pan-Canadian Oncology Drug Review

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

Afatinib (Giotrif) for Advanced Non-Small Cell Lung Cancer

May 2, 2014

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Afatinib

Name of registered patient advocacy Lung Cancer 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 ____ agrees in part __X__ disagree

Please explain why the patient advocacy group agrees, agrees in part or disagrees with the initial recommendation.

Lung Cancer Canada disagrees with the initial recommendation as:

1) The recommendation is overly restrictive. In comparison to other similar treatments that have received a funding recommendation, it appears that afatinib was evaluated using a higher standard both in terms of trial design and efficacy, and economic modelling.
2) This recommendation takes away patient choice and may deprive patients the potential benefits derived from EGFR TKI's (e.g. those with uncommon mutations). It also does not place enough value on the benefits of oral medications.

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.

____ 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.

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	pERC Recommen-dation	Paragraph 1.	The recommendation is overly restrictive and should be worded as follows: "pERC recommends funding for afatinib as a replacement therapy to first line platinum doublet chemotherapy with EGFR mutation +ve adenocarcinoma of the lung and with an ECOG performance status of 0 – or 1."
4	Summary of	"An economic	Economic impact can be modeled and is

	pERC deliberations	model comparing afatinib wih cisplatin-gemcitabine or other platinum based doublets was not provided…. Therefore pERC considered … cost effectiveness unknown."	regularly performed by pCODR as part of their economic panel's mission. There are published guidelines that can be used by pCODR to inform the continued consideration of this drug. Reference: Guidelines for health technologies: specific guidance for oncology products in Canada. Mittmann N1, Evans WK, Rocchi A, Longo CJ, Au HJ, Husereau D, Leighl NB, Isogai PK, Krahn MD, Peacock S, Marshall D, Coyle D, Taylor SC, Jacobs P, Oh PI. Value Health. 2012 May;15(3):580-5. doi: 10.1016/j.jval.2011.12.006. Epub 2012 Feb 16.
5	Comparator Information	Whole section	The recommendation unfairly holds afatinib to a different standard than other agents. While the available data do not allow direct comparison of afatanib vs. other EGFR TKI's, they still establish that afatanib is superior to platinum based chemotherapy. The study design should be judged according to the standards that existed when the trial was started. At that time, EGFR TKI therapy was not routinely available, so it is hard to dismiss the trial results on the basis that it does not compare afatanib to another EGFR TKI. The trial establishes the superiority in PFS over chemotherapy, in the same way that gefitinib is superior to platinum based chemotherapy. Gefitinib is not the only option available for this patient population. The available evidence supports afatanib as one option in the first line therapy for EGFR mutation positive NSCLC. There are many examples of multiple drugs of the same class being reimbursed without direct comparative data, such as aromatase inhibitors in breast cancer and oral agents in kidney cancer.
6	Access to first line TKI's	Whole section	Restricting coverage to one TKI may deprive certain patient populations of benefits offered by TKI's. Afatinib demonstrated efficacy in both studied and previously unstudied patient populations. LUX Lung 6 was conducted in patients with documented EGFR mutations detected by the Therascreen test. This test detects more mutations than those included in the registration and retrospective studies for gefitinib and erlotinib. Approximately 10% of LUX Lung 6 patients would not have been included in the gefitinib or erlotinib trials. This

			is the first EGFR TKI to show benefit in a greater spectrum of EGFR mutations and superiority over platinum based chemotherapy in this larger group. EGFR mutations detectable by Therascreen include exon 18 (G719A), exon 19 deletions, exon 20 (T790M, S768I and 2 insertions), exon 21 (L858R, L861Q) mutations.

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
6	Patient Choice of treatment		Based on the efficacy demonstrated by the current studies, asking patients and clinicians to wait for additional trial results for a drug with proven activity places an unnecessary barrier to treatment. In addition, other countries (eg. UK, Australia and Scotland) have multiple EGFR TKI's available for their patients – why not Canada?
6	Patient Choice of treatment	Value of oral medications	Patients value oral treatments and the economic benefits of oral treatments have been presented. pERC's funding denial ignores the value of having additional oral targeted agents. The continued development of new agents and innovation will be hampered if pERC will only approve one agent per class.

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 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.