

CADTH

pCODR PAN-CANADIAN
ONCOLOGY DRUG REVIEW

**pan-Canadian Oncology Drug Review
Patient Advocacy Group Feedback on a
pCODR Expert Review Committee Initial
Recommendation**

**Regorafenib (Stivarga) for Hepatocellular
Carcinoma**

April 18, 2018



Canadian Liver Foundation
Fondation canadienne du foie

Bringing liver research to life
Donner vie à la recherche sur le foie

Canadian Liver Foundation Stakeholder Feedback on pCODR Expert Review Committee Initial Recommendation for Regorafenib

Submission Date: Monday, April 9, 2018

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s): Regorafenib (Stivarga) for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

Eligible Stakeholder Role in Review (Submitter and/or Manufacturer, Patient Group, Clinical Organization Providing Feedback): Canadian Liver Foundation

*The pCODR program may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR.

3.1 Comments on the Initial Recommendation

a) Please indicate if the eligible stakeholder agrees, agrees in part, or disagrees with the Initial Recommendation:

agree agree in part disagree

The Canadian Liver Foundation agrees with pERC’s Initial Recommendation for the following reasons:

- **Clinical Benefit**
 - Improvement of 2.8 months in overall survival is meaningful in a population with a poor prognosis.
 - Treatment with regorafenib did not cause detriment to patients’ quality of life.
 - For patients who experience progression while being treated with sorafenib, there are currently no available treatments outside of clinical trials.

- **Patient-Based Values**
 - Prolonged survival, an absence of detriment to quality of life and the manageable toxicity profile reported in the RESORCE trial would be meaningful to patients with unresectable HCC.
 - 2.8 additional months of survival in the late stages of HCC may not seem significant to some people, but for those who want to have this extra time with family/friends, patients and their physicians should be able to make the choice that is best for each individual patient’s wishes.
- **Economic Evaluation**
 - Regorafenib compared to best supportive care alone, and at the submitted price, is not cost-effective.
 - The Canadian Liver Foundation urges the manufacturers of Regorafenib to work vigorously with the pan-Canadian Pharmaceutical Alliance to address issues of cost as quickly as possible.

b) Please provide editorial feedback on the Initial Recommendation to aid in clarity. 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	1 st paragraph and bullet point	pERC conditionally recommends reimbursement of regorafenib if cost-effectiveness is “ <i>improved to an acceptable level.</i> ” It is unclear what would constitute “ <i>an acceptable level</i> ” as this can be a very subjective determination. This may require a more precise definition which may then lead to a more robust and targeted negotiation during the pCPA phase.

3.2 Comments Related to Eligible Stakeholder Provided Information

Notwithstanding the feedback provided in part a) above, please indicate if the Stakeholder would support this Initial Recommendation proceeding to Final pERC Recommendation (“early conversion”), which would occur (2) Business Days after the end of the feedback deadline date.

<input checked="" type="checkbox"/> Support conversion to Final Recommendation. Recommendation does not require Reconsideration by pERC.	<input type="checkbox"/> Do not support conversion to Final Recommendation. Recommendation should be Reconsidered by pERC.
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If the eligible stakeholder does not support conversion to a Final Recommendation, please provide feedback on any issues not adequately addressed in the Initial Recommendation based on any information provided by the Stakeholder in the submission or as additional information during the review.

Please note that new evidence will not be 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 providing is eligible for a Resubmission, please contact the pCODR program.

Additionally, if the eligible stakeholder supports early conversion to a Final Recommendation; however, the stakeholder has included substantive comments that will require further interpretation of the evidence, the criteria for early conversion will be deemed to have not been met and the Initial Recommendation will be returned to pERC for further deliberation and reconsideration at the next possible pERC meeting.

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity

About Completing This Template

pCODR invites those registered patient advocacy groups that provided input on the drug under review **prior** to deliberation by the pCODR Expert Review Committee (pERC), to also provide feedback and comments on the initial recommendation made by pERC. (See www.cadth.ca/pcodr 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.cadth.ca/pcodr for a description of the pCODR process.) The 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 patient advocacy groups agree or disagree with the 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 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, including registered patient advocacy groups, agree with the recommended clinical population described in the initial recommendation, it will proceed to a final pERC 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 final pERC 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 final pERC 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 registered patient advocacy groups that provided input at the beginning of the review of the drug can provide feedback on the initial recommendation.
 - Please note that only one submission per patient advocacy group is permitted. This applies to those groups with both national and provincial / territorial offices; only one submission for the entire patient advocacy group will be accepted. If more than one submission is made, only the first submission will be considered.
 - Individual patients should contact a patient advocacy group that is representative of their condition to have their input added to that of the group. If there is no patient advocacy group for the particular tumour, patients should contact pCODR for direction at www.cadth.ca/pcodr.
- b) Feedback or comments must be based on the evidence that was considered by pERC in making the initial recommendation. No new evidence will be considered during this part of the review process; however, it may be eligible for a Resubmission.

- c) The template for providing *pCODR Patient Advocacy Group Feedback on a pERC Initial Recommendation* can be downloaded from the pCODR website. (See www.cadth.ca/pcodr for a description of the pCODR process and supporting materials and templates.)
- d) At this time, the template must be completed in English. Patient advocacy groups 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 to their group. Similarly, groups 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 initial pERC recommendations **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 new references. New evidence is not considered during 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 by logging into www.cadth.ca/pcodr and selecting "Submit Feedback" by the posted deadline date.
- i) Patient advocacy group feedback must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.
- j) If you have any questions about the feedback process, please e-mail pcodrinfo@cadth.ca. For more information regarding patient input into the pCODR drug review process, see the *pCODR Patient Engagement Guide*. Should you have any questions about completing this form, please email pcodrinfo@cadth.ca

Note: Submitted feedback is publicly posted and also may be used in other documents available to the public. The confidentiality of any submitted information at this stage of the review cannot be guaranteed.