PAN-CANADIAN ONCOLOGY DRUG REVIEW

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

Canadian Liver Foundation

July 24, 2019

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Lenvatinib (LENVIMA)

Name of registered patient advocacy: Canadian Liver Foundation

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

1.1 Comments on the Initial Recommendation

a) Please indicate if the patient advocacy group agrees or disagrees with the initial recommendation:

__X__ agrees ____ agrees in part ____ disagree

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

- **Clinical Benefit**
  - Unfortunately, 1 in 4 Canadians may be affected by liver disease and left undiagnosed and untreated, many forms of liver disease may progress to HCC. Clinicians in Canada are already facing a rise in the number of HCC patients and this is projected to continue to rise in the coming years. Clinicians want/need more treatment options to address this growing HCC challenge in Canada.
  - While "non-inferior" Overall Survival (OS) may not initially appear to be a significant clinical benefit for patients with HCC, when you couple the OS with statistical superiority (compared to sorafenib) in the key secondary end points of Progression Free Survival (PFS), Time to Progression (TTP), and the Objective Response Rate (ORR), their combined impact becomes more pertinent for clinicians who treat patients with HCC.
  - While lenvatinib and sorafenib each have side effects/toxicities which impact a patient's quality of life, the toxicities related to lenvatinib have been reported as being more clinically manageable and cause less impact on a patient's quality of life compared to sorafenib.
- **Patient-Based Values**
  - If overall survival is comparable between sorafenib and lenvatinib, HCC treatments which demonstrated less toxicity and improved quality of life would be meaningful to patients with unresectable HCC.
  - If the quality of the life of the patient is improved, so is the quality of life of the caregiver as the two are inextricably tied together during the HCC treatment phase.
- **Economic Evaluation**
  - While we respect that pERC analyzed cost-effectiveness based on the economic impact of treatment on the healthcare system, the Canadian Liver Foundation urges pERC to also consider the economic impact on patients and caregivers.

- The Canadian Liver Foundation urges the manufacturers of lenvatinib to work vigorously with the pan-Canadian Pharmaceutical Alliance (pCPA) to ensure that costs do not exceed the public drug plan cost of treatment with sorafenib as the CLF would not want the cost of lenvatinib to be the obstacle that clinicians and patients face when reviewing availability of treatment options.

- **Adoption Feasibility**
  - The CLF supports any pERC recommendation which will result in greater treatment options for patients with unresectable HCC, whether this be for first-line treatment or a switch to/from another treatment on which the patient has not progressed.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient advocacy group would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

__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.

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
9	Adoption Feasibility	1st paragraph, line 3	pERC notes "For patients who have not progressed on sorafenib but are intolerant, pERC agreed that it would be reasonable to switch to lenvatinib." As pERC's recommendation is reimbursement of lenvatinib for "first-line treatment" of unresectable HCC, we feel it is unclear whether switching from sorafenib to lenvatinib as described above would be considered "first-line treatment" and whether the cost of lenvatinib would be included in the recommendation for reimbursement in this switching scenario.

1.2 Comments Related to Patient Advocacy Group Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient advocacy group input provided at the outset of the review on outcomes or issues important to patients that were identified in the submitted patient input. Please note that new evidence will be 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 providing is eligible for a Resubmission, please contact the pCODR Secretariat.

Examples of issues to consider include: what are the impacts of the condition on patients' daily living? Are the needs of patients being met by existing therapies? Are there unmet needs? Will the agents included in this recommendation affect the lives of patients? Do they have any disadvantages? Stakeholders may also consider other factors not listed here.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient advocacy group input

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments

pCODR Patient Advocacy Group Feedback on a pERC Initial Recommendation

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.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 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 two (2) Business Days after the end of the feedback deadline date. 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 info@pcodr.ca.

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.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. 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.pcodr.ca 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 info@pocr.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 info@pcodr.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.