pan-Canadian Oncology Drug Review

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

Ruxolitinib (Jakavi) for Myelofibrosis

January 14, 2013

INQUIRIES

Inquiries and correspondence about the pan-Canadian Oncology Drug Review (pCODR) should be directed to:

pan-Canadian Oncology Drug Review
1 University Avenue, suite 300
Toronto, ON
M5J 2P1

Telephone: 416-673-8381
Fax: 416-915-9224
Email: info@pcodr.ca
Website: www.pcodr.ca

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Jakavi

Name of registered patient advocacy group: Canadian MPN Network

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

Please explain why the patient advocacy group agrees, agrees in part or disagrees with the initial recommendation. *Overall, we are highly supportive of the recommendation and indeed grateful for the very thorough and thoughtful review. We also appreciated the clarity of the recommendation and the reasons provided*

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

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
1	Recommendation	P1, L4	We agree with identified patient population as stated but we stress the need for flexibility in both wording and implementation.
1	Recommendation	P1, L5-6	We are very pleased to see that treatment is extend to those who not successful on other therapies; this is an important inclusion.
2	Summary of pERC Deliberations	P1, L2-5	In response to the reasons, we are very pleased to see the acknowledgement of significant improvements to quality of

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
			life as important outcomes and recognition by committee of the value of impact on daily living
3	Summary of pERC Deliberations	P2, L2-3	We urge the funding agencies to acknowledge the comment re: burden of illness and the small impact based on incident population
5	Evidence in Brief	P3	In terms of the response to implementation of therapy, we strongly support the value of monitoring for response to treatment, with initial indication at appropriate times.

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
1	Recommendation	P1, L4	We urge you to recognize that some of us (patients) may not be rated at intermediate-2 (e.g., intermediate-1) but do have other symptoms, such as enlarged spleen, that would indicate serious disease impact and warrant treatment.
2	Summary of	P1, L2-5	We hope that the funding agencies will pay particular attention to the importance you

Page Number	Section Title	Paragraph, Line Number	Additional Comments
	pERC Deliberations		have accorded to very limited treatment options currently available and, indeed, the fact that for many patients, none of these are appropriate.
3	Summary of pERC Deliberations	P3	The issue of cost-effectiveness is not one which we as patients feel qualified to address; however, we do believe it is critically important that the funders and the suppliers are able to arrive at a reasonable decision as soon as possible, since there are patients waiting for access or waiting for confirmation that their current access will be continued under a funded program.
5	Evidence in Brief	P3	However, we stress that there needs to be patient input on the determination of criteria for continuing or stopping, at both the guidelines level and the individual level. The criteria should be transparent to all, including the physician and patent (family).
7	Adoption Feasibility	P1-2	In all cases, there is a need for flexibility in (start/stop) criteria based not only on the best and most up-to date evidence and clinical practice learning but also based on a specific individual profile (e.g., comorbidity, previous therapy, disease status, and lifestyle) as well as the opportunity for patients to review the criteria and to get additional opinions, as warranted. Here too we believe the patients and the healthcare system will be best service is there is sufficient flexibility in guidelines to allow patients to adapt (physically and psychologically) if the drug is to be discontinued. In all cases, the wishes of the patient and the need to "err on the side of the patient" should be the primary considerations. We recognize that if patients were clearly not appropriate for Jakavi based on clearly defined consensual criteria for starting and/or stopping, then it would be neither safe nor best use of healthcare resources to provide the drug. In all cases, the need for ongoing monitoring is paramount and should be the standard of care. The potential impact on cancer center or other healthcare resources should be more than offset by the improved patient care and the improved patient outcomes. These are

Page Number	Section Title	Paragraph, Line Number	Additional Comments
			effective use of healthcare resources. Finally, we urge that all jurisdictions, including the private drug plans and the suppliers, collaborate to collect patient data from patients based on real-world usage and that these data be available, anonymous, for ongoing evaluation as to effectiveness and safety. To the degree possible, collated Canadian data should be available for international data analysis and learning. In closing, we thank pERC for their review and recommendation and thank pCODR for the engagement of the patient community. We urge that the patient support community continue to be consulted and engaged with the healthcare providers and assessors to ensure that all decisions are patient-informed. That also serves the best interests of the patients and the healthcare system.

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 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) 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.