**CADTH Reimbursement Review**

**Resubmission and Reassessment Eligibility Form**

**Instructions for Sponsors**

Prior to filing a resubmission or reassessment, sponsors are required to have its eligibility assessed by CADTH.

Sponsors must complete this form and submit it to requests@cadth.ca. CADTH will assess the information, consulting with our advisory committees and working groups as required, and notify the sponsor regarding eligibility.

Please read the instructions below and consult the recommended documentation before completing the template.

Before Completing the Template:

Please review the following documents to ensure an understanding of CADTH’s procedures and submission guidelines:

* [Procedures for CADTH Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf)
* [CADTH 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.

Completing the Template:

Please complete all sections of the template. Section 4 should be completed as follows:

* For a pending resubmission, summarize how the new information addresses issues that were raised in the previous CADTH recommendation(s) for a pending resubmission.
* For a pending reassessment, summarize how the new information supports the sponsor’s request for revised reimbursement criteria for the drug.

When the template is complete, delete this cover page with the instructions (including the CADTH document header). Save the completed template in Microsoft Word format.

Filing the Completed Template:

Send the completed template to requests@cadth.ca along with copies of one or more new studies that address specific issues identified by the expert review committee.

**CADTH Reimbursement Review**

**Resubmission or Reassessment Eligibility Form**

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| **Confidentiality Guidelines** |
| By filing this *Resubmission or Reassessment Eligibility Form* with CADTH, the sponsor accepts and agrees to the terms of the [*Procedures for CADTH Reimbursement Reviews*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Reimbursement_Review_Procedures.pdf) and its Confidentiality Guidelines and consents to comply with the requirements of the Confidentiality Guidelines, which form an agreement between CADTH and the sponsor. For clarity, the sponsor acknowledges that CADTH may share certain information, including this document with the authorized recipients. |

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| 1. **SPONSOR INFORMATION**
 |
| Name of sponsor | *Please provide the complete company name of the sponsor* |
| Primary contact | *Provide name, title, email, phone number* |
| Secondary contact | *Provide name, title, email, phone number* |
| 1. **DRUG INFORMATION**
 |
| Drug name | *non-proprietary (Brand):* |
| Indication | *Please list the indications that are relevant to the proposed resubmission or reassessment interest* |
| Requested reimbursement criteria | *Please state the reimbursement criteria that would be included in the proposed resubmission or reassessment* |
| Anticipated filing date | *Please state the anticipated date of filing the resubmission or reassessment with CADTH (if eligibility criteria are met)* |
| 1. **RATIONALE FOR THE RESUBMISSION OR REASSESSMENT**
 |
| Indicate if the reason for the resubmission or reassessment is due to new clinical and/or new economic evidence. Check all that apply: |
| New clinical information  |[ ]
| Improved efficacy |[ ]
| Improved safety |[ ]
| New economic information |[ ]
| 1. **ISSUES ADDRESSED BY THE NEW INFORMATION**
 |
| **Issues being addressed with new evidence** | **New evidence that addresses the issue** |
| *Clearly state the issue*  | *Add brief summary of new evidence* |
| *Clearly state the issue* | *Add brief summary of new evidence* |
| *Clearly state the issue*  | *Add brief summary of new evidence* |
| *Add or remove rows as required* |  |
| 1. **SUMMARY OF NEW CLINICAL INFORMATION**
 |
| *This section should not exceed THREE pages and should include:** *a description of any new clinical information that was not available at the time of the last review*
* *a brief overview of new clinical studies, including a description of the study design, population, intervention, comparators, and outcomes*
* *a brief summary of the key results from the new studies*
* *citations to main articles if clinical data are published.*
 |
| 1. **SUMMARY OF NEW ECONOMIC INFORMATION**
 |
| *This section should not exceed THREE pages and should include a description of any new economic information that was not available at the time of the last review.* |
| 1. **ELIGIBILITY ASSESSMENT (FOR CADTH USE ONLY)**
 |
| **Issues being addressed with new evidence** | **CADTH assessment** |
| *Issue raised by the sponsor* | *To be completed by CADTH* |
| *Issue raised by the sponsor* | *To be completed by CADTH* |
| *Issue raised by the sponsor* | *To be completed by CADTH* |
| 1. **CONCLUSION (FOR CADTH USE ONLY)**
 |
| CADTH has concluded that the proposed resubmission or reassessment: |
| * Meets the eligibility criteria
 |[ ]
| * Does not meet the eligibility criteria
 |[ ]
| Date: |  |