Evidence Presentation Briefing Paper

**Instructions for Sponsors**

Sponsors are required to complete this template for all evidence presentation meetings reimbursement review applications to Canada’s Drug Agency (CDA-AMC). This template must be filed **no later than 10 business days** prior to the scheduled date of the meeting. Failure to provide the form within this time frame may result in postponement of the meeting.

Before Completing the Template:

Please review the following documents to ensure an understanding of CDA-AMC 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:

The briefing paper is intended to provide a **concise summary** of key evidence and must not exceed 10 pages.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 disclaimer, header, footer, etc. as required. Save the completed template in a Microsoft Word format.

Filing the Completed Template:

The completed document must not exceed 10 pages. The completed template along with a draft version of the meeting slides (in .pptx form) must be uploaded to the Pharmaceutical Submissions SharePoint site in the “Evidence Presentation Meeting” folder. The briefing paper and slides must be filed no later than 10 business days prior to the scheduled date of the meeting, with the final slides submitted 1 business day in advance. Failure to provide these documents within this time frame may result in postponement or cancellation of the meeting. Please refer to the [Pharmaceutical Submissions SharePoint Site – Set-Up Guide](https://www.cda-amc.ca/sites/default/files/Drug_Review_Process/CADTH_SP_Application_Instructions.pdf) for full instructions on requesting access to the SharePoint site and uploading files.

Should there be any changes to this information, please upload a revised template to the same folder within the Pharmaceutical Submissions SharePoint site and advise CDA-AMC via email (formulary-support@cda-amc.ca) as soon as possible.

Briefing Paper for an Evidence Presentation Meeting

| **Meeting Date and Time** |  |
| --- | --- |
| **Sponsor** |  |
| **Drug**  | Brand (generic); dosage form; route of administration |
| **Indication to be reviewed** |  |
| **Requested reimbursement criteria** |  |
| **Sponsor contact**  |  |

|  |
| --- |
| **Confidentiality Guidelines** |
| By filing this document with Canada’s Drug Agency (CDA-AMC), the sponsor accepts and agrees to the terms of the [*Procedures for Reimbursement Reviews*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/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 CDA-AMC and the sponsor. For clarity, the sponsor acknowledges that CDA-AMC may share certain information, including this document and all presubmission or pipeline meeting materials with the authorized recipients. |

1. **Meeting Attendees**

|  |  |
| --- | --- |
| **Organization** | **Attendees** |
| Sponsor  | * Name; Job title; company or organization
* Include all sponsor employees, clinical experts and/or consultants in this section
 |
| CDA-AMC | * Director, Pharmaceutical Reviews, or designate
* Pharmaceutical Review Manager(s)
* Health Economics Manager or Lead (as needed)
* Other CDA-AMC staff may attend as needed
 |
| Drug Programs | * Invited by CDA-AMC, but attendance is optional
 |

1. **Meeting Agenda**

A sample agenda is provided below. Please modify the agenda as required and delete these instructions.

|  |  |  |
| --- | --- | --- |
| **Time** | **Topic** | **Lead** |
| 3 min | Welcome and opening remarks | CDA-AMC |
| 5 min | 1. Background information  | *Add sponsor lead* |
| 5 min | 2. Target patient population  | *Add sponsor lead* |
| 5 min | 3. Proposed place in therapy | *Add sponsor lead* |
| 10 min | 4. Clinical evidence | *Add sponsor lead* |
| 10 min | 5. Economic evidence  | *Add sponsor lead* |
| 5 min | 6. Questions and Answers | All |
| 2 min | Wrap up  | CDA-AMC |

1. **Background Information**

|  |  |
| --- | --- |
| **Date of NOC**  | DD-MM-YYYY (issued or anticipated) |
| **Health Canada** **review type** | [ ]  Standard review[ ]  Priority review[ ]  Advance consideration under NOC/c[ ]  Project Orbis[ ]  To be confirmed (Health Canada decision pending)[ ]  Other expedited pathway (please specify) |
| **NOC status at filing**  | [ ]  Pre-NOC [ ]  Post-NOC[ ]  Unlabeled indication  |
| **Health Canada Information Sharing** | [ ]  Health Canada will be or has been provided with a completed consent form. [ ]  No, Health Canada will not be provided with a completed consent form. [ ]  Not applicable (post-NOC submission, resubmission, or reassessment). |

NOC = Notice of Compliance; NOC/c = Notice of Compliance with Conditions

1. **Target Patient Population**

Present a very brief outline of the disease, how patients are diagnosed (i.e., what testing resources are used), and noting the incidence/prevalence in Canada.

