CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

pan-Canadian Oncology Drug Review
Patient Engagement Guide

RECORD OF UPDATES

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INQUIRIES

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TABLE OF CONTENTS

RECORD OF UPDATES ..... **ii**

INQUIRIES ..... **iii**

2 Background **3**

3 pCODR Review Process **3**

4 Participating in the pCODR review process **4**

4.1 How can patients participate in the pCODR review process? 4

4.2 Who is eligible to provide patient input on a review and feedback on a recommendation? 4

4.3 How can individual patients participate in the pCODR review process? 5

4.4 How do members of patient groups (or individual patients or caregivers in cases where there is no patient group) register with pCODR? 5

4.5 How is patient group (or individual patient or caregiver in cases where there is no patient group) input on a drug review and feedback on recommendations used in the review process? 6

4.6 How do patient groups (or individual patients or caregivers in cases where there is no patient group) provide input on a drug review or feedback on an initial recommendation? 6

4.7 How do patient groups (or individual patients or caregivers in cases where there is no patient group) know when to submit input in the early stage of a review? 8

4.8 How many submissions can patient groups (or individual patients or caregivers in cases where there is no patient group) submit per drug? 8

4.9 How much time do patient groups (or individual patients or caregivers in cases where there is no patient group) have to provide input on a drug review? 9

4.10 How will patient groups (or individual patients or caregivers in cases where there is no patient group) know when to provide feedback on a pERC initial recommendation? 9

4.11 How much time do patient groups (or individual patients or caregivers in cases where there is no patient group) have to provide feedback on a pERC initial recommendation? 9

4.12 Tracking a pCODR review and recommendation 9

4.13 What are the steps to submit input on a drug review or feedback on a recommendation? 10

5 A guide to completing the pCODR Patient Group / Individual Patient or Caregiver Conflict of Interest Declarations **10**

6 A guide to completing the pCODR Patient Group Input / Individual Patient or Caregiver Input on a Drug Review Template **11**

6.1 Submission length 11

6.2 Information to complete the Patient Group Input Template 11

6.3 Completing the Patient Group Input Template 12

7 A guide to completing the pCODR Patient Group / Individual Patient or Caregiver Feedback on a pERC Initial Recommendation Template **14**

7.1 Submission length 14

7.2 Information to Complete the Recommendation Feedback Template 14

Appendix A: pCODR Patient Group Conflict of Interest Declaration **15**

Appendix B: Patient Input Template for CADTH CDR and pCODR Programs 16

Appendix C: pCODR Patient Group / Individual Patient or Caregiver Feedback on a pERC Initial Recommendation..... 19

1 pCODR Invites Patient Engagement

The role of the pan-Canadian Oncology Drug Review (pCODR), a program of the Canadian Agency for Drugs and Technologies in Health (CADTH), is to assess the clinical evidence and cost-effectiveness of cancer drugs, and to use this information to make recommendations to the provinces and territories to guide their drug funding decisions. Canadian patient groups registered with pCODR are invited to provide input about the cancer drugs under review by pCODR.

Patient input on drug reviews and feedback on recommendations is important to the pCODR drug review process as it ensures patients' experiences of living with cancer and undergoing treatment are routinely considered as part of the pCODR Drug Review Process. In particular, patient input means that those reviewing the drug can begin to appreciate the impact (both good and bad) that the drug under review may have on those taking it, as well as on those caring for patients living with cancer.

As part of the work to align CADTH's pCODR and the Common Drug Review programs, and to build upon the best practices of both review processes, pCODR will accept patient input from individual patients or caregivers when there is no patient group representing patients for the particular tumour or cancer type for which a drug under review is indicated.

IMPORTANT NOTE: Individual patients or caregivers who wish to provide input on a drug or indication are encouraged to first contact pCODR for direction by emailing pcodrinfo@cadth.ca

Please note that individual patient or caregiver input will **not** be accepted in cases where patient group(s) representing the particular tumour exist. In these cases, individual patients or caregivers who wish to provide input are encouraged to work with a patient group to have that group include the information in its submission.

See "Process in Brief" on the pCODR section of the CADTH website (www.cadth.ca/pcodr) for a full description of the pCODR process.

