PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

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

Eribulin (Halaven) for Metastatic Breast Cancer

August 2, 2012

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Eribulin (Halaven) for metastatic breast cancer

Endorsed by: Provincial Advisory Group Vice-Chair

Feedback was provided by eight of the 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:

____ agrees __x__ agrees in part ____ disagree

Please explain why the PAG (either as individual PAG members and/or as a group) agrees, agrees in part or disagrees with the initial recommendation.

On balance, PAG members providing feedback agreed with the recommendation but raised questions regarding the implementation aspects associated with the requirement for disease recurrence within six months of the last chemotherapy.

PAG noted that the requirement for disease recurrence within six months of last treatment may be difficult to implement from a policy perspective. While PAG recognized that the pERC initial recommendation aligns with the patient population included in the EMBRACE study, PAG requested clarity on if there would be similar benefit or less benefit of using eribulin in patients whose disease recurs later than six months (e.g. after 8 months or 10 months) and if funding would be appropriate for these patients as well. PAG considered that additional guidance from pERC on how this would be expected to affect the clinical and cost-effectiveness of eribulin would be important.

PAG also discussed whether or not there could be challenges implementing the recommendation only for patients who had progressed on chemotherapy and if there may be some patients who would have progressed on hormone therapy in whom eribulin funding would be appropriate.

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.

____	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.

Because PAG members raised questions regarding the implementation aspects associated with the requirement for disease recurrence within six months of the last chemotherapy, PAG indicated that the 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
1	RECOMMENDATION	Paragraph 1, Line 7	PAG requested clarity on why the criterion of funding for patients "who have progressed within the last six months of chemotherapy" was included. Providing details to support this criterion elsewhere in the document would improve the clarity of the recommendation.
3	EVIDENCE IN BRIEF Patient Population	Paragraph 6, Line 1-2	The Clinical Guidance Report (see Table 1) notes that only patients "who have progressed within six months of the last chemotherapy" were included in the EMBRACE study. It would provide clarity to the initial recommendation if this detail were added to the "Patient Population" section.
6	ECONOMIC EVALUATION Drug Costs	Paragraph 2, Line 2-8	Details on the average cost per treatment cycle are only provided for the list price. It would provide clarity to include this level of detail for both the list price and submitted price
6	ECONOMIC EVALUATION Cost Effectiveness Estimates	Paragraph 4, Line 8	It is only mentioned that eribulin is not cost-effective at the submitted price. It would improve clarity to say that eribulin was not cost-effective at both the list and the confidential submitted price.

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
NA	NA	NA	PAG noted that the pERC initial recommendation addressed the majority of the issues potentially impacting on feasibility of adopting the funding recommendation as identified by PAG input at the outset of the review.

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
NA	NA	NA	No additional comments were received.

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 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 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.