pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review

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

Pomalidomide (Pomalyst) for Multiple Myeloma

July 31, 2014

3 Feedback on pERC Initial Recommendation

Name of the drug indication(s): Pomalidomide (Pomalyst) for Multiple Myeloma

Endorsed by: Provincial Advisory Group Chair

Feedback was provided by nine of nine provinces (Ministries of Health and/or provincial cancer agencies) participating in 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

Most members agree with the recommendation except two members who agrees in part because the flat pricing structure of the capsules is not ideal for adoption feasibility and the concerns with defining of what would be considered not logistical for administration of bortezomib

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 within 2(two) business days of the end of the consultation period.

__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.

All PAG members support conversion of the initial recommendation to final. Two members who would like pERC to provide further clarity on the patient population that the recommendation applies to, recognize that this may require reconsideration.

- Does the recommendation apply to patients with ECOG 0-1 only as in the trial or include patients with ECOG >1?
- Can pERC help define intolerance to bortezomib?
- What is considered to be not logistically possible to administer bortezomib?
- Can pERC help define prior treatments?
- Does the recommendation apply to patients who have used lenalidomide in the maintenance setting?

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	Line 3	Suggest revising the statement from "who have previously failed two treatments" to "who have previously failed AT LEAST two treatments" to be consistent with MM-003 trial criteria
1	pERC Recommendation	Line 8	The phrase "bortezomib…cannot be administered logistically…" is vague and could be misused. Thus provinces may need to define what is considered logistics in their province which may differ amongst the provinces. It is unclear what the intent of this criteria is in the clinical trial and how this could be implemented by the provinces.
1	pERC Recommendation	Additional line	Please also indicate here that "pERC considered there was insufficient evidence to make a recommendation to fund pomalidomide in patient with slowly progressing disease" as in the Summary section.
1	Potential Next Steps	Additional paragraph	The controlled distribution program mandated by Health Canada is not simply a one time registration of the patients. Monthly monitoring and additional administrative work is required. Add to this section, the additional resources required for pomalidomide distribution, as in the lenalidomide recommendation: "**Additional Resources Required Due to Controlled Distribution** pERC noted that lenalidomide can only be obtained currently through a controlled distribution program and that expansion of lenalidomide use to the maintenance setting may require additional pharmacy and human"

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.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial PAG input
3	Summary of pERC Deliberations	Paragraph 2, second sentence	The controlled distribution program mandated by Health Canada is not simply a one time registration of the patients. Monthly monitoring and additional administrative work is required. For consistency, the wording from the lenalidomide recommendation on the controlled distribution program would appropriately acknowledge the additional workload and resources required for pomalidomide.
7	Adoption Feasibility	Paragraph 1, last sentence	

3.3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
4	Overall Clinical Benefit	Paragraph 3, first sentence	Patients in trial had ECOG status of 0 or 1. This was not addressed in the pERC recommendation on page 1. Does the recommendation apply to patients with ECOG 0-1 only?
4	Overall Clinical Benefit	Paragraph 5, beginning of first sentence	CGP noted that there were no patients where bortezomib was contraindicated that were enrolled in the trial. Please clarify.
4	Overall Clinical Benefit	Paragraph 5, end of first sentence	Is it possible for pERC to define what "cannot be administered to patients for logistical reasons" includes?
5	Overall Clinical Benefit	Paragraph 2	Could other EORTC QLQ-30 metrics also be included?
5	Overall Clinical Benefit	Paragraph 3, Line 10	Could "similar drug" be elaborated?

About Completing This Template

pCODR invites the Provincial Advisory Group (PAG) to provide feedback and comments on the initial recommendation made by the pCODR Expert Review Committee. (See www.pcodr.ca for information regarding review status and feedback deadlines.)

As part of the pCODR re view 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 pERC 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 PAG, either as individual PAG members and/or as a group, agrees or disagrees with the pERC 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 pERC 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 agree with the recommended clinical population described in the initial recommendation, it will proceed to a pERC final 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 a pERC final 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 pERC final 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 members of the PAG can provide feedback on the pERC initial recommendation; delegates must work through the PAG representative to whom they report.
    a. Please note that only one submission is permitted for the PAG. Thus, the feedback should include both individual PAG members and/or group feedback.

b) Feedback or comments must be based on the evidence that was considered by pERC in making the pERC initial recommendation. No new evidence will be considered at this part of the review process, however, it may be eligible for a Resubmission.

c) The template for providing *Provincial Advisory Group (PAG) 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. PAG 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. Similarly, PAG 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 pERC Initial Recommendation 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 related to new evidence. New evidence is 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 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 to the pCODR Secretariat by the posted deadline date.

i) If you have any questions about the feedback process, please e-mail submissions@pcodr.ca.

Note: Submitted feedback may be used in documents available to the public. The confidentiality of any submitted information cannot be protected.