CADTH

Proposed Revisions to the Clinician Engagement Process for CADTH's pan-Canadian Oncology Drug Review Program

1. Proposal Objectives

CADTH is inviting stakeholder comments on the proposed revisions to the clinician engagement process for the pan-Canadian Oncology Drug Review (pCODR) program. The proposal is intended to customize the questions posed to clinicians so they can provide their experience on the unique aspects of their clinical practice to better inform the pCODR Expert Review Committee (pERC) deliberations and recommendations. The revisions also seek to extend the opportunity to oncology pharmacists and oncology nurses who meet the proposed criteria to participate in the clinician input and feedback process.

Highlights of the proposed revisions are summarized in section 3 of this document.

2. Background

In February 2016, CADTH launched a pilot project on clinician engagement for the pCODR program. As of December 31, 2017, we are pleased to report that we have 169 oncologists registered and 36 of 41 reviews (88%) have included clinician input.

A key guiding principle of the pCODR process is to support continuous process improvements. Based on feedback from a survey that included registered clinicians, as well as members of the Provincial Advisory Group and pERC, we heard that information from practising clinicians on how the drug would be used or how the drug is being used in their practice is valuable to pERC's deliberation and recommendation. In particular, information from the clinicians' experience with the drug is most helpful to inform implementation issues in cases where the information may not be apparent from the clinical trial data.

Currently, there is a standard template for submitting clinician input on a drug under review. There are five key questions plus a section for additional information. The current Registered Clinician Input on a Drug Review template is applied to all drugs under review. Information about the drug under review, including the funding request, is posted on the CADTH website and provided as a courtesy in an email notification.

3. Summary of Clinician Input and Feedback for the pCODR Process

A. Proposed Changes to Input Template and Questions

The pCODR Registered Clinician Input on a Drug Review template will be available on the CADTH website on the pCODR Drug Details webpage for registered clinicians. The link to the customized template will be provided to registered clinicians in the email notifications. The customized template will contain information specific to the drug and the indication that is being requested:

- Drug name
- Submitter's funding request or reimbursement criteria (which may or may not be the same as the Health Canada-approved indication)

- Citation or reference to the pivotal trial being submitted for review, and if available:
  - URL to the ClinicalTrials.gov trial description
  - URL to the trial publication* or to the abstract
- Provincial funding status and funding algorithms of current treatments, if available

Note: a subscription or a membership to some online journals is required to access the full article.

The Registered Clinician Input on a Drug Review template was recently updated on February 13, 2018 with the following sections and questions to provide additional clarity:

1. **Current Treatments**
   a. Please list the current standard treatment(s) in your jurisdiction for the defined patient population according to the funding request.
2. **Eligible Patient Population**
   a. In your opinion, will there be a high incident and/or prevalent patient population defined by the funding request?
   b. Does the patient population in the funding request meet the needs in clinical practice?
   c. Can the inclusion and exclusion criteria of the clinical trial be applied in clinical practice?
   d. What patient population would you prescribe the new treatment to and what patient population would you prescribe current treatments to? Please briefly explain your rationale.
3. **Relevance to Clinical Practice**
   a. In your opinion, how important would it be to have this new treatment (must have, nice to have, doesn't add anything to currently available therapy)? Is there an unmet need?
   b. How or when would you use the new treatment? Is there any population/subpopulation where you particularly want to use this drug?
   c. Have you prescribed the new treatment for the indication being reviewed (through clinical trials, manufacturer's access program, private drug insurance)?
   d. How is the new treatment for the indication being reviewed different than currently available treatments with respect to efficacy, safety, and tolerability?
4. **Companion Diagnostic**
   a. If companion diagnostic testing is required for the new drug, is the test available in your jurisdiction? Is it funded by your jurisdiction?
   b. What concerns, if any, do you have on the test and turn-around time for test results?
   c. Are there specific considerations to a testing algorithm that you think would be important to share with the pCODR Expert Review Committee?

The proposed template may have additional questions specific to the drug and indication for which input is being requested, in addition to the standard questions listed above. These questions may include, but are not limited to:

- Can the inclusion and exclusion criteria in the clinical trial be applied in clinical practice?
- Are there subgroups of patients not included in the clinical trial that need to be considered in the recommendation?

