Feedback on Draft Recommendation

**Instructions for Interested Parties**

This template is for eligible interested parties to provide feedback and comments on draft reimbursement recommendations. Draft recommendations are available for feedback for 10 business days. Separate from the draft recommendation are the draft report and supplemental material which are made available for information only and are not subject to feedback.

Canada’s Drug Agency (CDA-AMC) will only consider feedback received from eligible interested parties, including the sponsor, patient groups, clinician groups, and the participating drug programs. Individuals interested in providing feedback should contact the relevant patient and clinician organizations. This template may also be used by eligible industry parties to provide feedback on draft recommendations from the non-sponsored review process (i.e., any current or future Drug Identification Number [DIN] holders for the drug under review).

The sponsor may use this form to provide general feedback on the draft recommendation if they are not filing a request for reconsideration. If the sponsor is filing a request for reconsideration, they must complete the [reconsideration template](https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Reconsideration_Template.docx) and should not complete this template.

All submitted feedback must be disclosable and will be posted on the CDA-AMC website.

If you have questions, please [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

Before Completing the Template:

Please review the following to ensure an understanding of the reimbursement review procedures:

* [Procedures for Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf)
* Pharmaceutical Review Updates for any applicable information.

Completing the Template:

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).

Comments should be restricted to the content of the draft recommendation and should not contain any language that could be considered disrespectful, inflammatory or could be found to violate applicable defamation law.

Feedback must be based on the information that was considered by the expert committee in making the draft recommendation. No new evidence will be considered at this part of the review process.

Feedback must not exceed 3 pages in length, using a minimum 11-point font on 8.5″ by 11″ paper. If comments exceed 3 pages, the feedback will not be accepted. References may be provided separately; however, these cannot be related to new evidence.

**Patient groups must complete Appendix 1.**

**Clinician groups must complete Appendix 2**.

Filing the Completed Template:

The feedback must be provided in Microsoft Word format by using the Submit link next to the drug on the [Open Calls](https://www.cda-amc.ca/open-calls-input-and-feedback-0) page. To ensure fairness in the reimbursement review procedures, all feedback must be received by the deadline posted on the CDA-AMC website.

Feedback on Draft Recommendation

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| **Interested party information** |  |
| Project number |  |
| Brand name (generic)  |  |
| Indication(s) |  |
| Organization  |  |
| Contact informationa | Name: |
| **Interested party agreement with the draft recommendation**  |
| 1. **Does the interested party agree with the committee’s recommendation.**
 | Yes |[ ]
|  | No |[ ]
| Please explain why the interested party agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. |
| **Expert committee consideration of the input** |
| 1. **Does the recommendation demonstrate that the committee has considered the input that your organization provided?**
 | Yes |[ ]
|  | No |[ ]
| If not, what aspects are missing from the draft recommendation? |
| **Clarity of the draft recommendation** |
| 1. **Are the reasons for the recommendation clearly stated?**
 | Yes |[ ]
|  | No |[ ]
| If not, please provide details regarding the information that requires clarification. |
| 1. **Have the implementation issues been clearly articulated and adequately addressed in the recommendation?**
 | Yes |[ ]
|  | No |[ ]
| If not, please provide details regarding the information that requires clarification. |
| 1. **If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?**
 | Yes |[ ]
|  | No |[ ]
| If not, please provide details regarding the information that requires clarification. |

a CDA-AMC may contact this person if comments require clarification.

**Appendix 1. Conflict of Interest Declarations for Patient Groups**

* To maintain the objectivity and credibility of the CDA-AMC drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
* This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
* CDA-AMC may contact your group with further questions, as needed.
* Please see the *Procedures for Drug Reimbursement Reviews* for further details.

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| **A. Patient Group Information** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  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. |
| **B. Assistance with Providing Feedback** |
| 1. **Did you receive help from outside your patient group to complete your feedback?**
 | No | [ ]  |
|  | Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| 1. **Did you receive help from outside your patient group to collect or analyze any information used in your feedback?**
 | No | [ ]  |
|  | Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| **C. Previously Disclosed Conflict of Interest** |
| 1. **Were conflict of interest declarations provided in patient group input that was submitted at the outset of the review and have those declarations remained unchanged? If no, please complete section D below.**
 | No | [ ]  |
|  | Yes | [ ]  |
| **D. New or Updated Conflict of Interest Declaration** |
| 1. **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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

**Appendix 2. Conflict of Interest Declarations for Clinician Groups**

* To maintain the objectivity and credibility of the CDA-AMC drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
* This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
* CDA-AMC may contact your group with further questions, as needed.
* Please see the *Procedures for Drug Reimbursement Reviews* for further details.
* For conflict of interest declarations:
	+ Please 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.
	+ Please note that declarations are required for each clinician that contributed to the input.
	+ If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
	+ Please add more tables as needed (copy and paste).
	+ All new and updated declarations must be included in a single document.

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| **A. Assistance with Providing the Feedback** |
| 1. **Did you receive help from outside your clinician group to complete this submission?**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| 1. **Did you receive help from outside your clinician group to collect or analyze any information used in this submission?**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please detail the help and who provided it. |
| **B. Previously Disclosed Conflict of Interest** |
| 1. **Were conflict of interest declarations provided in clinician group input that was submitted at the outset of the review and have those declarations remained unchanged? If no, please complete section C below.**
 | No | [ ]  |
| Yes | [ ]  |
| If yes, please list the clinicians who contributed input and whose declarations have not changed:* Clinician 1
* Clinician 2
* *Add additional (as required)*
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**C. New or Updated Conflict of Interest Declarations**

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| **New or Updated Declaration for Clinician 1** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| 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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

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| **New or Updated Declaration for Clinician 2** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| 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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

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| **New or Updated Declaration for Clinician 3** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[x]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| 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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

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| **New or Updated Declaration for Clinician 4** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| 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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |

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| **New or Updated Declaration for Clinician 5** |
| **Name** | *Please state full name* |
| **Position** | *Please state currently held position*  |
| **Date** | *Please add the date form was completed (DD-MM-YYYY)* |
|[ ]  **I hereby certify** that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation. |
| **Conflict of Interest Declaration** |
| 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** |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add company name* | [ ]  | [ ]  | [ ]  | [ ]  |
| *Add or remove rows as required* | [ ]  | [ ]  | [ ]  | [ ]  |