2 Background

While scientific and economic evidence has been used in making funding recommendations and decisions in Canada since the 1960s, the use of patient information (evidence) is recent with Quebec's Conseil du Médicaments, the Ontario Drug Benefit Program, the Common Drug Review and BC PharmaCare all having implemented patient involvement in their drug review processes, beginning in 2007. pCODR has considered these Canadian initiatives, as well as international processes, in developing its framework for patient engagement. Patient groups have also been involved in creating many aspects of the framework.

3 pCODR Review Process

The pCODR review process is a methodical and consistent review of the scientific and economic evidence, and of patient perspectives. In summary, each review follows these steps:

- A pharmaceutical manufacturer or a tumour group sends an "intent to submit" form to pCODR, signalling that they will be submitting a cancer drug for review.
- During this planning phase, key pieces of information are gathered from the manufacturer or tumour group intending to make the submission. Clinical & Economic

Guidance panels involved with the pCODR review are assembled or confirmed. Information is also gathered from registered clinician(s) and the Provincial Advisory Group (PAG).
    - The PAG provides primarily operational, as well as strategic advice, to ensure recommendations are useful to drug funding decision makers. The group consists of appointed representatives from each of the provincial Ministries of Health and provincial cancer care agencies participating in pCODR.
- The pharmaceutical manufacturer or tumour group then submits the drug for review.
- Within 10 business days of the submission being received by pCODR, patient groups (or individual patients or caregivers in cases where there is no patient group) and registered clinician(s) submit their input which is then incorporated into the reports being written by the economic guidance panel and the clinical guidance panel. This input is also sent directly to the pCODR Expert Review Committee (pERC). For more information on the guidance panels and pERC, please visit "About pCODR" on the pCODR section of the CADTH website (www.cadth.ca/pcodr).
- pERC posts their initial recommendation and patient groups can then submit their feedback on that initial recommendation, along with other eligible stakeholders.
- pERC then posts their final recommendation, taking into consideration the feedback provided on the initial recommendation.

Details on how to participate in the pCODR process are the focus of this guide. Details on the types of information to provide at each participation step of a drug review are found in the *Patient Input Template for CDR and pCODR* and the *Patient Group Feedback on a pERC Initial Recommendation* templates. Both templates are available under "Process in Brief" on the pCODR section of the CADTH website (www.cadth.ca/pcodr). For individual patients or caregivers who wish to provide input on a drug or indication are encouraged to first contact pCODR for direction by emailing pcodrinfo@cadth.ca.

4 Participating in the pCODR review process

4.1 How can patients participate in the pCODR review process?

- Registered patient groups (or individual patients or caregivers in cases where there is no patient group) are invited to provide written comments at two points in the pCODR review process:
    - Input can be provided early in the process for use in preparation of reports used by the pCODR Expert Review Committee (pERC) to develop its recommendations;
    - Feedback can be provided later in the review after pERC makes its initial recommendation.
- Patient groups (or individual patients or caregivers in cases where there is no patient group) can **only** provide feedback on the initial recommendation if they first provided input in the early stages of the review.

4.2 Who is eligible to provide patient input on a review and feedback on a recommendation?

- Canadian patient groups (or individual patients or caregivers in cases where there is no patient group) registered with pCODR are eligible to provide patient input on drug reviews. Input from patient y groups (or individual patients or caregivers in cases where there is no patient group) is accepted to ensure that the perspectives of many patients and caregivers are captured and reflected, collectively, in the pCODR review process.

- Patient groups (or individual patients or caregivers in cases where there is no patient group) must register to participate in the pCODR process. (See section 4.4 of this guide for information on how to register)
- While more than one registration per patient group can be made, only one input submission per group will be accepted. If more than one submission is made, only the first submissions will be considered.
- To be eligible to register with pCODR, patient groups must:
    1. Have a mandate that pre-dates the group's decision to register with pCODR.
    2. Have a means of contacting and communicating with its membership.
    3. Represent patients or caregivers impacted by cancer.
    4.
- At the time of registration, patient groups are requested to provide general information on potential sources of conflict of interest. At the time of providing input on a specific drug review, a more detailed conflict of interest declaration must be completed for each patient advocacy group. These more detailed declarations of conflict of interest are requested for transparency and will not preclude the input from being considered in a drug review.
- For individual patients or caregivers to be eligible to register with pCODR, there must be no patient group(s) available in Canada representing the particular condition. The individual patient or caregiver will be required to identify him or herself and provide conflict of interest information, including whether any assistance was provided in preparing the submission. The name of the author will not be made publicly available.
- Patient groups (or individual patients or caregivers in cases where there is no patient group) are **only eligible to** provide feedback on the initial recommendation if they first provided input in the early stages of the review.

