pan-Canadian Oncology Drug Review

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

Ceritinib (Zykadia) Resubmission for Metastatic Non-Small Cell Lung Cancer

Lung Cancer Canada

March 21, 2017

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s):	Zykadia (ceritinib)
Name of registered patient advocacy group:	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:

_X___ agrees ____ agrees in part ____ disagree

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

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
Pg. 9	**Economic Evaluation**	**Drug Costs:** Ceritinib costs $67.47 per 150 mg tablet. At a dosing regimen of 750 mg/day, ceritinib costs $337.33 per day and $9,445.32 per 28-day course.	While we agree that cost effectiveness of ceritinib needs to be improved, we believe that in the age of personalized medicine, when a targeted therapy is clearly efficacious and superior to chemotherapy, comparison of the new drug to a targeted therapy would be more meaningful.
Pg. 2	**Potential Next Steps**	Time-limited need for patients currently on or having recently completed treatment with chemotherapy or an immune check-point inhibitor	LCC applauds PCODR-CADTH for considering ALK+ patients who may have for a number of reasons (e.g. participation in other trials, lack of public reimbursement etc.), not received ceritinib following progression or intolerance to crizotinib. This consideration avoids "penalizing" patients who harbour the mutation and allows them to have a chance to benefit from a more efficacious and personalized option. As stated in the initial Guidance Report, it is a time-limited need that will be resolved as ceritinib gets integrated into our system. It is an important consideration. For example it allows those that are contemplating trial to participate without fear of exclusion from future treatment.
Pg. 2	**Potential Next Steps**	Upon implementation of ceritinib reimbursement, pERC recognizes collaboration among provinces to develop a common approach for treatment sequencing would be of value.	Treatment sequencing is something that should be discussed, however LCC believes that there is a generalized consensus regarding sequencing in the medical community that it should not be a factor to delay PCPA discussion and potential provincial listings. As LCC points out in our submission, there is a high unmet need in this area and ceritinib makes a big difference in the lives of patients and their families. With generalized clinician agreement and pERC's own recognition of the likely sequencing, discussion on this topic, whether in the context of CDIAC or otherwise, should not delay next steps.
Pg. 4	**Summary of pERC Deliberations**	pERC also noted that the increased but manageable toxicity profile of ceritinib compared with	As noted, side effects reported by patients were generally manageable and therefore a worthwhile trade-off since, according to LCC data, patients found permanent, lasting, life extending effects from ceritinib. Patients also much preferred oral therapies, such as ceritinib, to chemotherapy.

Page Number	Section Title	Paragraph, Line Number	Comments and Suggested Changes to Improve Clarity
		chemotherapy may be challenging for patients.	

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
			LCC supports conversion of this initial recommendation to final recommendation. We applaud PCODR for the consideration of the needs of a broad range of patients, including those with time-limited needs. We do believe that in the age of personalized medicine, whenever possible, evaluations and cost considerations for targeted therapies should be made against another targeted therapy within the same treatment algorithm. Discussions around treatment algorithms are beneficial but recognition of the generalized consensus amongst clinicians, the current lack of options and the unmet need, LCC strongly believes that these discussions, including CDIAC, should not delay the start of the PCPA process. Ceritinib was approved by the FDA on April 29, 2014; Health Canada approved ceritinib 332 days later. As of the date of this submission (March 17, 2017) 1054 days have passed since FDA approval and 722 days have passed since Health Canada approval. Patients and their families have no time to wait and our system cannot make them wait any longer. Ceritinib already has a positive pCODR recommendation. There is a

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient advocacy group input
			demonstrative high unmet need. The PCPA process and provincial adoption needs to occur quickly and should not be further delayed by the prospects of other potential drug approvals in order to move forward now and save lives.

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 www.cadth.ca/pcodr.

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.cadth.ca/pcodr 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 pcodrinfo@cadth.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 pcodrinfo@cadth.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.