Frequently Asked Questions

A. Process-Related Questions

1. **Will the new requirements, including the development of a provisional algorithm, affect ongoing cancer drug products under review by the CADTH pan-Canadian Oncology Drug Review (pCODR) process?**

   No. The new requirements only apply to new pre-submission information forms received under the pCODR process on or after July 1, 2019.

   The Cancer Drug Implementation Advisory Committee under the Canadian Association of Provincial Cancer Agencies will continue to function for a period of time to support reviews of any submissions or resubmissions received prior to July 1, 2019.

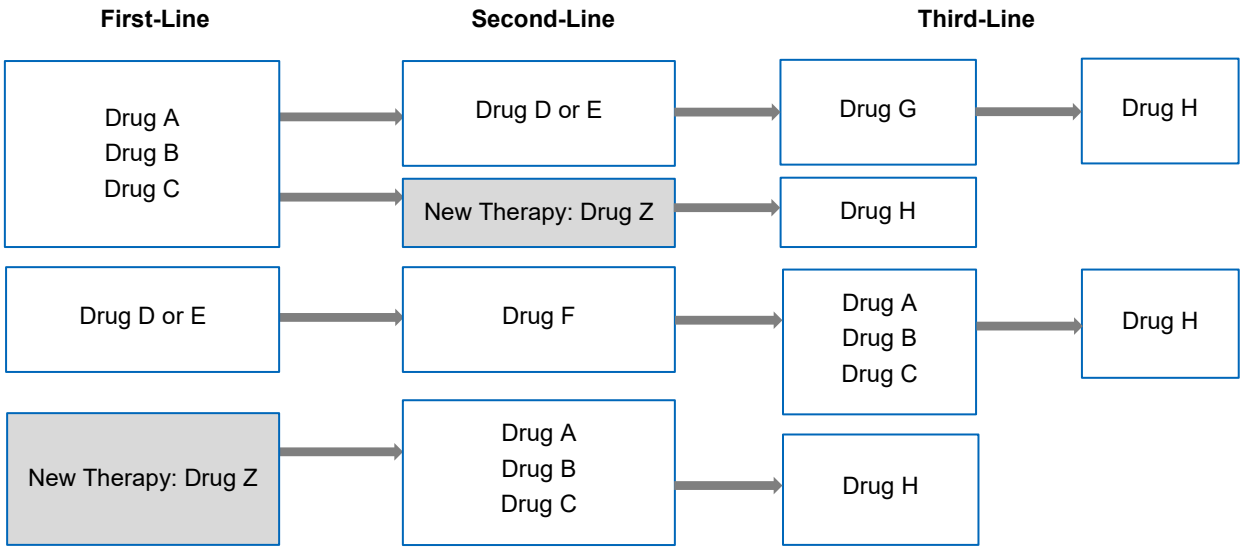
2. **Will drugs reviewed through the CADTH Common Drug Review (CDR) process used in the symptomatic management of cancer be affected by this process?**

   No. The new requirements only apply to drugs used for active treatment of cancer that are reviewed under the pCODR process.

3. **What is meant by a provisional algorithm?**

   A provisional algorithm will be developed for each new cancer drug or indication to indicate how the new therapy could be used compared to existing funded treatments, and the impact on the sequence of use for other existing funded therapies to better support jurisdictional decision-making for drug reimbursement. The provisional algorithm is current only at the time of publication and will not capture new drugs that may come to market in the future. It is not a comprehensive list of all available funded treatments, nor is it intended to be used as a treatment algorithm and should not be used as a substitute for the application of clinical judgment in the care of a particular patient or as a substitute for professional medical advice.

Illustrative Example of a Provisional Algorithm for a Cancer Indication With an Identified Mutation



4. **Is the provisional algorithm binding?**

   For greater clarity, the inclusion of a provisional algorithm does not presuppose the outcome of a reimbursement recommendation by the pCODR Expert Review Committee (pERC) and does not in any way bind participating jurisdictions to fund the new therapy or follow the provisional algorithm. As such, a provisional algorithm will only be included as part of the implementation considerations in the recommendation if pERC recommends reimbursement, or reimbursement with clinical criteria and/or conditions, to support jurisdictional decision-making and negotiations by the pan-Canadian Pharmaceutical Alliance. A provisional algorithm will not be published if pERC issues a "do not reimburse" recommendation.

5. **Will clinical experts be involved in the development of the provisional algorithm?**

   Yes, an ad hoc clinical panel may be established and/or an online survey may be distributed to the clinical leads affiliated with provincial cancer agencies with experience in the diagnosis and management of the condition for which the drug under review is indicated. This will support the development of a provisional algorithm. Some key factors for establishing an ad hoc clinical panel may include the potential for challenging implementation issues or the delivery of care considerations. In addition, the provisional algorithm will include information from registered clinicians, patients, and the submitter as part of the continuum of the process.

6. **Can the same physician be on an ad hoc clinical panel and also complete the clinician input?**

   Yes, the same physician may participate on an ad hoc clinical panel and also complete the clinician input. However, if a physician participates on an ad hoc clinical panel or has provided clinician input, that clinician will not be able to participate on the CADTH pCODR Clinical Guidance Panel for that specific drug and indication. A pERC member cannot participate on ad hoc clinical panel or a Clinical Guidance Panel or provide clinician input.