4.3 How can individual patients participate in the pCODR review process?

- Individual patients who wish to provide comments or input are encouraged to contact a patient group representing their diagnosis, to request that their information be included with that group's submission.
- If there is no patient group for the particular tumour, patients should contact pCODR for direction by emailing pcodrinfo@cadth.ca.

4.4 How do members of patient groups (or individual patients or caregivers in cases where there is no patient group) register with pCODR?

- Members of patient groups (or individual patients or caregivers in cases where there is no patient group) go to the "pCODR Patient Input and Feedback" page on the pCODR website (www.cadth.ca/pcodr).
- For patient groups, the member confirms that the group meets the eligibility criteria for patient groups (see section 4.1 of this guide for eligibility criteria).
- For individual patients or caregivers, the patient or caregiver confirms that there is no patient group(s) available in Canada representing the specific tumour and to complete the eligibility criteria for individual patients or caregivers (see section 4.1 of this guide for eligibility criteria).
- The group member (or individual patient or caregiver in cases where there is no patient group) completes the online registration request form and submits it to pCODR. (Please note: Group members can check pCODR's online list of registered groups to determine whether a member(s) of your group has already registered.)

The list is available under "Submit and Contribute" on the pCODR section of the CADTH website.

- pCODR will email the group member (or individual patient or caregiver in cases where there is no patient group) a unique link to pCODR's registration page.
- The group member (or individual patient or caregiver in cases where there is no patient group) completes the registration form and is provided with a username.
- The group member (or individual patient or caregiver in cases where there is no patient group) is required to send an email notification to pCODR indicating that they have completed their registration and notifying pCODR of their username.
- The group member (or individual patient or caregiver in cases where there is no patient group) can log in to the secure pCODR site as soon as they receive confirmation back from pCODR that their registration has been completed.

If group members (or individual patient or caregiver in cases where there is no patient group) have any questions regarding the process, do not receive the email with the link to the Registration page, do not receive the confirmation email or are unable to login, please contact support@cadth.ca.

4.5 How is patient group (or individual patient or caregiver in cases where there is no patient group) input on a drug review and feedback on recommendations used in the review process?

- Receiving patient group (or individual patient or caregiver in cases where there is no patient group) input early in the review process allows pCODR to use the information to establish the plan (protocol) for conducting the review. It is important to incorporate outcomes and issues that are important to patients, into that plan.
- In addition to its use in the pCODR process, the information provided in patient group (or individual patient or caregiver in cases where there is no patient group) submissions may be shared with the federal drug plans, provincial and territorial ministries of health, and cancer agencies that participate in pCODR, for use in their decision-making. Any patient-specific personal information will be removed.
- Obtaining feedback from patient groups (or individual patient or caregiver in cases where there is no patient group) on an initial recommendation allows the pCODR Expert Review Committee (pERC) to further consider outcomes and issues that are important to patients and to improve the clarity of its recommendations. It is important to note that the initial recommendation may or may not change following further pERC deliberations, based on the feedback of patient groups (or individual patient or caregiver in cases where there is no patient group) and other stakeholders.

4.6 How do patient groups (or individual patients or caregivers in cases where there is no patient group) provide input on a drug review or feedback on an initial recommendation?

- Registered patient groups (or individual patient or caregiver in cases where there is no patient y group) are invited to provide written input at two points in the pCODR review process: early in the process for use in preparation of reports used by the pCODR Expert Review Committee (pERC) to develop its recommendations; and after pERC makes its initial recommendation.

