**CADTH Reimbursement Review**

**Patients Accessing a New Drug**

**Instructions for Sponsors**

The purpose of this table is to provide CADTH and participating drug plans with information regarding the number of patients in Canada currently accessing the drug under review.

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the CADTH submission filing process or requirements, 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:

This template is to be completed only for a new drug submission or a new combination product submission when one of the components of the combination product is a “new drug”, defined as a new active substance that has not been previously marketed in Canada, regardless of when the NOC or NOC/c was issued.

The number of patients for which the drug costs are funded through private drug plans does not need to be included.

Delete the instructions cover page once completed.

Filing the Completed Template:

Save the completed table as an unlocked PDF file or Microsoft Word document. Please consult the relevant procedural documentation for details on how to file the application with CADTH.

**CADTH Reimbursement Review**

**Number of Patients Accessing a New Drug**

**Patients Accessing [Insert drug brand name]**

The following table summarizes information regarding the number of patients in Canada currently accessing [insert drug brand name], [a new drug; a new combination product containing a new drug – select appropriate], to within 20 business days of the filing the submission with CADTH.

|  |  |
| --- | --- |
| **Mechanism for Patient Access** | **Number of Patients** |
| Compassionate supply from the sponsora |  |
| Health Canada’s Special Access Programme |  |
| Clinical trial(s) |  |
| Add lines as needed to identify any other applicable means by which patients are currently accessing the drug. |  |

a Include a brief description of the compassionate supply program(s) and whether or not the drug is provided to patients free of charge.