pan-Canadian Oncology Drug Review

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

Olaparib (Lynparza) for Ovarian Cancer

Ovarian Cancer Canada

September 29, 2016

1 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Olaparib (Lynparza)

Name of registered patient advocacy: Ovarian Cancer Canada

Please explain why the patient advocacy group agrees, agrees in part

**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

Please indicate if the patient advocacy group agrees or disagrees with the initial recommendation: *or disagrees with the initial recommendation.*

____ agrees ____ agrees in part _x Disagree

On behalf of Ovarian Cancer Canada we are writing to express our disappointment with the initial recommendation of pERC regarding Olaparib as treatment for ovarian cancer. pERC based its initial recommendation primarily on the fact that it was not confident that there was a net clinical benefit of Olaparib maintenance compared with placebo due to the limitations in the evidence from the available subgroup analysis of the non-comparative phase 2 clinical trial. This viewpoint is curious to us given the following: 1) according to experts in the field, Study 19 clearly established a net clinical benefit in women with relapsed ovarian cancer; 2) Olaparib has been evaluated and approved by approximately 16 other jurisdictions (and in 49 countries) based on the same data; 3) Olaparib was also reviewed and found to be acceptable by Health Canada. It is very distressing to us that a difference in interpretation of the data will result in women diagnosed with ovarian cancer in Canada having a significant disadvantage to other women in the world.

pERC's suggestion that a decision be made after review of the results of SOLO 2 is not a solution. We have been told that these results will not be forthcoming until late fall (at the earliest) and will not be available for Canadian women until 2018. Women with ovarian cancer can't afford the luxury of waiting for these results.

As a maintenance drug that has positively impacted progression-free survival, Olaparib is a welcome drug to those living with ovarian cancer. Progression-free survival and the value of being able to prolong a recurrence cannot be overstated in this group. Women diagnosed with ovarian cancer know that they will die from their disease and are looking for extra months and years of survival. Further, by taking a maintenance therapy the extreme anxiety of a recurrence is reduced and many are able to go back to work and continue aspects of their lives that are meaningful to them. Importantly, by staying off chemotherapy, they can also postpone the time when they will become resistant to chemotherapy; the value of this benefit cannot be stressed strongly enough.

Providing timely access to Olaparib will address a critical unmet need and gap in treatment for women diagnosed with BRCA-mutated ovarian cancer.

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a) 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.	_X___ Do not support conversion to final recommendation.
Recommendation does not require reconsideration by pERC.	Recommendation should be reconsidered by pERC.

b) 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?

The intent and reasons are clear.

1.2 Comments Related to Patient Advocacy Group Input

Please provide feedback on <u>any issues not adequately addressed</u> 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
12	Initial Clinical Guidance Report 3.1.2 Patients' Experiences with Current Therapy for Ovarian Cancer	1st paragraph in section	Although the majority of those surveyed said current treatments did manage their ovarian cancer, the direct quotes from the respondents indicate that the burden of the existing treatments were significant for these patients. While their chemotherapy managed the cancer for a time, the disease continued to come back over and over again which immensely impacted the respondents' quality of life.
14	Initial Clinical Guidance	1st paragraph	This quote cannot be stressed enough. Delaying their next recurrence is of utmost importance to a patient's physical health and

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	Report 3.1.2 Patients' Experiences with Current Therapy…		QOL. "Watch and wait" is not a benign state. It can cause significant anxiety and there are physical side effects when the cancer grows, including bowel obstructions, etc. As noted by the respondents, prolonging the period when the patient does not need chemotherapy is very important as it can help ensure that future treatment will be effective and not hindered by the patient achieving a non-sensitive status.
14	Initial Clinical Guidance Report 3.1.2 Patients' Experiences with Current Therapy…	4 paragraphs down, 2 quotations	The financial burden of chemo and in-cancer centre treatment on a patient and the patient's family cannot be overstated. Having an oral drug that can be taken at home helps to improve equity and access for patients in rural communities and those who are economically disadvantaged.
15	3.2.1 Patient Expectations for and Experiences to Date with Ovarian Cancer	7th paragraph	Side effects included in Ovarian Cancer Canada's survey were included because they are listed as side effects associated with Olaparib. Not surprisingly, when asked, most respondents did not select blood cancers or inflammation of the lungs as tolerable side effects. We don't think this is surprising as many people would not select these side effects when given the option. However, these responses should be contrasted with the responses about the patient's tolerance for additional side effects; these women are willing to manage additional side effects if it means progression free survival.

