PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Patient Advocacy Group Feedback on a pCODR Expert Review Committee Initial Recommendation

Bendamustine (Treanda) for indolent Non-Hodgkin Lymphoma and Mantle Cell Lymphoma

November 29, 2012

Feedback on pERC Initial Recommendation

Name of the drug and indication(s):	Bendamustine for First-line treatment of non-Hodgkin's lymphoma Bendamustine for non-Hodgkin's lymphoma refractory or relapse to rituximab-containing therapy
Name of registered patient advocacy group:	Lymphoma Foundation of Canada (LFC)

1.1 Comments on the Initial Recommendation

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

____ agrees ___x_ agrees in part ____ disagree

Summary

The LFC endorses pERC's recommendation to fund bendamustine as a first-line therapy.

The LFC also endorses pERC's recommendation to fund bendamustine in relapsed or refractory iNHL and MCL in combination with rituximab. However LFC requests that pERC remove wording regarding patients who have received "prior maintenance therapy" so that provincial payers do not interpret this as a potential access restriction.

LFC also requests that pERC amend its recommendation to allow access to bendamustine as a monotherapy in later stages when use in combination is no longer recommended by the treating physician.

Bendamustine as a first-line therapy

The LFC endorses pERC's recommendation to fund bendamustine as a first-line therapy for iNHL and MCL and supports the conversion of this portion of the initial recommendation to a final recommendation.

Broader Funding in the Relapsed/Refractory Setting

The LFC believes that pERC should amend their recommendation regarding use of bendamustine in the relapsed/refractory setting so that monotherapy funding (for bendamustine) in the 2nd line, and successive lines, be available to patients. The LFC believes that there is sufficient clinical rationale to justify funding in these settings, particularly for patients who are refractory to rituximab or who have experienced treatment failure on previous therapies. The options for these patients are extremely limited, and restricting access will unnecessarily obstruct the optimal treatment of patients. Awaiting the

results of the ROBIN trial to resolve perceived uncertainties will only further delay access to a necessary therapy, for up to 4 years[1], for a patient population in later stages of disease that cannot wait.

Bendamustine in combination with rituximab for patients who have received prior rituximab maintenance.

The LFC disagrees with pERC in regards to the uncertainty of funding bendamustine in combination with rituximab for patients who have received prior rituximab maintenance.
As recognized by pERC, rituximab maintenance monotherapy for up to 2 years or until disease progression is now considered current standard Canadian practice for patients responding to rituximab-based induction chemotherapy. Recognizing that the majority of patients with relapsed or refractory disease will now have received rituximab maintenance therapy, pERC's recommendation, as it currently stands, would make this cohort of patients ineligible for B-R, cutting off these patients from an effective, and much-needed treatment option that is supported by international treatment guidelines that are based on the findings of evidence-based medicine.
LFC believes that access to bendamustine when used in combination with rituximab in relapse or refractory setting should be similar and consistent with access to other chemotherapies that are used in combination with rituximab. None of the other chemotherapies used in these treatment settings (such as fludarabine) have a prior maintenance restriction when used in combination with rituximab in the relapsed or refractory setting.

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 within 2(two) business days of the end of the consultation period.

____ Support conversion to final recommendation.
Recommendation does not require reconsideration by pERC.

___X_ Do not support conversion to final recommendation.
Recommendation should be reconsidered by pERC.

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] Final data from the ROBIN trial will not be available until Oct. 2014. LFC estimates that a further year will be required for data to be analyzed, presented and made available to the manufacturer with yet another year required for resubmission and consideration by pCODR and implementation by provinces/territories.

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
3	Summary of pERC Deliberations	Para 1, lines 2-7	pERC has noted that bendamustine has clinical benefit and "may be less toxic than currently available therapies" yet, concludes that "it is uncertain how bendamustine would align with the patient value of improving or maintaining quality of life" As treatment toxicity and quality of life are directly related, LFC believes that a therapy that is less toxic, and has a PFS advantage would certainly improve or maintain quality of life. LFC suggests that pERC re-evaluate their conclusion that "it is uncertain how bendamustine would align with the patient value of improving or maintaining quality of life"

1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments

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 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 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) 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.