- Note that only one input per patient group (or one input from individual patient or caregiver in cases where there is no patient group), per review is accepted. If more than one input is received per patient group (or individual patient or caregiver in cases where there is no patient group), only the first submission from that group will be considered.
- Patient groups (or individual patient or caregiver in cases where there is no patient group) can **only** provide feedback on the initial recommendation if they first provided input in the early stages of the review.
- For each cancer drug that pCODR reviews, early in the review process, patient groups (or individual patient or caregiver in cases where there is no patient group) can provide perspectives on the experience of living with cancer and the impact of the cancer drug under review, on patients' lives.
    - This information, which gets incorporated into the guidance reports, is used to identify health outcomes and issues that are important to patients, and to inform the plan (protocol) that will be followed to review the cancer drug.
    - The clinical and economic guidance reports, with patient group input incorporated, are used by pERC in making its recommendations.
    - The patient group (or individual patient or caregiver in cases where there is no patient group) input is also directly shared with the pERC for consideration along with other information it must consider.
- Patient groups (or individual patient or caregiver in cases where there is no patient group) that provided input early in the pCODR process for use in the preparation of the guidance reports have an opportunity to provide feedback on the initial recommendation before it is finalized and issued to the participating federal drug plans, ministries of health and provincial cancer agencies. The template is available under "Process in Brief" on the pCODR section of the CADTH website (www.cadth.ca/pcodr).
- Patient groups must provide input on a submission by completing the *Patient Input Template for CDR and pCODR* which outlines the type of information that pCODR requires for the review process. Patient group input must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.
- Similarly, individual patients or caregivers must provide input on a submission by completing the above noted template which outlines the type of information that pCODR requires for the review process. Individual patient or caregiver input must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.
- If patient groups wish to provide feedback on the initial recommendation, and have provided input in the early stages, they must complete the *pCODR Patient Group Feedback on a pERC Initial Recommendation* template which outlines the type of feedback that pERC looks for regarding initial recommendations. Similarly, if individual patients or caregivers wish to provide feedback on the initial recommendation, and have provided input in the early stages, they must complete the feedback template which outlines the type of feedback that pERC looks for regarding initial recommendations. Feedback must be submitted within 10 business days of the pERC initial recommendation being posted on the pCODR section of the CADTH website. The template is available under "Process in Brief" on the pCODR section of the CADTH website (www.cadth.ca/pcodr).
- Two patient members and one patient alternate member serve on pERC. Patient members are selected based on their demonstration of personal knowledge of, experience with and understanding of issues related to cancer and its management (among other qualifications). They present the information provided by patient groups (or individual patient or caregiver in cases where

there is no patient group) directly to other members of the pCODR Expert Review Committee, along with participating with other members in the Committee's examination of the evidence as it deliberates to develop a recommendation.

4.7 How do patient groups (or individual patients or caregivers in cases where there is no patient group) know when to submit input in the early stage of a review?

- pCODR lists all drugs under review, and their corresponding deadlines for patient group (or individual patient or caregiver in cases where there is no patient group) input on a drug review and for patient group (or individual patient or caregiver in cases where there is no patient group) feedback on a pERC initial recommendation, on the pCODR section of the CADTH website under "Find A Review" (www.cadth.ca/pcodr).
- Patient groups (or individual patients or caregivers in cases where there is no patient group) can also monitor this site for upcoming (pending) drug reviews.
- In addition, pCODR emails all registered patient group members (or registered individual patient or caregiver in cases where there is no patient group) to advise them of a pending or received drug submission and the deadline date for providing input. These email notifications will typically be sent one month in advance of the expected submission date confirmed by the drug manufacturer or tumour group.
    - *Pending submissions from drug manufacturers and tumour groups*: pCODR has requested that manufacturers and tumour groups (the organizations responsible for initiating a submission), provide notification at least 120 calendar days in advance of filing a submission. As the intended submission date draws closer (about one month in advance), the submitter is asked to re-confirm the planned date of submission to pCODR. Once confirmed, pCODR will add the submission to the Drug Review Schedule and send e-mail alerts to all registered patient group members (or registered individual patient or caregiver in cases where there is no patient group). This gives patient group members (or individual patients or caregivers in cases where there is no patient group) lead time to prepare their patient input submission. pCODR posts the name of the drug, its indication, the name of the manufacturer (and tumour group if applicable) and the tentative deadline for patient group (or individual patients or caregivers in cases where there is no patient group) input. Once the pending submission is actually received, the tentative deadline for providing patient group (or individual patients or caregivers in cases where there is no patient group) input is replaced with a confirmed deadline.
    - *Received drug submissions*: pCODR posts the names of all drug submissions received, the names of the manufacturers, and the indication for the drugs and the deadline for submitting patient group (or individual patients or caregivers in cases where there is no patient group) input.

