

pan-Canadian Oncology Drug Review Procedural Review Guidelines

February 2016

INQUIRIES

Inquiries and correspondence about the pan-Canadian Oncology Drug Review (pCODR) should be directed to:

CADTH pan-Canadian Oncology Drug Review
154 University Avenue, suite 300
Toronto, ON
M5H 3Y9

Telephone: 1-866-988-1444
Fax: 1-866-662-1778
Email: info@pcodr.ca
Website: www.cadth.ca/pcodr

TABLE OF CONTENTS

RECORD OF UPDATES	ii
INQUIRIES	iii
TABLE OF CONTENTS	iv
1 What is a procedural review?	1
2 Who can submit a procedural review request?	1
3 On what basis can a procedural review request be submitted?	1
4 When can a procedural review request be submitted?	2
5 How is the procedural review process initiated?	2
6 Who conducts the procedural review?	2
7 How is a procedural review conducted?	3
8 What are the possible outcomes of a procedural review?	3
9 How are decisions on procedural reviews communicated?	4
10 How long does the procedural review process take?	4
APPENDIX A: pCODR Procedural Review Request Form.....	5

1 What is a procedural review?

The procedural review is a determination of whether pCODR and/or pERC have complied with review processes and procedures. After a pERC Final Recommendation for a drug reviewed by pCODR has been publicly posted on the pCODR section of the Canadian Agency for Drugs and Technologies in Health (CADTH) website (www.cadth.ca/pcodr), a request for a procedural review may be submitted to the CADTH President and Chief Executive Officer (CEO) on the grounds that pCODR failed to act in accordance with its procedures in conducting the review or that pERC failed to apply its deliberative framework in formulating the pERC Final Recommendation. pCODR is committed to following its posted review processes, including ensuring that the pERC deliberative framework is applied in formulating recommendations. A party who has participated in the pCODR review of a drug and who believes that the process has not been followed as set out in the *pCODR Procedures* or that the *pERC Deliberative Framework* was not applied, may submit a procedural review request on these grounds. These grounds relate only to whether or not process was followed and not to the content of the pERC Final Recommendation. The request for a procedural review is reviewed by the CADTH President and CEO to whom pERC and pCODR are accountable.

The capitalized terms in this document are as defined in the *pCODR Procedures* which are available on the pCODR section of the CADTH website (www.cadth.ca/pcodr). All references to number of days in this document are in Business Days, as defined in the *pCODR Procedures*, unless otherwise specified.

2 Who can submit a procedural review request?

Any one of the parties who participated in the pCODR review of the drug may submit a request for a procedural review:

- the Submitter of the drug submission,
- the Manufacturer of the drug under review, if they contributed information to the Submission or if they provided feedback on the pERC Initial Recommendation,
- Provincial Advisory Group (PAG),
- Registered patient advocacy groups (or individual patient or caregiver in cases where there is no patient advocacy group) who provided input on the drug under review or feedback on the Initial Recommendation, or
- Registered clinician who provided input on the drug under review or feedback on the Initial Recommendation

Multiple parties may submit a request for a procedural review of a pERC Final Recommendation but each of these parties may submit only one request per pERC Final Recommendation.

3 On what basis can a procedural review request be submitted?

A procedural review request may be submitted on the basis that:

- pCODR failed to act in accordance with its procedures in conducting the review
- pERC failed to apply its deliberative framework in formulating its recommendation

These grounds relate only to whether or not process was followed and not to the content of the pERC Final Recommendation. Differences in the interpretation and use of data during the review

do not constitute grounds for a procedural review, e.g. the selection of comparators, the use of data sets, the place in therapy. In addition, disagreement with pCODR's approach to managing Non-Disclosable Information that was provided in the Submission, including use or non-use in the review process, does not constitute grounds for a procedural review, provided processes were followed as outlined in the *pCODR Procedures* and the *pCODR Disclosure of Information Guidelines*.

4 When can a procedural review request be submitted?

A procedural review request must be submitted within 10 business days of a pERC Final Recommendation being publicly posted on the pCODR section of the CADTH website (www.cadth.ca/pcodr). Following the conduct of a procedural review, further procedural review requests related to the associated pERC Final Recommendation cannot be made. When the pERC Final Recommendation is posted following a re-deliberation, a *Notification to Implement* a pERC Final Recommendation will be issued by pCODR, indicating that P/T Ministries of Health and Provincial Cancer Agencies can proceed to implement the recommendation and that no further procedural review requests are permitted.

5 How is the procedural review process initiated?

A party who has participated in the pCODR review of the drug completes a pCODR Procedural Review Request Form (see Appendix A), which is available on the pCODR section of the CADTH website (www.cadth.ca/pcodr). The form is submitted, along with supporting documentation to pCODR either via email or through the secure portal on the pCODR section of the CADTH website (www.cadth.ca/pcodr) within 10 business days of a pERC Final Recommendation being issued. No extensions will be granted to the 10 business day period and all supporting documentation must be submitted within this period. Intent to submit supporting documentation after the 10 business day period will not be considered sufficient for initiation of the procedural review process.

