**Implementation Planning for a Cell or Gene Therapy**

**Instructions for Sponsors**

This form must be completed by sponsors for all submissions for cell or gene therapies. Canada’s Drug Agency (CDA-AMC) will 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 [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

Before 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

Please complete all sections of the template. References must be provided in the following format: in-text citations numbered in their order of appearance; and a numbered reference list in the JAMA Oncology citation format.

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

Filing the Completed Template:

Incorporate the completed template into the package of required documents. Please consult the relevant procedural documentation for details on how to file the application with CDA-AMC.

**Reimbursement Review**

**Implementation Planning for Cell or Gene Therapy**

# BACKGROUND INFORMATION

## Product Information

|  |  |
| --- | --- |
| **Non-proprietary name** | Please state the non-proprietary name of the drug under review |
| **Brand name** | Please state the confirmed or anticipated brand name of the drug under review |
| **Dosage form and strengths** | Please provide all formats and strengths included in the submission |
| **Sponsor(s)** | Please state the name of the submission sponsor |
| **Indication(s)** | Please list all indications to be reviewed |
| **Sponsor requested reimbursement criteria** | As per indication(s) to be reviewed  Other: please specify |
| **Drug is undergoing or underwent review by Health Canada through an expedited pathway** | No (standard review pathway)  Priority review  Notice of Compliance with conditions (NOC/c) filed at the outset  Another expedited pathway (please specify)  To be confirmed (requested, Health Canada decision pending) |
| **Date of Notice of Compliance**  **(issued or anticipated)** | DD-MM-YYYY |

## Disease Information

### Overview of the Condition

In this section, the sponsor is asked to provide a brief description of the disease condition.

### Estimated Disease Prevalence

In this section, provide a breakdown of prevalence by participating province and territory. If the drug under review is expected to fall within the coverage mandate of the Non-Insured Health Benefits program of the First Nations and Inuit Health Branch, please provide a separate estimate for the estimated prevalence in the First Nations and Inuit populations (if available).

**Sample table for presenting the estimated prevalence in each region**

|  |  |  |  |
| --- | --- | --- | --- |
| **Region** | **Estimated Prevalence** | | |
| **Lower Estimate** | **Best Estimate** | **Upper Estimate** |
| Canada |  |  |  |
| Alberta |  |  |  |
| British Columbia |  |  |  |
| Manitoba |  |  |  |
| New Brunswick |  |  |  |
| Newfoundland and Labrador |  |  |  |
| Northwest Territories |  |  |  |
| Nova Scotia |  |  |  |
| Nunavut |  |  |  |
| Ontario |  |  |  |
| Prince Edward Island |  |  |  |
| Quebec |  |  |  |
| Saskatchewan |  |  |  |
| Yukon |  |  |  |
| First Nations |  |  |  |

## Diagnosis of the Condition

### Diagnostic Testing Requirements

In this section, the sponsor is asked to provide a description of the diagnostic testing requirements for the indication(s) under review. Please clearly describe the diagnostic tests that would be required or recommended to identify the patient population that could be eligible for treatment with the drug under review. This should include:

* name and rationale for each diagnostic test
* timing of the testing procedures relative to receiving the drug under review (e.g., would the test results only be valid for a finite period of time due to anticipated progression of the disease?)
* setting for the diagnostic testing (e.g., hospitals or outpatient clinics)
* for any invasive testing procedures, the anticipated time and setting for recovery from the procedures and any factors that could influence recovery time
* the sponsor’s perspective on the appropriate health care professionals in Canada to confirm the diagnosis.

Please note if there are any confirmed or anticipated statements in the Canadian product monograph regarding specific diagnostic testing that is recommended for the drug under review.

### Availability of Diagnostic Testing

In this section, the sponsor is asked to provide a description of the availability of the diagnostic testing requirements for the indication(s) under review. Please provide a brief overview of the following:

* + availability of the diagnostic testing requirements at the time the submission is filed and by the time the review of the submission has been completed (i.e., when a final recommendation has been issued)
  + any provinces or territories where there is likely to be limited access to the diagnostic testing requirements for the indication(s) of interest at the time the review is targeted to be completed
  + any initiatives being undertaken by the sponsor to increase the availability of the diagnostic test in Canada
  + any known initiatives being undertaken by others to increase the availability of the diagnostic test in Canada.

# ACCESSIBILITY CONSIDERATIONS

## Ability to Supply

Irrespective of the reimbursement recommendation, please briefly comment on the ability to supply the drug to all eligible patients across Canada at the time the CDA-AMC review is targeted for completion (e.g., within six months of the filing date).

## Canadian Treatment Centres

In this section, the sponsor is asked to provide a description of where the treatment will be available in Canada. If relevant, please provide details regarding any certification or qualification activities that are required for the drug to be administered at a particular treatment centre. If the treatment will be limited to selected treatment centres (e.g., specialty clinics or tertiary hospitals), please provide a summary table that shows the number of centres in each of the provinces and territories.

**Sample table for presenting the number of treatment centres**

|  |  |  |  |
| --- | --- | --- | --- |
| **Province/Territory** | **Treatment Centres** | | |
| **Year 1** | **Year 2** | **Year 3** |
| Alberta |  |  |  |
| British Columbia |  |  |  |
| Manitoba |  |  |  |
| New Brunswick |  |  |  |
| Newfoundland and Labrador |  |  |  |
| Northwest Territories |  |  |  |
| Nova Scotia |  |  |  |
| Nunavut |  |  |  |
| Ontario |  |  |  |
| Prince Edward Island |  |  |  |
| Quebec |  |  |  |
| Saskatchewan |  |  |  |
| Yukon |  |  |  |

## Patient Support Programs

In this section, the sponsor is asked to briefly describe any patient support programs that are planned for the drug under review.