4.8 How many submissions can patient groups (or individual patients or caregivers in cases where there is no patient group) submit per drug?

Only one submission per drug will be accepted from each patient group, even if multiple members of the group are registered with the pCODR program. In the case of multiple submissions from a single group or individual patient or caregiver in cases where there is no patient group, only the first submission will be considered.

4.9 How much time do patient groups (or individual patients or caregivers in cases where there is no patient group) have to provide input on a drug review?

- Patient groups (or individual patients or caregivers in cases where there is no patient group) are asked to provide input within 10 business days of pCODR receiving a drug submission. Best efforts are made by pCODR to notify registered patient groups (or registered individual patient or caregiver in cases where there is no patient group) when confirmation of a pending drug review (about one month in advance) is received from a potential submitter, so that patient groups (or individual patients or caregivers in cases where there is no patient group) have as much notice as possible about a pending drug review. Specific deadlines for patient group (or individual patients or caregivers in cases where there is no patient group) input are posted on the pCODR section of the CADTH website.
- Patient group (or individual patient or caregiver in cases where there is no patient group) input must be submitted to the pCODR program by 5 P.M. Eastern Time on the day of the posted deadline.

4.10 How will patient groups (or individual patients or caregivers in cases where there is no patient group) know when to provide feedback on a pERC initial recommendation?

pERC Initial Recommendations and the deadline for stakeholder feedback on initial recommendations are posted under "Find a Review" on the pCODR section of the CADTH website (www.cadth.ca/pcodr). In addition, patient groups (or registered individual patient or caregiver in cases where there is no patient group) will be advised by email when the initial recommendation is posted.

The pCODR section of the CADTH website has templates which outlines the type of feedback that the pCODR Expert Review Committee looks for regarding initial recommendations; please see the *Patient Group Feedback on a pERC Initial Recommendation* template for patient groups. Patient groups (or individual patients or caregivers in cases where there is no patient group) must use this template to provide feedback. The template is available under "Process in Brief" on the pCODR section of the CADTH website (www.cadth.ca/pcodr). Patient group (or individual patient or caregiver in cases where there is no patient group) feedback must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.

4.11 How much time do patient groups (or individual patients or caregivers in cases where there is no patient group) have to provide feedback on a pERC initial recommendation?

Patient groups (or individual patients or caregivers in cases where there is no patient group) are asked to provide feedback within 10 business days of the pERC Initial Recommendation being posted on the pCODR section of the CADTH website. Patient group (or individual patients or caregivers in cases where there is no patient group) feedback must be submitted to the pCODR program by 5 P.M. Eastern Time on the day of the posted deadline.

4.12 Tracking a pCODR review and recommendation

The progress of a drug through the pCODR review process may be followed on the pCODR section of the CADTH website on the "Find a Review" page. (See www.cadth.ca/pcodr).

4.13 What are the steps to submit input on a drug review or feedback on a recommendation?

1. Register the patient group (or individual patient or caregiver in cases where there is no patient group) with pCODR, by completing the Online Registration Request form under "Submit and Contribute" on the pCODR section of the CADTH website (www.cadth.ca/pcodr). As this step can take between 2-5 business days to complete, groups (or individual patient or caregiver in cases where there is no patient group) are encouraged to register well before the deadline to provide input.

2. For patient groups, if submitting input into the early stages of the review, download and complete the *Patient Input Template for CDR and pCODR* from the pCODR section of the CADTH website. This document can be found under "Process in Brief" on the pCODR section of the CADTH website.

3. Submit the completed document on-line through the pCODR section of the CADTH website by the specified deadline for the drug under review. You must be logged in, using your username and password, to submit on-line. Alternatively, the completed forms can be emailed to: submissions@pcodr.ca. Patient group (or individual patient or caregiver in cases where there is no patient group) input must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.

4. For submitting feedback on an initial recommendation, download and complete the following document: the *pCODR Patient Group Feedback on a pERC Initial Recommendation* template. The template is available under "Process in Brief" on the pCODR section of the CADTH website. Patient group (or individual patient or caregiver in cases where there is no patient group) feedback must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.

5. Submit the single completed document on-line through the pCODR section of the CADTH website by the specified deadline. You must be logged in, using your username and password, to submit on-line. Alternatively, the completed forms can be emailed to: submissions@pcodr.ca.

