Procedural Review Request Form

**Instructions for Sponsors**

This form is to be used by stakeholders who wish to request a procedural review of a reimbursement review conducted by Canada’s Drug Agency (CDA-AMC) reimbursement review. Stakeholders are reminded that the ground for a procedural review relates only to whether the process was followed and not to the content or scientific issue that may or may not be included in the final recommendation (i.e., did CDA-AMC fail to act in accordance with its procedures in conducting the review and issuing the final recommendation).

The form must be submitted, along with supporting documentation, to CDA-AMC within 20 business days of a final recommendation being posted. No extensions will be granted to the 20-business day period and all supporting documentation must be submitted within this period.

If you have any questions, please email requests@cda-amc.ca with the complete details of your question(s).

Prior to 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/CADTH_Drug_Reimbursement_Review_Procedures.pdf)
* [Pharmaceutical Review Updates](https://www.cadth.ca/node/68411?keywords=&result_type%5B%5D=report&product_type%5B%5D=107782&sort=field_date%3Avalue-desc&amount_per_page=10&page=1) for any applicable information.

As indicated in the *Procedures for Reimbursement Reviews*, the Procedural Review Panel will not re-adjudicate matters on which it has already provided a ruling. Please be advised that the following matters will not be considered in the context of a procedural review:

* consistency of recommendations across similar drugs or consistency with previous levels of evidence (CDA-AMC strives for consistency in the application of the deliberative and decision-making process, but this does not mean each outcome will be the same. Each review is conducted independently, within the context of the treatment landscape and clinical practice that exists at the time of the reimbursement review);
* the substance of an alleged conflict of interest (the Panel will only arbitrate on whether the process was followed in the application of the agency’s COI policy and guidelines).

The preceding list will be updated as subsequent rulings are made by the Panel.

Completing the Template

Please complete all sections of the template using 10-point Arial font. When the template is complete, delete this cover page with the instructions (including the CDA-AMC document header). Please feel free to add company-specific elements such as a cover page, disclaimer, header, footer, etc. as required.

Filing the Completed Template:

The completed template must be emailed to requests@cda-amc.ca in Microsoft Word format.

Procedural Review Request Form

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| **Section 1: About the Applicant** |
| **Organization** |  |
| **Role in the review process** | ☐ | A sponsor that filed the submission, resubmission, or reassessment for the review in question (applies to reimbursement review products) |
| ☐ | A company whose product was assessed as part of a therapeutic category or a class review in question (applies to optimal use drug reviews) |
| ☐ | A patient group that provided input in response to a call by CDA-AMC for the review in question |
| ☐☐ | A clinician group that provided input in response to a call by CDA-AMC for the review in questionParticipating drug program members that engaged in the drug review reimbursement process  |
| **Contact information** | Name:Email:Phone: |
| **Date of procedural review request:** |  |
| **Section 2: Final recommendation for which procedural review is being requested** |
| **CDA-AMC project number** |  |
| **Therapeutic class or drug name(s) (as applicable)** |  |
| **Indication(s)**  |  |
| **Date final recommendation issued** |  |
| **Section 3: Ground for the procedural review request** |
| *Important note: Provide a detailed description, along with any relevant documentation, related to how you perceive that CDA-AMC failed to act in accordance with its procedures. Relevant CDA-AMC process steps should be clearly identified. Please provide a list of all supporting documentation. This section should be written clearly and succinctly and should not exceed 10 pages.* |

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| ☐ | By submitting this application, I hereby confirm that the information provided herein is accurate, correct, and complete, and that the documents submitted along with this form are relevant and complete. |