# HEALTH SYSTEM CONSIDERATIONS

## Health Care Professionals

### Prescribing Limitations

Please identify any confirmed or anticipated statements in the Canadian product monograph regarding restricting the prescribing and/or administration of the drug to certain health care professionals. If applicable, please provide details of any prescribing conditions related to limiting the prescribing and/or administration of the drug to certain health care professionals that have been proposed in reimbursement criteria that have been requested by the sponsor.

### Specialized Training for Health Care Professionals

In this section, the sponsor is asked to provide a description of any specialized training programs or certification requirements for health care professionals who would prescribe and/or administer the drug under review. Please focus on training that is specific to the drug under review. If applicable, please provide a brief overview of the accessibility of any specialized training programs, certification or qualification requirements across Canada.

## Health Care Resources

### Pre-Treatment Phase

Please describe the health care resources required in the pre-treatment phase for patients preparing to undergo treatment with the drug under review.

* Provide the following information for any drugs that are required in order to prepare the patient to receive the drug under review:
  + non-proprietary name, dosage, route of administration
  + timing relative to the receiving the drug under review
  + setting to administer the pre-treatment drugs (e.g., home, physician’s office, outpatient clinic, inpatient hospital setting).
* Provide the following information for any medical procedures that are required to prepare the patient to receive the drug under review:
  + name and rationale of the procedure
  + timing of the procedure relative to receiving the drug under review
  + setting for the procedure (e.g., physician’s office, outpatient clinic, inpatient hospital setting)
  + anticipated duration and setting expected for recovery from the procedures (e.g., hospitalization for a particular period of time) and factors that could influence recovery time.
* Provide the details of any additional diagnostic and clinical testing required to ensure the patient is a candidate for the treatment.
  + Please focus on any testing that is additional to the initial diagnostic criteria that were used to identify the patient as a candidate for treatment (e.g., physical examinations, laboratory testing, diagnostic imaging).

### Treatment Phase

Please describe the health care resources, including medications and hospitalization, required for patients to receive the drug under review.

* Include the following information for any concomitant drugs required or recommended for patients receiving the drug under review:
  + non-proprietary name, dosage, route of administration, timing relative to the receiving the drug under review
  + rationale for the concomitant medications
  + Health Canada approval status for the concomitant drugs (i.e., approved or off-label usage for the indication of interest).
* Describe the need for the drug to be administered by a physician or a clinical team and the setting of the treatment (e.g., physician office, outpatient clinic, inpatient hospital setting).

### Post-Treatment Phase

Please describe the health care resources required for patients in the post-treatment phase, including (but not limited to):

* any drugs required to prevent or reduce the risk of adverse events associated with the drug under review and/or the administration procedure(s)
  + non-proprietary name, dosage, route of administration
  + timing relative to the receiving the drug under review and duration of treatment
  + setting for the post-treatment drugs (e.g., home administration, physician’s office, outpatient clinic, inpatient hospital setting)
* any additional monitoring requirements to ensure the safety and well-being of the patient after receiving the drug
* anticipated duration and setting for recovery from the procedures (e.g., hospitalization or need to be near a specialized treatment centre for a particular period of time) and factors that could influence recovery time.

## Ancillary Requirements

In this section, the sponsor is asked to briefly describe any ancillary resources that may be required for patients who will receive the treatment and their caregivers (e.g., travel and lodging requirements). If applicable, please note the following:

* support for ancillary resources expect to be offered by the sponsor
* support for ancillary resources expect to be offered through other third-party organizations.

# AFFORDABILITY CONSIDERATIONS

## Budget Impact Analysis

In this section, the sponsor is asked to briefly summarize the reference-case results for its budget impact analysis. Please note that jurisdictions will be provided with the complete reports and models for the budget impact analyses; therefore, please provide a clear and concise summary that focuses on the key results.

**Sample Table for Summarizing the Reference Case of the Budget Impact Analysis**

|  |  |  |  |
| --- | --- | --- | --- |
| **Province/Territory** | **Estimated Budget Impact** | | |
| **Year 1** | **Year 2** | **Year 3** |
| Pan-Canadian a |  |  |  |
| Alberta |  |  |  |
| British Columbia |  |  |  |
| Manitoba |  |  |  |
| New Brunswick |  |  |  |
| Newfoundland and Labrador |  |  |  |
| Northwest Territories |  |  |  |
| Nova Scotia |  |  |  |
| Nunavut |  |  |  |
| Ontario |  |  |  |
| Prince Edward Island |  |  |  |
| Saskatchewan |  |  |  |
| Yukon |  |  |  |
| First Nations and Inuit |  |  |  |

a Estimated aggregate budget impact for all of the provinces and territories with the exception of Quebec.

## Other Considerations

In this section the sponsor may include any additional information it feels could be informative for the participating jurisdictions and pan-Canadian Pharmaceutical Alliance (pCPA). **This section of the document is optional for sponsors.**

**Status in Other Countries**

Examples of information that could be included:

* pricing information from other countries
* reimbursement conditions in other countries
* uptake of the drug being reviewed in other countries.

**Confidential Pricing Elements**

Examples of information that could be included:

* information in the economic model submitted to CDA-AMC (e.g., cap per patient year)
* caps used in the other countries.

**REFERENCES**

Please provide a numbered list of references using the JAMA Oncology citation format.