pan-Canadian Oncology Drug Review

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

Osimertinib (Tagrisso) for Non-small Cell Lung Cancer

Lung Cancer Canada

May 4, 2017

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Tagrissso (osimertinib)

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:** High drug acquisition cost,	While we agree that cost effectiveness of Tagrisso needs to be improved however we believe that in the age of personalized medicine when a targeted therapy is clearly efficacious and superior to

		generic pemetrexed available At the list price, osimertinib costs $294.6764 for the 40 mg or 80 mg tablet…	chemotherapy, comparison of the new drug to a targeted therapy would be more helpful.
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 EGFR T790M+ patients who may have for a number of reasons (e.g. participation in other trials, lack of public reimbursement etc.), not received osimertinib following failure on an EGFR TKI. 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 osimertinib 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 osimeritinib reimbursement, pERC recognizes collaboration among provinces to develop a common approach for treatment sequencing would be of value.	While treatment sequencing is something that should be discussed, we believe that in this case there is generalized consensus regarding sequencing in the medical community in regards to this topic and 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 osimertinib makes a 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.

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.

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			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. Patients and their families have no time to wait and our system cannot make them wait any longer. Osimertinib already has a positive pCODR recommendation. There is a 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

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Instructions for Providing Feedback

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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.

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Ontario Lung Association

May 4, 2017

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Name of registered patient advocacy: Ontario Lung Association

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The Lung Association-Ontario is pleased with the initial recommendation. As an organization, we are committed to helping ensure our patients have timely access to appropriate and effective medications and recognize that pCODR is just one step in the process of making the medication accessible to patients. We are hopeful that the next steps of the review and implementation in the provinces will be expedited so that our patients can benefit as soon as possible. Given the poor survival rates of lung cancer compared to other types of cancers, having access to appropriate medications is even more urgent. Improving the quality of the lives of the patients we work with is of utmost importance and the benefits of this medication as noted in the pERC document (overall feeling better; a return to normal daily life and meaningful activities with their families; relief from cough resulting in improved sleep and increased energy), were consistent with the outcomes that our patients were looking for.

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1.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments

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