- Is the definition of disease progression in the clinical trial applicable in clinical practice?
- What are the contraindications to an existing chemotherapy? What groups of patients would be considered ineligible for an existing chemotherapy?
- If the new drug is to be given in combination with an existing drug, would you consider using the new drug in combination with any other drug in that therapeutic class for the requested indication?
- If the clinical trial excluded patients who were treated with X drug and progressed within Y months of last dose, in your experience, would this be a reasonable assumption in clinical practice?

B. Registration and Eligibility Criteria

For a clinician to be eligible to provide input on a submission through the pCODR process, a clinician must:

- be registered with the pCODR program
- be an actively practising physician currently treating the cancer type for the drug under review
- submit a declaration of conflict of interests (COI).

As part of the clinician input and feedback process, CADTH is also considering expanding the eligible clinicians to include oncology pharmacists and oncology nurses who are part of a multi-disciplinary team involved in the care of a cancer patient. Often, oncology pharmacists and oncology nurses are members of a provincial drug advisory or therapeutics committee. To be eligible, CADTH is proposing that oncology pharmacists and oncology nurses:

- register with the pCODR program
- be actively practising and be a current member of a provincial cancer drug advisory or cancer therapeutics committee (e.g., the Cancer Care Ontario Breast Cancer Drug Advisory Committee)
- provide their input as part of a joint submission with a registered clinician or a group of registered clinicians
- submit a declaration of COI.

C. Notification and Deadline Dates — No Change

About one month before the submitter's anticipated submission filing date, CADTH posts details of the pending submission on the CADTH website. Stakeholders, including registered clinicians, receive an email notification of the pending submission plus the deadline date for input.

Eligible clinicians must submit their input by 5:00 p.m. ET on the posted deadline date in order for the pCODR program to make use of the information to develop the review plan (i.e., protocol). Eligible clinicians who register with the pCODR program will receive an email indicating that the submitter has provided the submission and a reminder of the deadline date for input.

D. Method for Submitting Completed Templates — No Change

Completed input templates are submitted online through the CADTH Collaborative Workspace. The completed input templates are dropped into the corresponding drug space.

E. Process for Feedback on Initial Recommendation — No Change

Stakeholders have the opportunity to provide feedback on the pERC initial recommendation. Only registered clinicians or clinician groups who have provided input at the beginning of the review are eligible to provide feedback.

Registered clinicians will receive an email notification indicating the initial recommendation has been posted and opened for feedback. Feedback on the initial recommendation must be submitted using the pCODR Registered Clinician Feedback on a pERC Initial Recommendation template by 5:00 p.m. ET on the posted deadline date. Feedback is submitted online through the CADTH Collaborative Workspace, similar to the input process.

CADTH continues to foster relationships with the clinician community and believes that increasing the opportunity for input and feedback into the pCODR process will enhance the quality of our reviews and contribute to broader discussions about drug funding decisions in Canada.

Please submit your written comments on these proposed revisions by email to pcodrinfo@cadth.ca using this feedback template by **April 20, 2018** at 5:00 p.m. ET. All feedback submitted by the deadline will be carefully considered and used to inform the proposed changes to the clinician input and feedback processes. We thank you in advance for your interest.

Instructions for Providing Feedback

To be eligible to provide feedback on this proposal, please note the following:

- You must identify yourself — feedback provided by individuals who do not identify themselves will not be considered.
- Only one response per submitter will be considered. If more than one response is received, only the first response that is received will be considered.
- Feedback should be provided in a Microsoft Word document using a minimum of an 11-point font.
- The maximum length of feedback is two pages.
- Feedback should be presented clearly and succinctly. The issue(s) should be clearly stated and specific reference should be made as appropriate to the section of the document under discussion (i.e., page number, section title, and paragraph).
- Unless requested and otherwise agreed to by CADTH, all materials or comments received from submitters in response to the notice will be considered public information and may be used and disclosed by CADTH as part of its review. CADTH may disclose materials or comments, or summaries of them, to other interested parties during and after the feedback period.
- CADTH will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent, unless required by law. However, CADTH may use and disclose the content of an individual's submission to assist CADTH in its review.

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