pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

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

Nab-paclitaxel (Abraxane) for Metastatic Pancreatic Cancer

September 23, 2014

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Nab-paclitaxel (Abraxane) for Metastatic Pancreatic Cancer

Endorsed by: Provincial Advisory Group Chair

Feedback was provided by eight of 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 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		Specify first-line
Throughout	pERC	Last sentence	Specify "nab-paclitaxel plus gemcitabine"

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document	Recommendation Potential Next Steps Summary of pERC Deliberations Evidence in Brief Economic Evaluation & Adoption Feasibility	 Paragraph 2 & 3 Page 3, Last paragraph & line Page 4, first paragraph & line Page 4, third paragraph Page 6, Paragraph 2, last sentence Paragraph 1, first sentence on both Pages 7 & 8	throughout document for more clarity and consistency Example: "The Committee noted that nab-paclitaxel *(plus gemcitabine)* could not be considered cost-effective compared with gemcitabine monotherapy…"
2	Potential Next Steps for Stakeholders	No Evidence in Adjuvant or Second-line USe	Suggest "beyond first line setting" instead of second-line setting
1	Potential Next Steps for Stakeholders,	Time Limited Need, first sentence	Suggest additional wording "....jurisdictions may consider addressing the short-term, time limited need for *adding* nab-paclitaxel for patients who are currently receiving *gemcitabine monotherapy* first-line treatment". *This will help distinguish those patients who are receiving first-line FOLFIRINOX therapy, therefore, not interpreted as a time-limited need for second-line following FOLFIRINOX'
2-3	Summary of pERC Deliberations	Paragraph 1, Line 13	Correction to "FOLFIRINOX"
2-3	Summary of pERC Deliberations	Paragraph 2	Can the p value for OS and the specific numbers associated with improvements in PFS be identified here?

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
4, 7, 8	Summary of pERC Deliberations		Drug wastage is not minimal, as indicated, and is important especially in smaller centres where vial sharing is not possible. A significant proportion of the

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	Economic Evaluation Adoption Feasibility		3rd vial used will be wasted, and given that the treatment is weekly, I believe this is not minimal waste - e.g. BSA of 1.8m2 - dose is 225mg - waste 75 mg of the 3rd 100 mg vial of drug (33% of the dose) and this would occur weekly x 3 doses each cycle.

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
5		Paragraph 5, Line 4	Please specify the results in the secondary endpoints measured
5		Paragraph 5, Line 10	Please specify the results in the updated overall survival analysis
7	Economic Evaluation	Paragraph 4, Lines 2 & 4	Indicate administration is "weekly for 3 weeks out of 4 week cycle" instead of "qw 3/4 weeks"
7	Economic Evaluation	Paragraph 6, Lines 4	Please indicate the drugs for CIV
7	Economic Evaluation	Paragraph 4, last sentence	Suggest a stronger statement on drug wastage such as: "pERC considered that provinces will need to consider the cost impact of wastage when used in clinical practice" as drug wastage would not be minimal but rather could be significant
8	Adoption Feasibility	Paragraph 1, Line 3	Correction to "…administered based on the ~~weight~~ body surface area of the patient…" And two commas in the last sentence of paragraph
			There could be perceived unfairness around why 1.8 month survival is clinically meaningful in pancreatic cancer but not in colorectal cancer. A more detailed explanation around the nature of the disease, the proportional increase in survival (rather than just absolute values), the clinical significance of the benefit and the incremental benefits over other therapies may be helpful.

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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

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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.

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