All input and feedback that is received will be acknowledged by e-mail to the registered member.

5 A guide to completing the pCODR Patient Group / Individual Patient or Caregiver 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. All participants must declare potential, perceived or real conflicts 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 patient group (or individual patient or caregiver in cases where there is no patient group) input. Patient groups (or individual patient or caregiver in cases where there is no patient group) must declare any potential conflicts of interest.

- At the time of registration with pCODR, patient groups (or individual patient or caregiver in cases where there is no patient group) are requested to provide general information on potential sources of conflict of interest. At the time of providing input on a specific drug review, a more detailed conflict of interest declaration must be completed for each patient group (or individual patient or caregiver in cases where there is no patient group).
- The detailed declaration is done by completing the *Patient Group Conflict of Interest Declaration Form*. This form requests the nature of financial support provided to the patient groups (e.g., payments, grants, holdings) and the estimated monetary value of these supports over the past two years.
- Details of the nature of supports received will be posted on the pCODR section of the CADTH website, however, monetary values will not be disclosed.

6 A guide to completing the pCODR Patient Group Input / Individual Patient or Caregiver Input on a Drug Review Template

6.1 Submission length

Patient group (or individual patient or caregiver in cases where there is no patient group) input should be clear, concise and at this time, only in English. It must be kept to a maximum of eight (8) typed pages (with a minimum 11-point font). If a submission exceeds eight pages, only the first eight will be considered. The appendix is NOT included in the eight (8) typed page limit for the *Patient Input Template for CDR and pCODR*.

6.2 Information to complete the Patient Group Input Template

Patient groups must be registered with pCODR to provide input on a drug review. To register with pCODR please go to "Submit and Contribute" on the pCODR section of the CADTH website, complete the online registration request form and submit the completed form to pCODR (See the *pCODR Patient Engagement Guide* for information on eligibility and registration).

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. Patient group input (or individual patient or caregiver in cases where there is no patient group) **must be submitted to pCODR by 5 P.M. Eastern Time on the day of the posted deadline.**

In addition to its use in the pCODR process, the information provided in your submission may be shared with the federal drug plans, provincial and territorial ministries of health and provincial cancer agencies that participate in the pCODR program, to use in their decision-making. Any patient-specific personal information will be removed.

Information about pCODR may be found at www.cadth.ca/pcodr. For more information regarding patient input into the pCODR drug review process, see the *pCODR Patient Engagement Guide*. Should you have any questions about completing this form, please email: pcodrinfo@cadth.ca.

6.3 Completing the Patient Group Input Template

1. **About Your Patient Group**: We're looking to understand who your group is and what your group does. You might describe your group's membership or audience base and geographic reach.

2. **Information Gathering:** Please describe how you gathered the patient perspectives shared in the input submission. Many different types of methods are appropriate. Depending on resources, groups might use one method or multiple methods. Groups can:
   - Interview patients, caregivers, or both
   - Draw on previous interviews, conversations or comments from patients
   - Draw from blog posts, on-line forums and chat rooms
   - Prepare, promote and gather survey data from the patient community in Canada, or internationally
   - Draw from past surveys and reports prepared by the patient group, or others

3. **Disease experience:** This section seeks perspectives on how the cancer (related to the drug under review) affects your day-to-day lives, as well as how it impacts those who give care to you as a patient. Consider:
   - Physical impacts
   - Limitations on activities (such as work, school, sports, hobbies)
   - Stigma or embarrassment
   - Impact on relationships with family members
   - Impact of relationship with friends and colleagues
   - Emotional impacts (such as self-esteem)

   We understand that each individual's experience with an illness is unique, and that experience might vary from day to day. Reading about different individual's best days and worst days offers a greater understanding of that variability than a focus on the worst days alone. Direct quotations can powerfully communicate a patient's or caregiver's story and illustrate an idea, although too many direct quotations can take away from your summary of the disease experience.

4. **Experience with Currently Available Treatments:** This section seeks perspectives on currently available therapy and its advantages and disadvantages, as well as whether there are subgroups of patients who are in greater need of this therapy than the overall population of patients with this cancer. Please provide any information that would be helpful for pCODR and the pCODR Expert Review Committee to understand your experience as a patient living with or caring for a person with this cancer. Please be specific in linking benefits, side effects and any difficulties to named treatments.

