Expert Review Committee. (See www.pcodr.ca for information regarding review status and feedback deadlines.)

As part of the pCODR re view 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 pERC 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 PAG, either as individual PAG members and/or as a group, agrees or disagrees with the pERC 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 pERC 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 agree with the recommended clinical population described in the initial recommendation, it will proceed to a pERC final 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 a pERC final 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 pERC final 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 members of the PAG can provide feedback on the pERC initial recommendation; delegates must work through the PAG representative to whom they report.
    a. Please note that only one submission is permitted for the PAG. Thus, the feedback should include both individual PAG members and/or group feedback.

b) Feedback or comments must be based on the evidence that was considered by pERC in making the pERC initial recommendation. No new evidence will be considered at this part of the review process, however, it may be eligible for a Resubmission.

c) The template for providing *Provincial Advisory Group (PAG) 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. PAG 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. Similarly, PAG 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 pERC Initial Recommendation 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 related to new evidence. New evidence is 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 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 to the pCODR Secretariat by the posted deadline date.

i) If you have any questions about the feedback process, please e-mail submissions@pcodr.ca.

Note: Submitted feedback may be used in documents available to the public. The confidentiality of any submitted information cannot be protected.