pan-Canadian Oncology Drug Review

Submitter or Manufacturer Feedback on a pCODR Expert Review Committee Initial Recommendation

Lenvatinib (Lenvima) for Differentiated Thyroid Cancer

September 20, 2016

3 Feedback on pERC Initial Recommendation

Name of the Drug and Indication(s):	LENVIMA® (lenvatinib)
Role in Review (Submitter and/or Manufacturer):	Submitter/Manufacturer
Organization Providing Feedback	Eisai Limited

**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 Submitter (or the Manufacturer of the drug under review, if not the Submitter) agrees or disagrees with the initial recommendation:

X agrees agrees in part disagree

Eisai agrees with the initial recommendation to reimburse LENVIMA for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (RR-DTC) for patients with a good performance status and who otherwise meet the eligibility criteria of the SELECT trial. Eisai also agrees with the reasons for recommendation, in that LENVIMA demonstrates an overall clinical benefit based on a clinically meaningful and statistically significant improvement in progression-free survival (PFS), a likely improvement in overall survival (OS), and a manageable toxicity profile.

Eisai Limited is committed to working with the pan-Canadian Oncology Drug Review (pCODR)-participating plans to facilitate access to LENVIMA in a timely manner.

b) Notwithstanding the feedback provided in part a) above, please indicate if the Submitter (or the Manufacturer of the drug under review, if not the Submitter) 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
-	-	-	No comments or suggested changes to improve clarity.

3.2 Comments Related to Submitter or Manufacturer-Provided Information

Please provide feedback on any issues not adequately addressed in the initial recommendation based on any information provided by the Submitter (or the Manufacturer of the drug under review, if not the Submitter) in the submission or as additional information during the review.

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.

Page Number	Section Title	Paragraph, Line Number	Comments related to Submitter or Manufacturer-Provided Information
-	-	-	No comments related to Submitter or Manufacturer-Provided information.

3.3 Additional Comments About the Initial Recommendation Document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments
2	SUMMARY OF pERC DELIB-ERATIONS	2nd paragraph, lines 5-8 "The Committee discussed wastage and that it could have a significant impact on	LENVIMA is available in 4mg and 10mg capsules. The recommended daily dose in the Product Monograph is 24mg, with dose reductions to 20mg, 14mg, and 10mg, sequentially as required for persistent and intolerable Grade 2 Adverse Reactions, Grade 3 Adverse Reactions, or Grade 4 Laboratory Abnormalities. Given the potential for confusion and the associated downstream

Page Number	Section Title	Paragraph, Line Number	Additional Comments
		the incremental cost-effectiveness of lenvatinib, based on the dose modifications and interruptions reported in the SELECT trial and the availability and pricing structure of lenvatinib in pre-packaged blister packs."	potential for patient medication errors, Eisai elected to supply LENVIMA in a blister card format in the following compliance packaging configurations: • 24 mg daily-dose carton containing 6 blister cards (each 5-day blister card contains ten 10 mg capsules and five 4 mg capsules) • 20 mg daily-dose carton containing 6 blister cards (each 5-day blister card contains ten 10 mg capsules) • 14 mg daily-dose carton containing 6 blister cards (each 5-day blister card contains five 10 mg capsules and five 4 mg capsules) • 10 mg daily-dose carton containing 6 blister cards (each 5-day blister card contains five 10 mg capsules) Eisai, following discussion with Health Canada, believes that the compliance pack format represents the best alternative to reduce the potential for medication errors and should not be mixed to achieve best price value.
9	ECONOMIC EVALUATION: Cost-effective-ness estimates: Not cost-effective at submitted price	1st paragraph, lines 9-10 "…pERC agreed with the adjustment of pricing such that patients were assumed to mix packs for best price value."	

About Completing This Template

pCODR invites the Submitter, or the Manufacturer of the drug under review if they were not the Submitter, to 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 Submitter (or the Manufacturer of the drug under review, if not the Submitter), agrees or disagrees 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 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 the group making the pCODR Submission, or the Manufacturer of the drug under review can provide feedback on the initial recommendation.

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 at this part of the review process, however, it may be eligible for a Resubmission.

c) The template for providing *Submitter or Manufacturer Feedback on 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. The Submitter (or the Manufacturer of the drug under review, if not the Submitter) 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, the Submitter (or the Manufacturer of the drug under review, if not the Submitter) 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.