

pan-Canadian Oncology Drug Review

Registered Clinician Input on a Drug Review

February 2018

**RECORD OF UPDATES**

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| **Update** | **Version** | **Reported on pCODR Website** |
| Original | February 2016 | February 1, 2016 |
| Revised | February 2018 | February 2018 |
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INQUIRIES

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# About Completing This Template

* The following template form should be used by the registered clinician(s) to submit input at the beginning of a drug review. Please note that there is a separate template for providing feedback on an initial recommendation.
* The clinician(s) **must be** [**registered**](https://drugreviewsadmin.cadth.ca/Landing/Register/Register.aspx?Lang=EN) **with the pCODR program** to provide input. (See <https://www.cadth.ca/pcodr/registration> for information on eligibility and registration.)
* The registered clinician(s) must also complete the [*pCODR Clinician Conflict of Interest Declarations Template*](#_Appendix_A:_pCODR) when providing input at the beginning of a drug review (see Appendix A of this document). While CADTH encourages collaboration among registered clinicians and that feedback submitted for a specific drug or indication be made jointly, each registered clinician must complete their own separate [*pCODR Clinician Conflict of Interest Declarations Template*](#_Appendix_A:_pCODR). For each drug and indication under review, a clinician may only submit once (e.g., if a clinician submits an individual input, that clinician should not be included in a joint submission for that same drug and indication).
* Please ensure that the input is in English, and that it is succinct and clear. Please use a minimum 11-point font and do not exceed six (6) typed, 8 ½″ by 11″ pages. If a submission exceeds six pages, only the first six will be considered.
* The registered clinician(s) 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 registered clinician(s) should not feel restricted by the space allotted on the form and can expand the tables in the template as required. The categories and questions outlined are only examples, to guide identification of relevant clinical factors for pERC’s consideration. CADTH’s pCODR program maintains the discretion to remove any information that may be out of scope of the review.
* It is important to note that scientific published references are not required, as pCODR has access to current scientific literature through the manufacturer’s submission, tumour groups, and a rigorous, independent literature search.
* The registered clinician(s) must be submitted by the **deadline date** for this drug, posted on the pCODR section of the CADTH website under [*Find a Review*](https://www.cadth.ca/node/79219/)so that it can be available in time to be fully used in the pCODR review process. If more than one submission is made by the same registered clinician(s), only the first submission will be considered.
* In addition to its use in the pCODR process, the information provided in this submission may be shared with the provincial and territorial ministries of health and Provincial cancer agencies that participate in pCODR, to use in their decision-making.

Should you have any questions about completing this form, please email [pcodrinfo@cadth.ca](mailto:pcodrinfo@cadth.ca)

# Information about the Registered Clinician

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| --- | --- | --- |
| **Name of the drug and indication:** | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Name of registered clinician:** | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Title:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Specialty (if applicable):** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Province:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Membership: (e.g., Provincial Cancer Agency, National Cancer Organization or Other)** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Phone:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Email:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

* 1. If this is a joint clinician submission, please list the names of the other clinicians, their title and specialty (if applicable). Please note all clinicians listed must also register with CADTH.
  2. Do you have experience with prescribing the drug under review?

□ Yes □ No

* 1. Confirmation of Authorship

I declare that I am the author of this submission and to confirm that no other parties have written or participated in the writing of the submission, except for those named above in this joint submission (if applicable).

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature | Date (YYYY/MM/DD) |

1. Key Questions for Clinician Input

## 2.1 Current Treatment(s) for this Type of Cancer

* Please list the current standard treatment(s) you use for the defined patient population in the funding request.

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## 2.2 Eligible Patient Population

* In your opinion, does the patient population in the funding request meet the needs in the clinical practice setting? Is there any population/sub-population where you specifically want to use this drug?
* Can the inclusion and exclusion criteria of the clinical trial be applied in clinical practice?
* Please describe which patient population would you prescribe the new drug under review if it becomes available and which patient population would you prescribe current treatments?
* Please briefly explain your rationale.

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## Relevance to Clinical Practice

* In your opinion, how important would it be to have this new treatment (e.g., must have, nice to have, doesn’t add anything to currently available therapy)? Is there an unmet need? How or when would you use the new treatment?
* Have you prescribed the new treatment for the indication being reviewed (e.g., through clinical trials, manufacturer’s access program, private drug insurance)? How is the new treatment, in your clinical opinion, different than currently available treatments with respect to efficacy, safety and tolerability?

Important Note: Scientific published references are not required, as pCODR has access to current scientific literature through the manufacturer’s submission and a rigorous, independent literature search.

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## 2.4 Sequencing and Priority of Treatments

* Please describe how the new treatment could be sequenced with current treatment(s), if appropriate.
* In your opinion, in the event that the drug under review becomes available for funding in your jurisdiction, would the new treatment be a replacement of current treatment(s) or another option?

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## 2.5 Companion Diagnostic Testing

* If companion diagnostic testing is required for the new drug, is the test available in your jurisdiction? Is it funded by your jurisdiction? What concerns, if any, do you have on the test and turn-around time for test results? Are there specific considerations to a testing algorithm that you think would be important to share with the pCODR Expert Review Committee?

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1. Additional Information

Please provide any additional information that would be helpful to pCODR. This could include suggestions for improving the clinician input process, indicating whether the questions are clear, etc.

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# Appendix A: pCODR Clinician Conflict of Interest Declarations

**Please Note: Each registered clinician must complete their own separate pCODR Clinician Conflict of Interest Declarations Template even if the submission is made jointly.**

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| **Name of registered clinician:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Name of drug and indication under review:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Conflict of Interest Declarations**

To maintain the objectivity and credibility of the pCODR process, all participants in the pCODR review process must disclose any conflicts of interest. A registered clinician must declare any potential conflicts of interest that may influence or have the appearance of influencing the information submitted. Conflict of interest declaration is requested for transparency — it does not negate or preclude the use of the clinician input.

Examples of conflicts of interest include, but are not limited to:

* financial support from the pharmaceutical industry or other entities e.g., educational or research grants, honoraria, gifts, and salary;
* affiliations or personal or commercial relationships with drug manufacturers or other interest groups.

***Section A: Payment Received***

1. Have you received any payments over the previous two years from any company or organization that may have direct or indirect interest in the drug under review?

|  |  |
| --- | --- |
| □ | Yes |
| □ | No |

If no, please go to Section B

1. What form of payment did you receive? (Check all that apply.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| □ | Advisory role (e.g., advisory boards, HTA submission advice) | □ | Program or Operating Funding (e.g., website) |  |
| □ | Conference attendance | □ | Research/educational grants |  |
| □ | Royalties | □ | Travel grants |  |
| □ | Gifts | □ | Sponsorship of Events |  |
| □ | Honoraria | □ | Other, please specify: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Please provide the names of companies and organizations and the amounts of the payments in the box below.

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***Section B: Holdings or Other Interests***

Have you received or is it in possession of stocks or options of more than $10,000 (excluding mutual funds) for organizations that may have a direct or indirect interest in the drug under review? If yes, please list in the table below.

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***Section C: Affiliations, personal or commercial relationships***

Do you have personal or commercial relationships either with a drug or health technology manufacturer (including such manufacturer’s parent corporation, subsidiaries, affiliates and associated corporations) or other interest groups? If yes, please provide the names of the companies and organizations and outline the nature of these relationships in the table below.

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I hereby certify that I have disclosed all relevant information with respect to any matter involving a Party that may place me in a real, potential or perceived conflict of interest situation.

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| --- | --- | --- |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_ | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |