pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

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

Sunitinib (Sutent) for pancreatic neuroendocrine tumours

May 3, 2012

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Sunitinib Malate (Sutent) for pNET

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

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.

The majority of PAG members providing feedback agreed with the initial pERC recommendation and the findings which outline that sunitinib provides an overall clinical benefit but is not cost-effective.

PAG recognized that pERC does not have a set threshold for cost-effectiveness when reviewing a drug submission. However, as pERC has indicated that each of the jurisdictions may want to consider pricing arrangements to improve the cost-effectiveness of sunitinib to an acceptable level, PAG would reiterate to pERC that cost-effectiveness and affordability are separate but related considerations for jurisdictions before they would proceed to implement a pERC 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.	____ Do not support conversion to final recommendation.
Recommendation does not require reconsideration by pERC.	Recommendation should be reconsidered by pERC.

The majority of PAG members providing feedback supported the conversion of the pERC initial recommendation to a pERC final recommendation with no further reconsideration required 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	NA	Although pERC has made a conditional recommendation, PAG noted that it was not implicitly clear in the wording. PAG agreed that the conditional aspect of the recommendation should be more apparent. This issue was raised by several jurisdictions.
1	RECOMMENDATION	1, line 7	Two jurisdictions indicated that the end of the sentence 'to the funding jurisdiction' should be deleted from the recommendation. This ties in with the comment made in section 3.1. a) where PAG noted that jurisdictions would be responsible for considering cost-effectiveness and affordability.
1	RECOMMENDATION	1, lines 5-6	One jurisdiction noted that disease progression was not specifically defined and indicated that further information or clarification regarding what would be considered disease progression in pNET would be helpful.
1	RECOMMENDATION	NA	One jurisdiction indicated that the conditional recommendation would be difficult for their jurisdiction to implement. They would prefer a recommendation which stated that PERC does not recommend sunitinib be funded on the basis of cost-effectiveness.
2	SUMMARY OF pERC DELIBERATIONS	5, line 6	One jurisdiction noted that some information has been redacted in this sentence with the explanation that it is "non-disclosable economic information". It was noted that this sentence refers to the manufacturers' assumptions around risk of death that is found in the economic evidence. PAG agreed that clarity of the wording of this sentence would be helpful to avoid any misinterpretation.
3	EVIDENCE IN BRIEF, OVERALL CLINICAL BENEFIT, KEY EFFICACY RESULTS & LIMITATIONS	Page 3, paragraph 6, line 7 & Page 4, paragraph 3, lines 2-3	One jurisdiction noted that the use of 'clinical meaningful' in the section on key efficacy results and 'difference in effectiveness between sunitinib and placebo is likely an overestimate' in the limitations section require clarification as it is not clear if the one study which closed early provided the clinical evidence required to state that the benefit is clinically meaningful.
5	ECONOMIC EVALUATION, COST-EFFECTIVENESS ESTIMATES	7, lines 4-7	One jurisdiction noted that the Economic Guidance Panel conducted an analysis that assumed a patient's risk of death before tumor progression and the risk of death after tumor progression to be different. However, the

			rationale for doing this analysis was not explained in the recommendation document, although further detail is found in the EGR summary. This may require a sentence to explain or readers could be referred to the EGR summary.

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 for sunitinib as identified by PAG in 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
5	ECONOMIC EVALUATION	6, line 4-8	One jurisdiction noted the cost of sunitinib therapy would depend upon the duration of therapy. Although the duration of sunitinib therapy cannot be estimated from the trial due to early stopping, it would be valuable to have an idea of the potential duration, perhaps from another source as this would help to better inform budget impact.
NA	NA	NA	One jurisdiction recognized that while this therapy was not found to be cost-effective, the total number of patients accessing the therapy is likely to be small.
NA	NA	NA	One jurisdiction noted an alternative agent for the treatment of pNET, streptozocin, is more toxic, has weaker evidence to support its use and requires a Special Authorization Program (SAP) approval from Health Canada.
NA	NA	NA	One jurisdiction noted the process of implementing pricing agreements may not allow patients to have immediate access to this treatment.
NA	NA	NA	One jurisdiction noted the small number of patients may be a barrier to a meaningful evidence-gathering process for real world cost-effectiveness evaluation.

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.