6 Who conducts the procedural review?

Procedural review requests submitted to pCODR are forwarded to the CADTH President and CEO. The CADTH President and CEO, on the advice of the pCODR Advisory Committee (PAC) Chair and Vice-Chair, will review the *pCODR Procedural Review Request Form* and supporting documentation to determine if grounds for a procedural review exist. The CADTH President and CEO may ask for clarification or additional information from the party making the request to assist in determining if grounds for a procedural review exist. This clarification must be provided by the procedural review requestor, as outlined by the CADTH President and CEO, within 15 days of a Final Recommendation being posted on the pCODR section of the CADTH website, otherwise the request for a procedural review may not be accepted.

- If the request for a procedural review is not accepted, the party who made the request will be notified in writing by the CADTH President and CEO. A *Notification to Implement* a pERC Final Recommendation will be issued by pCODR, allowing the P/T Ministries of Health and Provincial Cancer Agencies to proceed with implementation of the pERC Final Recommendation.
- If the request for a procedural review is accepted, the party who made the request will be notified in writing by the CADTH President and CEO, who will then appoint three (3)

to five (5) members from the pCODR Advisory Committee (PAC) to conduct the full procedural review, as needed. In certain circumstances, the PAC panelists may determine that additional expertise is required and may request advice from other PAC members or external experts while conducting the procedural review.

7 How is a procedural review conducted?

The appointed PAC panelist members reviews the submitted request for a procedural review and the supporting documentation.

At the beginning of the Procedural Review, the pERC Chair or pCODR staff has the option to provide a provisional response for consideration by the PAC panelists.

As may be required throughout the procedural review, the PAC panelists may request additional information from the party who made the request, the pERC, pCODR staff or other parties that participated in the pCODR review of the drug.

The PAC panelists will consider the information provided and make a recommendation to the CADTH President and CEO who will determine the outcomes of the procedural review, which are outlined in section 8. This determination will be communicated in writing to the party who made the request, PAC and pCODR. It is important to note that the outcome of the procedural review may or may not result in a change to the pERC Final Recommendation.

P/T Ministries of Health and Provincial Cancer Agencies do not implement the pERC Final Recommendation while a procedural review is being conducted. pCODR will issue a *Notification to Implement* a pERC Final Recommendation, indicating that the recommendation can be implemented.

8 What are the possible outcomes of a procedural review?

The PAC panelists may make the following recommendation to the CADTH President and CEO, who may determine that:

1. No changes are required to the pERC Final Recommendation and a *Notification to Implement* a pERC Final Recommendation should be issued by pCODR.
2. Steps in the pCODR review process must be revisited and/or the submission must be re-deliberated by pERC at the next possible pERC meeting. A re-deliberation may result in the pERC Final Recommendation being maintained or being changed.
 - If the pERC Final Recommendation is maintained following the re-deliberation, a *Notification to Implement* a pERC Final Recommendation will be issued by pCODR.
 - If the pERC Final Recommendation is changed following the re-deliberation, a new pERC Final Recommendation will be publicly posted and a *Notification to Implement* a pERC Final Recommendation will be issued by pCODR.

If steps in the pCODR review process must be revisited and/or the recommendation re-deliberated, the submission receives priority placement on the pERC meeting agenda at which it will be re-deliberated and work on the submission would be prioritized within pCODR.

9 How are decisions on procedural reviews communicated?

High-level details of any submitted procedural review request will be publicly posted on the pCODR section of the CADTH website.

If there are no grounds for a procedural review, this will be determined within 15 business days of the submitted date of an application for a procedural review, and it will be communicated on the pCODR section of the CADTH website that the pERC Final Recommendation can be implemented.

When a pERC Final Recommendation can be implemented, pCODR will issue a *Notification to Implement* a pERC Final Recommendation and this will be communicated on the pCODR section of the CADTH website.

The party who made the request will be informed by the CADTH President and CEO in writing of the following key procedural review decisions:

- After a procedural review request has been submitted, if the procedural review request has been accepted or not accepted.
- If accepted, whether the PAC panelists determine if the submission will be re-deliberated by pERC or if a *Notification to Implement* a pERC Final Recommendation will be issued without a re-deliberation of the submission.

The details and outcomes of the procedural review will be communicated in the pERC Final Recommendation.

10 How long does the procedural review process take?

A decision on whether or not to conduct a procedural review will take place within 15 business days of the submitted date of an application for a procedural review. The duration of the procedural review may vary, depending on the complexity and nature of the request.

APPENDIX A: pCODR Procedural Review Request Form

Date Procedural Review Request Submitted: _____

Final Recommendation for which Procedural Review is being Requested

Drug Name: _____

Indication: _____

Date pERC Final Recommendation Issued: _____

Information on Party making the Request

Organization: _____

Role in pCODR Review
Process: _____

Contact Name: _____

Contact
Email: _____

Contact
Phone: _____

Grounds for the Procedural Review Request

Please check the following grounds that may apply:

- pCODR failed to act in accordance with its procedures in conducting the review
- pERC failed to apply its deliberative framework in formulating recommendations.

Provide a detailed description and any relevant documentation of how pCODR failed to act in accordance with its procedures or how pERC failed to apply its deliberative framework. Relevant pCODR process steps and components of the pERC deliberative framework should be clearly identified (see the *pCODR Procedures Document*, which is available on the pCODR section of the CADTH website, www.cadth.ca/pcodr). This section should not exceed five pages.

Signature: _____

Date: _____