



**pan-Canadian Oncology Drug Review
Provincial Advisory Group (PAG) Feedback on a
pCODR Expert Review Committee Initial
Recommendation**

**Sorafenib (Nexavar) for Differentiated Thyroid
Cancer**

July 16, 2015

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Sorafenib (Nexavar) for DTC

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:

Agrees Agrees in part Disagree

Most PAG members agree in part with the recommendation given that the radioactive iodine refractory thyroid cancer is rare, there is an unmet need in this patient population and that the toxicities contributing to deterioration in quality of life is managed differently in the real-world setting versus in the clinical trials. One member disagrees with the recommendation based on comments from their provincial tumour group outlined below.

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. Do not support conversion to final recommendation.
 Recommendation does not require reconsideration by pERC. Recommendation should be reconsidered by pERC.

PAG would like pERC to reconsider the unmet need for a treatment option in patients with symptomatic disease.

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

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

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
4-5	Safety		deterioration in quality of life due to toxicities seen in clinical trials is different in practice because the toxicities are managed differently
			<p>Comments from one provincial disease site group:</p> <ol style="list-style-type: none"> 1. We concur with the pCODR assessment that there is a clear unmet need for treatment for patients with locally advanced or metastatic progressive differentiated thyroid cancer resistant to RAI. We feel that there is a clinical priority to provide treatment to this patient population in view of positive phase III trial results. 2. We acknowledge that the pCODR review addressed the lack of an overall survival benefit. However, we would also like to highlight that the cross over study design may have been a factor. There is no data to suggest that PFS is not correlated to OS in locally advanced or metastatic progressive differentiated thyroid cancer resistant to RAI. 3. There was a lot of emphasis placed on the QoL results but we would like to highlight that there is considerable clinical expertise using sorafenib in other clinical scenarios for which sorafenib is funded indications at similar doses. 4. In the absence of full funding support of sorafenib, we suggest funding for patients at the time of development of cancer related symptoms. Metastatic radioactive iodine refractory thyroid cancer is rare and almost always followed and treated with oncologists with particular expertise with this malignancy. As such, it is recognized that these patients often have prolonged, slow and asymptomatic progression of disease that doesn't warrant treatment since the possible toxicity of the treatment (and its cost) outweigh any possible benefit to the patient. However, there almost invariably comes a point when patients become symptomatic from disease progression and, for these

Page Number	Section Title	Paragraph, Line Number	Additional Comments
			<p>patients, sorafenib has the potential to offer real benefit with its proven clinical efficacy easily outweighing its possible toxicity.</p> <p>5. Lastly, sorafenib and other similar tyrosine kinase inhibitors are being used increasingly in a number of malignancy types and practitioners have become well versed in the management of toxicities and optimization of treatment.</p>

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.