pan-Canadian Oncology Drug Review

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

Idelalisib (Zydelig) for Chronic Lymphocytic Leukemia

The Leukemia & Lymphoma Society of Canada (LLSC) and CLL Patient Advocacy Group (CLL PAG)

August 18, 2015

3 Feedback on a pERC Initial Recommendation

Name of the drug indication(s):	**idelalisib (Zydelig)** in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL).
Name of registered patient advocacy group:	The Leukemia & Lymphoma Society of Canada and CLL Patient Advocacy Group (CLL PAG)

**pCODR 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 patient advocacy group agrees or disagrees with the initial recommendation:

X agrees ____ agrees in part ____ disagree

The Lymphoma and Leukemia Society of Canada and the CLL Patient Advocacy Group agree with pERC Initial Recommendation for Zydelig (idelalisib). We recognize the challenges preparing this PERC Initial Recommendation due to the lack of comparator drug regimes available in Canada and the lack of long-term data regarding efficacy and toxicities. Zydelig is indicated for relapsed chronic lymphocytic leukemia, and statistics regarding the number of eligible patients are confidential. It is hoped that the cost of this drug regime will not be outweighed by the need of patients who have run out of other treatment options. The lack of a standard of care for relapsed CLL patients will hopefully not result in use of this drug regime where it is not appropriate. The improvement in PFS and OS that idelalisib and rituximab provides makes it an important drug regime in the tool chest of CLL treatment.

b)

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)

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
			No Comments

3.2 Comments Related to Patient Advocacy Group Input

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient advocacy group input
3	Summary of pERC Deliberations	4th paragraph, second and third line	Page 3 states that "commonly reported symptoms of CLL include fatigue, difficulties with concentration, insomnia and mood swings. This comment was altered from the Initial Clinical Guidance report which states "***Some respondents with CLL expressed difficulties with concentration, emotions, stress levels, insomnia and mood swings".*** As noted on Page 6, Patient-Based Values, last paragraph "fatigue, increased white blood count and enlarged lymph nodes are the most commonly reported symptoms experienced by patients.

3.3 Additional Comments About the Initial Recommendation Document

Page Number	Section Title	Paragraph, Line Number	Additional Comments
3	**Summary of pERC Deliberations**	**First paragraph, first and second line**	**"Chronic lymphocytic leukemia (CLL) is a common leukemia with a long natural history".** **This comment is misleading as CLL is the most common type of ADULT leukemia but it is considered a rare disease with the incidence of 4.8 cases/100,00 persons. (page 8, Initial Clinical Guidance Report, 2.1 Context for the Clinical Guidance, 2.1.1 Introduction).** **.**

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 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.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.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.