**Proposed Place in Therapy Template**

**Instructions for Sponsors**

The purpose of this template is for the sponsor to clearly indicate where it believes the drug under review should be used compared to existing treatments that are currently reimbursed, as well as the impact of reimbursing the drug under review on the sequence of use for other available therapies used before, after, or as alternatives to the submitted therapy.

Sponsors must complete this template and submit it to Canada’s Drug Agency (CDA-AMC) at the same time they are providing advance notification (i.e., at least 30 business days prior to the anticipated date of filing) and at the time of filing their application.

The sponsor is to provide the following: an overview of the existing treatment algorithm used in Canada for the indication of interest (Section 2); a proposed provisional algorithm showing the place in therapy for the drug or regimen under review and the potential impact on the place in therapy of the currently reimbursed treatment options (Section 3). If drug sequencing varies by patient subpopulations, the sponsor should consider providing multiple algorithms, with each appropriately labelled to indicate the patient category.

CDA-AMC will assess the proposed algorithm and determine if any additional information or clarifications are required for it to be accepted. CDA-AMC will notify the sponsor whether the proposed algorithm has been accepted for review. If you have any questions regarding the submission filing process or requirements, please [contact us](https://www.cda-amc.ca/contact-us) 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/Drug_Reimbursement_Review_Procedures.pdf)
  + Pharmaceutical Review Updates for any applicable information.

Completing the Template

Complete all sections of the template. Please use 10-point Arial font for text inside the provisional algorithm boxes, and 11-point Arial font for all other text. Please use generic drug names.

The completed template must not exceed five pages, excluding the reference list and copies of references provided. Section 3 must be referenced in the JAMA Oncology citation format and a copy of all supporting documentation must be provided at the time the template is filed.

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, and so forth. Save the completed template in Microsoft Word format.

Filing the Completed Template:

The completed template should be uploaded to the Pharmaceutical Submissions SharePoint site’s “Advance Notification” folder within the “Sponsor Submissions” subfolder for your assigned project.

**Reimbursement Reviews**

**Proposed Place in Therapy Template**

**Section 1: Background Information**

|  |  |
| --- | --- |
| **Background** | **Information** |
| **Sponsor** | *Please provide the complete company name of the submission sponsor* |
| **Drug under review** | Brand name: *Please state the brand name (if known)*  Generic name: *Please state the generic name* |
| **Approved or anticipated indication to be reviewed by CDA-AMC** | *Please list the indications that are approved or undergoing review by Health Canada for the drug of interest* |
| **Sponsor’s requested reimbursement criteria** | As per indication(s) to be reviewed by CDA-AMC  Other *(please specify):* |
| **Anticipated date of filing with CDA-AMC** | *Day, Month, Year* |
| **Contact information** | Name:  Title:  Email:  Phone: |

**Section 2: Current Treatment Algorithm**

**2.1 Current Treatment Algorithm Diagram**

In this section, the sponsor must provide complete details regarding the current treatment algorithm for the indication of interest. A sample table for reporting current treatment algorithm is provided as follows.



**2.2 Current Treatment Algorithm Details**

In this section, the sponsor must provide complete details regarding the current treatment algorithm for the indication of interest.Please clearly state the drugs and/or treatment regimens that are used, or likely to be used, for the indication of interest. The sponsor can clarify whether some options are only available for a subset of patients. Alternatively, multiple tables can be created to expand on the different subsets.Clearly identify all current treatment options as being reimbursed or undergoing review by CDA-AMC, under negotiation by the pan-Canadian Pharmaceutical Alliance (pCPA), or under consideration by the drug programs. In the reimbursement status column, please identify the status as follows: reimbursed by a majority of drug programs; reimbursed by a minority of drug programs; under review for reimbursement.

**Sample Table for Reporting Current Treatment Algorithms**

|  |  |
| --- | --- |
| **Drugs** | **Reimbursement status** |
| **First-line treatment options** | |
| List drug or regimen |  |
| Add rows as required |  |
| **Second-line treatment options** | |
| List drug or regimen |  |
| Add rows as required |  |
| **Third-line treatment options** | |
| List drug or regimen |  |
| Add rows as required |  |
| **Fourth-line treatment options** | |
| List drug or regimen |  |
| Add rows as required |  |

Please add abbreviations

**Section 3: Sponsor’s Proposed Place in Therapy Algorithm**

**3.1 Proposed Place in Therapy**

In this section, the sponsor is required to provide its proposed place in therapy for the drug under review. Please provide a clearly stated rationale for the proposed place in therapy, noting if the rationale is based on evidence from clinical studies, clinical expert opinion, cost-effectiveness relative to alternative treatments, and so forth.

**3.2 Potential Impact on Currently Reimbursed Treatments**

Please briefly describe the potential impact (if any) of the indication of interest on currently reimbursed treatments. Examples of impact include different position in sequence, replacement or elimination of treatment, change in reimbursement criteria, and so forth. Please ensure that this section of the document contains references to all relevant documentation supporting the sponsor’s rationale for the place in therapy.

**3.3 Provisional Algorithm Diagram**

In this section, the sponsor is required to provide one or more figures illustrating the proposed place in therapy of the drug or regimen under review and to demonstrate the potential impact (if any) on currently reimbursed treatments for the indication.



**References**