**CADTH Reimbursement Review**

**Eligibility and Complexity Assessment Form**

**Instructions for Sponsors**

This form is used by CADTH to determine if a product is eligible for review through one of the single drug review pathways and to assess the complexity of the pending submission.

This form should only be completed for products that have received or are eligible to receive a drug identification number (DIN) in Canada. If you have questions about a product that is or will be regulated as a medical device (e.g., eligible to receive a Medical Device Licence) or another type of product, please contact [requests@cadth.ca](mailto:requests@cadth.ca).

This form must be completed by sponsors before filing a submission in the following situations:

* + the sponsor is seeking direction regarding whether or not a product is eligible for review through CADTH’s reimbursement review processes
  + the sponsor is planning to file a submission for a cell or gene therapy.

CADTH will review the information in the form and seek advice from the drug programs (as needed). CADTH will typically notify the sponsor regarding eligibility within 10 business days of receiving the form (in some cases a longer duration may be required in order to consult with the drug programs). CADTH may share this form with the federal, provincial, and territorial governments, including their agencies and departments and the pan-Canadian Pharmaceutical Alliance (pCPA).

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions, please email [requests@cadth.ca](mailto:requests@cadth.ca) with the complete details of your question(s).

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

When the template is complete, delete this cover page with the instructions (including the CADTH document header). Please feel free to add sponsor company-specific elements such as a disclaimer, header, footer, etc. as required. Save the completed template in PDF or Microsoft Word format.

Filing the Completed Template:

Send the completed template to [requests@cadth.ca](mailto:requests@cadth.ca).

**Section 1: Background Information**

|  |
| --- |
| **Confidentiality Guidelines** |
| By filing this *Eligibility and Complexity Assessment 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. |

|  |  |
| --- | --- |
| **Details** | **Sponsor’s Responses** |
| **Sponsor name** | Please provide the complete company name of the submission sponsor. |
| **Product name** | Please state the brand name (if known) |
| **Generic name** | Please list the non-proprietary names of active substance(s) included in the drug of interest. |
| **Dosage forms and strengths** | Please identify the dosage forms and strengths (if applicable) |
| **Indication(s) for consideration by CADTH** | Please list the indications that are approved or undergoing review by Health Canada for the drug of interest |
| **Health Canada approval status** | Pre-NOC  Post-NOC  Date of approval: Date or anticipated date of Health Canada approval |
| **Contact information** | Name:  Title:  Email:  Phone:  Mailing Address: |
| **Questions for CADTH** | Please state the specific questions that you have regarding CADTH’s processes: |

**Section 2: Eligibility for CADTH Single Drug Review Process**

|  |  |
| --- | --- |
| **Product Characteristics** | **Sponsor’s Responses** |
| **Please complete this section for all products that are regulated as drugs** | |
| **What is the prescription status of the drug in question?** | Prescription drug  Over the counter  Ethical  Other, please specify: |
| **Which of the following best describes the product and indication(s) in question?** | New active substance  New indication for existing drug  New combination product  New dosage form or strength of an existing drug  Subsequent entry non-biologic complex drug  Other, please specify: |
| **Which of the following best describes the drug in question?** | Chemically synthesized drug  Biologic  Radiopharmaceutical  Gene therapy  Cell therapy (e.g., chimeric antigen receptor T cells)  Preventive vaccine  Therapeutic vaccine  Other, please specify: |
| **Please state the route of administration for the drug** | Oral  Intravenous  Intramuscular  Inhalation  Subcutaneous  Sublingual  Other, please specify: |
| **What type of submission has been or will be filed with Health Canada?** | New drug submission (NDS)  Supplemental new drug submission (S/NDS)  Abbreviated new drug submission (A/NDS or S/ANDS)  Other, please specify: |
| **Is the drug in question used in the treatment of cancer?** | No  Drug is used in the active treatment of cancer  Drug is used as a supportive therapy for cancer patients |
| **Is the drug in question a blood or a plasma-related product?** | No  Drug is derived from human blood or plasma  Drug is not derived from human blood or plasma, but has the potential to displace existing drugs that are derived from human blood or plasma  Drug is not derived from human blood or plasma, but has the potential to impact the need for the transfusion of blood in Canada |
| **Does the product in question fit within the reimbursement mandate of one or more the following? (check all that apply)** | Public drug plans and/or cancer agencies  Canadian Blood Services  Hospital formularies  Public health agencies  Uncertain  Other, please specify: |

**Section 3: Complexity of the Drug Submission**

|  |  |
| --- | --- |
| **Product Characteristics** | **Sponsor’s Responses** |
| **Regulatory review** | |
| **Please indicate if the drug is undergoing or underwent review by Health Canada through an expedited pathway** | No (standard review pathway)  Yes (priority review)  Yes (Notice of Compliance with conditions [NOC/c] filed at the outset)  To be confirmed (requested or will be requested)  Other expedited pathway, please specify: |
| **Information about how the drug is administered to patients** | |
| **Please identify the location of administration** | Home administration  Outpatient clinic or infusion centre  Hospital setting  Physician’s office  Other setting, please specify: |
| **Please provide details regarding the peri-treatment period for the drug** | **Pre-treatment period**  Please provide details regarding the pre-treatment regimen for the drug under review (if applicable). For example, details about the setting and specific therapeutic regimen that patients would need to undergo in order to prepare to receive the drug of interest.  **Treatment period**  Please provide details regarding the administration of the drug of interest, including the treatment setting.  **Post-treatment period**  Please provide details regarding the post-treatment follow-up period, including the setting (e.g., need for hospitalization) and all details regarding monitoring for adverse events. |
| **Is administration limited to specialized centres in Canada?** | No  Yes  Please explain your answer: |
| **Are prescribing physicians required to undergo training specific to the drug treatment?** | No  Yes  Please explain your answer: |
| **Information about the indication for drug of interest** | |
| **Does the drug have a companion diagnostic test?** | No  Yes  If yes, please provide a brief description of the following:   * do all patients require testing to be eligible for the drug? * is the test currently available in all or some Canadian provinces and territories? |
| **Has the drug been given orphan drug designation?** | Please check all that apply  No  Yes (United States Food and Drug Administration)  Yes (European Medicines Agency)  To be confirmed (requested or will be requested) |
| **Epidemiological information** | Estimated prevalence in Canada:  Estimated incidence in Canada: |
| **Information about the comparators** | |
| **Comparator(s)** | Please provide a brief list of the comparators for the drug of interest and provide a description of how they are currently reimbursed (if applicable) |
| **Does the drug in question have a novel mechanism of action relative to comparators?** | No  Yes  Please explain your answer: |
| **Clinical development program and comparative efficacy** | |
| **Overview** | Please provide a brief description of the clinical development program for the drug and indication. |
| **Are comparative efficacy data available for the drug versus appropriate comparators** | No  Yes (direct comparison)  Yes (indirect comparison) |