1.3 Additional About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
1	Initial Clinical Guidance Report 1.2.4 Interpretation	1st paragraph	Ovarian cancer removes women from the workforce (and their caregivers in some cases). PFS and the delay of a recurrence is very valued by patients as it keeps them working and contributing to the economy.
1	Initial Clinical Guidance Report 1.2.4 Interpretation	5th paragraph	pERC concludes that "Study 19 met its primary endpoint objective and demonstrated an improvement in PFS of patients treated with maintenance Olaparib." When living with ovarian cancer,

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			a fatal disease, PFS is valued by patients. It keeps their emotional well-being in check and enables them to lead productive lives, including working and participating as active members of society.
7	Initial Clinical Guidance Report 2.2 Accepted Clinical Practice	4th paragraph	Study 19 showed Olaparib resulted in a significantly longer PFS than placebo, especially for those in the BRCA mutated subgroup. Respondents in the patient submission noted how important PFS is to them.
18	Initial Clinical Guidance Report 4.1 Factors Related to Comparators	2nd paragraph	PAG's need for overall survival data to make a definitive recommendation on this drug seems to demonstrate the lack of understanding of the burden of ovarian cancer and how important PFS is to this population group. In addition, it is often difficult to show overall survival in ovarian cancer trials due to the nature of the disease. Further, their need for this information is questionable given the approval in 49 countries based on this study and the data submitted.
18	Initial Clinical Guidance Report 4.2 Factors Related to Patient Population	1st paragraph	While a phase 3 trial may be feasible to conduct, it would result in women who are living with a fatal disease to wait longer (many of whom may die in the process) while additional data is collected. This is not just when this drug has already been approved throughout the world and is currently in use in 49 countries based on the same data.
18	Initial Clinical Guidance Report 4.2 Factors Related to Patient Population	4th paragraph	To clarify, quality of life gains from access to this treatment include a significant reduction in anxiety because the patient's cancer is under control, an ability to work and/or be a productive member of society, time and energy from not having to travel to a cancer centre for treatment and importantly, more time with family and friends as the patient's non-sensitive platinum status will be protected.
19	Initial Clinical Guidance Report 4.4 Factors Related to Implementation	2nd paragraph	PAG notes that the resources needed to manage the side effects would be significant. It is our understanding that the risk of blood cancers from this drug is low. Ovarian cancer is a rare disease and the number of women eligible for this drug will be even smaller. It would appear that the

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	Costs		resources for those very few women diagnosed with a blood cancer are not as significant as suggested by PAG.
19	Initial Clinical Guidance Report 4.5 Factors Related to the Health System	2nd paragraph	It is true in some jurisdictions oral medications are not funded in the same manner as IV cancer medications and that this may cause a burden on some families. This policy inequity is a problem in ON and the Atlantic provinces. It is not our opinion that delaying approval of a drug based on this policy inequity is sufficient reasoning. The burden of not having access to this effective treatment is a more significant burden to these women and families.
20	Initial Clinical Guidance Report 5.3 Identify Key Benefits and Harms with Olaparib	Last paragraph on page	The importance of delaying recurrence outlined by the clinicians cannot be stressed enough from a patient perspective. The physical toll of recurrence is extensive.
21	Initial Clinical Guidance Report 5.3 Identify Key Benefits and Harms with Olaparib	First paragraph	The impact of delaying chemo treatment provided by the clinicians is also very important. This is a disease with very few 'weapons in the arsenal'. To extend the length of time between chemo treatments can help to delay resistance to chemotherapy which will result in women with better QoL.
21	Initial Clinical Guidance Report 5.3 Identify Key Benefits and Harms with Olaparib	2nd paragraph	The reduced toxicity of a parp-inhibitor vs chemo would have an extremely positive impact on patients living with ovarian cancer.

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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.

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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.

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