pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

Provincial Advisory Group (PAG) Feedback on a pCODR Expert Review Committee Initial Recommendation

Olaparib (Lynparza) for Ovarian Cancer – Resubmission

September 20, 2017

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): **Olaparib Resubmission for Ovarian Cancer**

Contact person*: _____

Title: _____

Phone: _____

Email: _____

**pCODR may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR.*

3.1 Comments on the Initial Recommendation

a) Please indicate if the PAG (either as individual PAG members and/or as a group) agrees or disagrees with the initial recommendation:

___x_ agrees ____ agrees in part ____ disagree

All PAG members providing feedback agree with the initial recommendation and support conversion to final recommendation, upon clarification of treatment until disease progression and switching from capsules to tablets if there is evidence in the future to support the switch.

b) Notwithstanding the feedback provided in part a) above, please indicate if the PAG would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) Business Days after the end of the feedback deadline date.

__x__	Support conversion to final recommendation. Recommendation does not require reconsideration by pERC.	____	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 Recommendation**		PAG noted that one jurisdiction misinterpreted the 'starting olaparib within 8 weeks of the last dose of platinum-based chemotherapy' to being used in the setting of platinum-resistant

			disease, as the definition of platinum-sensitive disease immediately preceded this statement. Perhaps placing this statement earlier in the recommendation would help avoid this misunderstanding.
2	**Next Steps for Stakeholders**	Availability of Tablets	PAG suggests adding a statement to determine when tablets will be available in Canada
2	**Next Steps for Stakeholders**	Guidance on Transitioning From Capsules to Tablets	Because the tablets and capsules are not considered interchangeable at this time, PAG suggests a statement that patients initiated on capsules should stay on capsules and patients initiated on tablets should stay on tablets. Once tablets are available, all new patients should start on tablets. Patients who have started on capsules would stay on capsules, unless there is new evidence to inform switching mid-therapy from capsules to tablets. The capsules should be phased out over time once all patients on capsules have completed therapy.
			PAG would like confirmation that the intent is to fund treatment until disease progression, and not beyond progression (e.g., oligoprogression has occurred but the clinician thinks the patient may still be benefit from treatment). Page 1 states that "treatment should continue until unacceptable toxicity or disease progression." However on page 8, it states that "Treatment with olaparib continued until disease progression or until investigator deemed that a patient was no longer benefiting from treatment in SOLO-2." It was noted that the main drivers of incremental cost in the analysis included treatment duration and the economic reanalysis used PFS instead of time to discontinuing treatment to represent treatment duration as the CGP felt that patients would not continue treatment with olaparib beyond progression in actual practice."
1	**pERC Recommendation**		It would be helpful for implementation if the pERC recommendation also stated the criteria for discontinuing due to disease progression (e.g., radiologic evidence vs. biochemical/CA-125 vs. clinical) and which assessments should be used to confirm no disease progression if there is a treatment interruption (e.g., no disease progression confirmed radiologically) and re-initiation of treatment is desired.

3.2 Comments related to PAG input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on the PAG input provided at the outset of the review on potential impacts and feasibility issues of adopting the drug within the health system.

Please note that new evidence will be not considered at 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 operational, capital, human resources, legislative, regulatory factors that may either important enablers or barriers to recommendation implementation.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial PAG input

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments