pan-Canadian Oncology Drug Review

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

Dabrafenib (Tafinlar) for Metastatic Melanoma

Melanoma Network of Canada

December 5, 2013

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Tafinlar (Dabrafenib)

Name of registered patient advocacy Melanoma Network of Canada

**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:

____ agrees X agrees in part ____ disagree

We are very pleased that Tafinlar has been recommended at a first line therapy. As you are well aware, there are just not sufficient treatment options for metastatic melanoma. While Zelboraf was approved in most provinces in Canada in 2012, it is not a first line therapy in a number of provinces and still remains unavailable for public funding in 2 provinces. In addition, this drug -Tafinlar - is not the same molecular structure as Zelboraf. For most of the patients in the clinical studies, the side effects were significantly reduced from those of Zelboraf. Patients reported no extreme sun sensitivity; less fatigue; no development of secondary skin cancers like basal cell or squamous cell carcinoma. As such, this needs to be considered as a viable option for patients as an alternative to Zelboraf or perhaps for patients that have failed Zelboraf.

Patients and physicians need to be able to decide what is in the best interests of the patient, given their individual needs. By posing restrictions, you limit the potential of targeted therapies that are most effective for the individual patients. You handcuff the physicians. pERC also has to keep in mind that while costs of these drugs may seem high, the number of patients that will actually be able to access these for treatments is low. By consistently stating that this drug is not cost effective in comparison to dacarbazine is not as a potential reason not to cover the drug is not a valid or useful recommendation. It's just not meaningful. It is like comparing apples to oranges. It is common knowledge that dacarbazine is not an effective treatment for melanoma with less that 10% response rate. The side effects are significant, which only lead to a weakening of the patients overall condition and a waste of money and resources. I would strongly suggest that the committee remove this commentary as it does nothing to assist the provinces in making their funding decisions; nor does it benefit the health of patients dealing with a disease that is highly untreatable when it has metastasized.

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

1.2 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
7	Related information	3.2	'Patients were also asked what their quality of life has been like since taking Dabrafenib. Patients indicated: 1) Very normal. Very active life (skiing, baseball, normal workload) 2) My quality of life is excellent, after being put on steroids for some side effects, I have not experienced any side effects, and I can do what I want

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient advocacy group input
			whenever I want, as long as I take 2 pills a day, absolutely amazing! In the information gathered from our patients the side effects of this drug were reported as very well tolerated more so than other therapies we have seen to date. This is providing patients with an excellent quality of life and significant hope for the future.' This is typical of the patient responses while on this new therapy. We would strongly suggest that this drug be made available as one of to in the arsenal to treat melanoma patients with the V600E mutation and that you also make mandatory recommendations for coverage of the screening test as it is required.

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) 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.