Reimbursement ReviewsProposedPlaceinTherapyForm

# Instructions for Sponsors

The purpose of this form 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 form and submit it to Canada’s Drug Agency (CDA-AMC) at the same time as providing advance notification (i.e., at least 30 business days before the anticipated date of filing) as well as at the time of filing the application.

The sponsor is to provide 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 2). If drug sequencing varies by patient subpopulations, the sponsor should consider providing multiple algorithms, with each appropriately labelled to indicate the patient category.

Canada’s Drug Agency will assess the proposed algorithm and determine if any additional information or clarifications are required for it to be accepted. Canada’s Drug Agency 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).

Before Completing the Form

Please review the following documents to ensure an understanding of our procedures and submission guidelines:

* [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 Form

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

The completed form must not exceed 5 pages, excluding the reference list and copies of references provided. References must be in the *JAMA Oncology* citation format. A copy of all supporting documentation must also be provided at the time the form is filed.

When the form is complete, delete the Instructions for Sponsors section. Please feel free to add company-specific elements, such as a cover page, disclaimer, header, footer, and so forth. Save the completed form in Microsoft Word format.

## Filing the Completed Form

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

Section 1: Background Information

**Sponsor:** Enter sponsor name

**Drug under review:**

**Brand name (if known):** Enter brand name of drug under review

**Generic name:** Enter generic name of drug under review

**Approved or anticipated indication(s) to be reviewed by Canada’s Drug Agency**:

Enter indication(s) to be reviewed

**Sponsor’s requested reimbursement criteria:**

[ ]  As per indication to be reviewed

[ ]  Other (please specify):

Enter other reimbursement criteria

**Anticipated date of filing with Canada’s Drug Agency (dd-mm-yyyy):** Select or enter date of filing

**Contact information:**

**Full name:** Enter first and last name of contact

**Current position:** Enter current position or title of contact

**Email:** Enter email address of contact

**Phone:** Enter phone number of contact

# Section : Sponsor’s Proposed Place in Therapy Algorithm

## 2.1 Proposed Place in Therapy

In this section, the sponsor is required to provide the 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.

## 2.2 Potential Impact on Currently Reimbursed Treatments

Briefly describe the potential impact (if any) on currently reimbursed treatments for the indication of interest. Examples of impact include change in treatment sequencing, replacement, or elimination of a treatment; change in reimbursement criteria; and so forth. Please ensure that this section of the document cites and includes a reference list to all relevant documentation supporting the rationale for the proposed place in therapy.

## 2.3 Provisional Algorithm Diagram

In this section, the sponsor is required to provide 1 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. Please use the formats presented in Figures 1 to 3 and use light grey shading to indicate the cells with the therapy under review. For compliance with the Accessibility for Ontarians with Disabilities Act (AODA), all figures must include alternative text (alt text). Alt text is a concise description of the figure that conveys its essential information to readers who use a screen reader. Example alt text is presented with Figures 1 to 3.

Figure : Sponsor’s Drug Would Be an Additional Treatment Option Within the Existing Algorithm

Example alt text: In the treatment of <disease area>, the following are funded treatment options: drug A in first line, sponsor’s drug and drug B in second line, drug C in third line, and drug D in fourth line. The sponsor’s drug and drug D are under review for funding.



Figure : Sponsor’s Drug Would Displace a Treatment Option Within the Existing Algorithm

Example alt text: In the treatment of <disease area>, the following are funded treatment options: drug A in first line, sponsor’s drug in second line, drug C in third line, and drug D in fourth line. The sponsor’s drug and drug D are under review for funding.



Figure : Sponsor’s Drug Would Shift and Displace the Treatment Options Within the Existing Algorithm

Example alt text: In the treatment of <disease area>, the following are funded treatment options: sponsor’s drug in first line, drug A in second line, drug C in third line, and drug D in fourth line. The sponsor’s drug and drug D are under review for funding.



## Reference List

Use AMA style format (e.g., style used in *JAMA Oncology*) for reference list. Please also provide a copy of all supporting documents at time of submission.