7. **Will ad hoc clinical panel members be required to complete a conflict of interest declaration?**

   The principles of transparency and disclosure are essential to ensuring the highest ethical standards and to maintaining the integrity of the CADTH pCODR process. By disclosing to CADTH any and all relevant personal, occupational, and financial connections or interests, participants in the pCODR process will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of the pCODR process. Similar to all participants in the process, an ad hoc clinical panel member will be required to complete a conflict of interest declaration. This information will be posted on the CADTH website; however, similar to members of the review team, the name of members of the ad hoc clinical panel, or clinical leads, will not be attributed to a specific submission or resubmission.

8. **Who can provide feedback?**

   As part of the pCODR process, any patient group(s), registered clinician(s) who provided input at the beginning of the review, the submitter, and the Provincial Advisory Group can provide feedback on an initial recommendation, including the provisional algorithm. Feedback on the provisional algorithm will only relate to the new drug under review and its place in therapy. Additional comments about other therapies will be considered out of the scope.

9. **Will there be changes made to the advisory committees for the pCODR program?**

   Yes, the Provincial Advisory Group membership has been expanded to include the Canadian Association of Provincial Cancer Agencies and two clinician members. This information is reflected in the terms of reference. There are no changes to the composition of pERC.

B. Submission-Related Questions

10. **How will the 120-day pre-submission advance notification period be applied?**

    A submitter must provide the pre-submission information using the online form at least 120 calendar days before the anticipated date of filing the complete pCODR submission or resubmission. If the anticipated submission-received date falls on a weekend or statutory holiday, the following business day will be applied. If a submitter fails to meet the 120 calendar days advance notification requirement, a submitter will be required to revise and refile the pre-submission information with the corrected information and the time will be reset back to day zero for the submitter until the requirement is fulfilled (i.e., the new starting date will be from the time of receipt of the refiled date of the *CADTH Pre-Submission Requirements Information Form*). The reset of the time will not apply to the updated information in the *CADTH Pre-Submission Requirements Information Form* filed at the time of the submission or resubmission.

    Pre-submission information should be provided to the pCODR program using the online form that follows. In order to ensure that the information remains secured, a submitter must be registered with the pCODR program in order to access the form through the secure Collaborative Workspaces site. Details about the registration process can be found here: https://www.cadth.ca/pcodr/registration

    - pCODR Pre-submission Information Requirements Form — Submissions
    - pCODR Pre-submission Information Requirements Form — Resubmissions

11. **How frequently will submitters be granted a pre-submission meeting?**

    Submitters will be required to provide a completed *CADTH Pre-submission Information Requirements Form* in order to receive a pre-submission meeting date. A pre-submission meeting will be scheduled by teleconference for each submission and resubmission, pending the completion of the *CADTH Pre-submission Information Requirements Form*. Submitters may request an in-person pre-submission meeting with the pCODR program, but this will be limited to one meeting in a six-month period in order to ensure fair access to CADTH staff and relevant experts (if appropriate) involved in the pCODR review process. All pre-submission meetings will be scheduled for a maximum of up to one hour.

12. What are the considerations when including comparators?

At the time of filing the pre-submission information form, a submitter will be required to include relevant comparators that, at a minimum, received an initial or final pERC recommendation, are undergoing negotiations through the pan-Canadian Pharmaceutical Alliance, or is publicly funded, including case-by-case funding. If this information is not included, a submission or resubmission will be deemed incomplete.

13. What are the requirements for a submission to be deemed complete and to be initiated into the review process?

At the time of filing the submission or resubmission, all relevant documents must be included. A submitter is encouraged to review the pCODR pre-submission, submission, and resubmission guidelines for the complete requirements. The timeline for the review will not be initiated until the submission or resubmission is deemed complete and the submission or resubmission will not enter in the review queue until the requirements are satisfied.

C. General Questions

14. Where can I find a complete description of the changes?

We encourage all stakeholders to review our updated procedure documents for a complete description of the changes:

- *pCODR Procedures*
- pCODR Pre-Submission, Submission and Resubmission Guidelines
- *pan-Canadian Oncology Drug Review Disclosure of Information Guidelines*.

We have also made administrative changes to the templates subsequently identified for the pCODR program to provide additional clarity and guidance to all stakeholders. We kindly ask that all stakeholders use these updated templates for new submissions to pCODR:

- Online pCODR Pre-submission Information Form – Submission and Resubmission
- Template for Summary Table Listing Submitted Non-Disclosable Information
- Template for pCODR Structured Summary of Economic Information for Disclosure
- Patient Input Template for CADTH CDR and pCODR Programs
- Stakeholder Feedback on a pCODR Expert Review Committee Initial Recommendation.

15. How will CADTH evaluate this new process addition?

CADTH intends to review this new process addition in one year from the implementation date and will consult with stakeholders as part of the evaluation.

16. Who should I contact if I have additional questions?

Please contact us at requests@cadth.ca for additional questions about the new requirements or about the CADTH pCODR process.