5. **Improved Outcomes:** Improvements might be small – less nausea, greater predictability of length of effectiveness, fewer appointments to receive treatment – and make a tremendous difference to patients' and their families' lives. We imagine that patient views will not change substantially from review to review, of the same disease area, unless the treatment

landscape changed dramatically. Groups or individuals do not need to know anything about the drug in review to comment in this section.

6. **Experience with Drug Under Review:** This section asks for comments on the anticipated impact this drug may have. For those who have used the drug being reviewed, this section seeks your perspective on how the drug meets your needs and preferences and those of the caregivers, your perceived advantages and disadvantages over currently available therapies and medicines, and the impact the drug may have on patients' and caregivers' lives. To find patients with experience, some groups contact the clinical trial investigators; others speak with patients outside of Canada. We'd like to hear patient feedback when improvements were slight or substantial, when patients experienced problems of any kind or saw mixed results.

7. **Companion Diagnostic Test:** If the drug in review has a companion diagnostic test, it will be indicated on CADTH's website. Only complete this section if there is a companion diagnostic test.

8. **Biosimilar:** If the drug in review is a biosimilar it will be indicated on CADTH's website. Only complete this section if the drug is a biosimilar. This section replaces CADTH's earlier template specific for biosimilars.

9. **Anything else:** This section provides the opportunity to submit any other information that would be helpful to the pCODR and the pCODR Expert Review Committee deliberations.

pCODR is keen to learn from experience and to develop a user-friendly patient group input process. We would be grateful for comments on these materials, the templates or any other aspect of providing input. Your comments may be submitted to pcodrinfo@cadth.ca.

7 A guide to completing the pCODR Patient Group / Individual Patient or Caregiver Feedback on a pERC Initial Recommendation Template

7.1 Submission length

Patient group (or individual patient or caregiver in cases where there is no patient group) feedback should be clear, concise and at this time, only in English. Feedback on the initial pERC 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 pERC.

7.2 Information to Complete the Recommendation Feedback Template

7.2.1 Section 3.1 - Comments on the Initial Recommendation

This section seeks to understand if patient groups (or individual patient or caregiver in cases where there is no patient group) agree, in whole or in part, with the initial pERC recommendation and the specifics as to why such an opinion is held. It also seeks to understand if patient groups (or individual patient or caregiver in cases where there is no patient group) are in favour of seeking further deliberation and reconsideration of the recommendation by pERC using the feedback provided. If further deliberation is not felt to be needed or desirable, the recommendation could proceed to a final recommendation; this would need the agreement of all stakeholders providing feedback to proceed with finalizing the recommendation.

Lastly, this section is an opportunity for pERC to learn if there is any lack of clarity in the recommendation document, and if see what could be done to improve the clarity of the information in the initial recommendation.

7.2.2 Section 3.2 – Comments related to Patient Group Input (or individual patient or caregiver in cases where there is no patient group)

It is important for pERC to know if it has understood the patient group (or individual patient or caregiver in cases where there is no patient group) input provided in the early stages of the review process and that this understanding is accurately reflected in the summary of its deliberations. It also allows patient groups (or individual patient or caregiver in cases where there is no patient group) to reflect on whether they feel their initial input was adequately addressed in the initial recommendation.

Lastly, this section provides the opportunity to submit any other feedback that would be helpful to the pCODR and the pCODR Expert Review Committee deliberations. It is important to note that new evidence would not be considered at this part of the review process, however, it may be eligible for a Resubmission. The pCODR program can help determine if new information could be eligible for a Resubmission.

pCODR would be grateful for comments on the feedback template or on any other of the approaches used to strengthen patient engagement in the review process. Your comments may be submitted to pcodrinfo@cadth.ca.

Appendix A: pCODR Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	$0 to 5,000	$5,001 to 10,000	$10,001 to 50,000	In Excess of $50,000

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name:

Position:

Patient Group:

Date:

Appendix B: Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	
Name of the Patient Group	
Author of the Submission	
Name of the Primary Contact for This Submission	
Email	
Telephone Number	

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways?

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

8. Biosimilar

If the drug in review is a biosimilar (also known as a subsequent entry biologic), please outline any expectations or concerns held by patients, caregivers, and families about the biosimilar. If the biosimilar was less expensive than the brand name drug, what would the impact be for patients, caregivers, and families?

9. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

Appendix C: pCODR Patient Group / Individual Patient or Caregiver Feedback on a pERC Initial Recommendation

About Completing This Template

pCODR invites those registered patient groups (or individual patient or caregiver in cases where there is no patient group) that provided input on the drug under review **prior** to deliberation by the pCODR Expert Review Committee (pERC), to also 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 patient groups (or individual patient or caregiver in cases where there is no patient group) agree or disagree 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, including registered patient groups (or individual patient or caregiver in cases where there is no patient group), agree with the recommended clinical population described in the initial recommendation, it will proceed to a final pERC recommendation two (2) business days after the end of the feedback deadline date. 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 federal drug plans, 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 registered patient groups (or individual patient or caregiver in cases where there is no patient group) that provided input at the beginning of the review of the drug can provide feedback on the initial recommendation.

- Please note that only one submission per patient group is permitted. This applies to those groups with both national and provincial / territorial offices; only one submission for the entire patient group will be accepted. If more than one submission is made, only the first submission will be considered. This condition applies equally to individual patient or caregiver in cases where there is no patient group.
- Individual patients should contact a patient group that is representative of their condition to have their input added to that of the group. If there is no patient

group for the particular tumour, patients should contact pCODR for direction at pcodrinfo@cadth.ca.

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

c) The template for providing *pCODR Patient Group/Individual Patient or Caregiver Feedback on a pERC Initial Recommendation* can be downloaded from the pCODR section of the CADTH 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. Patient groups (or individual patient or caregiver in cases where there is no patient group) 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 to their group/individual. Similarly, groups/individuals 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 initial pERC recommendations **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 new references. New evidence is not considered during 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 program.

h) The comments must be submitted via a Microsoft Word (not PDF) document by logging into www.cadth.ca/pcodr and selecting "Submit Feedback" by the posted deadline date.

i) Patient group (or individual patient or caregiver in cases where there is no patient group) feedback must be submitted to pCODR by **5 P.M. Eastern Time** on the day of the posted deadline.

j) If you have any questions about the feedback process, please e-mail pcodrinfo@cadth.ca. For more information regarding patient input into the pCODR drug review process, see the *pCODR Patient Engagement Guide*. Should you have any questions about completing this form, please email pcodrinfo@cadth.ca

Note: Submitted feedback is publicly posted and also may be used in other documents available to the public. The confidentiality of any submitted information at this stage of the review cannot be guaranteed.

Feedback on pERC Initial Recommendation

Name of the drug indication(s): _____

Name of registered patient group/individual patient or caregiver*: _____

Contact person*: _____

Title: _____

Phone: _____

Email: _____

**pCODR may contact this person if comments require clarification. Contact information will not be included in any public posting of this document by pCODR. Name of individual patient or caregiver will not be included in any public posting of this document by pCODR.*

1 Comments on the Initial Recommendation

a) Please indicate if the patient group agrees or disagrees with the initial recommendation:

____ agrees ____ agrees in part ____ disagree

Please explain why the patient group (or individual patient or caregiver in cases where there is no patient group) agrees, agrees in part or disagrees with the initial recommendation.

b) Notwithstanding the feedback provided in part a) above, please indicate if the patient group (or individual patient or caregiver in cases where there is no patient group) would support this initial recommendation proceeding to final pERC recommendation ("early conversion"), which would occur two (2) business days after the end of the feedback deadline date.

____ 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

2 Comments Related to Patient Group Input / Individual Patient or Caregiver Input

Please provide feedback on any issues not adequately addressed in the initial recommendation based on patient group input (or individual patient or caregiver in cases where there is no patient group) provided at the outset of the review on outcomes or issues important to patients that were identified in the submitted patient input. Please note that new evidence will be not considered during 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.

Examples of issues to consider include: what are the impacts of the condition on patients' daily living? Are the needs of patients being met by existing therapies? Are there unmet needs? Will the agents included in this recommendation affect the lives of patients? Do they have any disadvantages? Stakeholders may also consider other factors not listed here.

Page Number	Section Title	Paragraph, Line Number	Comments related to initial patient group / individual patient or caregiver input

3 Additional comments about the initial recommendation document

Please provide any additional comments:

Page Number	Section Title	Paragraph, Line Number	Additional Comments