Specify the proposed or approved indication of interest. Specify the reimbursement criteria that will be requested by the sponsor and provide a rationale.

Highlight key areas where there is unmet medical need for those who may be eligible for treatment with the drug to be reviewed.

1. **Proposed Place in Therapy**

Summarise the current treatment paradigm for the clinical management of the condition, including any diagnostic or other testing procedure(s) performed as part of routine care. Clearly state the sponsor’s interpretation for how the drug to be reviewed will impact the existing treatment paradigm, including impacts to testing resources.

For oncology drugs, sponsor must present diagrams showing the current and proposed funding algorithms for the drug to be reviewed (i.e., as described in the [*Proposed place in therapy template*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/Place_In_Therapy_Template.docx)).

Clearly identify the appropriate comparators for the drug under review.

1. **Clinical Evidence**
	1. **Randomized Controlled Trials and Pivotal Studies**

Present a brief outline of the clinical development program for drug and indication of interest.

Summarize the key results from the pivotal trials.

Clearly state if you anticipate updated data for any of the studies to become available during the CDA-AMC review.

* 1. **Indirect Comparisons (if applicable)**

Provide a summary of all indirect treatment comparisons that will be included in the application.

* 1. **Other Evidence (if applicable)**

Provide a summary of other relevant evidence, including long-term extension phase 4 studies or other studies that may address important gaps in the evidence derived from the clinical development program.

1. **Economic evaluation**

Present an outline of the economic evaluation.

* Include information on the form of analysis (i.e., cost-minimization analysis or cost-utility analysis), and proposed modelling approach (e.g., Markov, PSM, microsim)
* Include the proposed comparators and rationale
* Include information on the clinical claim:
	+ Better efficacy and/or safety
	+ Similar efficacy and safety
* How is the clinical information from the trial(s) and/or indirect comparison being incorporated in the economic model (e.g., transformed / non-transformed)?
* Is a survival analysis being used to extrapolate time-to-event data?
	+ If so, have the following parametric functions been fit: Weibull, Gompertz, gamma, exponential, generalised gamma, lognormal, and loglogistic?
* Include information on the cost claim:
	+ Is there a difference in drug acquisition costs with the comparators?
	+ Is there a difference in resource use and/or non-drug costs?
1. **Budget Impact Analysis**

Present a brief outline of the approach (epidemiological/market share/both) to estimating utilization forecasts, primarily of the submitted drug, but also of relevant changes in other in-scope health resources which warrant discussion.

1. **Diagnostic and Other Testing Resource Considerations (please delete if not applicable)**

Please note that test(s) and testing are defined as: "Interventions and/or procedures that can detect a condition, establish a diagnosis, inform a prognosis, plan treatment, or monitor treatment and its effect on a condition across time." (Reference: Medline Plus: Medical Tests. (n.d.) Published by the National Library of Medicine. Available from: https://medlineplus.gov/lab-tests/ Accessed 14 December 2023.)

* 1. **Is one or more diagnostic or other test(s) necessary to identify patient eligibility for this treatment (including medical imaging, companion diagnostic or other test[s])?**

​​​[ ]  Yes, required or recommended identify patients most likely to benefit from the drug

​​​[ ]  No

If required or recommended, please list the diagnostic or other test(s) that are necessary to identify patient eligibility for this treatment.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Diagnostic or other test** | **Required or Recommended** | **Purpose of the test** | **Timing of testing relative to treatment initiation** | **Test setting**  |
| State the test | State if required or recommended | State the purpose of the test (e.g., what parameters are being evaluated) | State when the test is to performed relative to treatment initiation | Please indicate where the test is typically performed (e.g., imaging clinic, blood lab, specialist clinic)  |
| Add rows as required |  |  |  |  |

* 1. **Is one or more test(s) necessary to monitor response to or safety of the treatment (check all that apply)?**

[ ]  Yes, required or recommended to evaluate clinical response / disease progression

[ ]  Yes, required or recommended to monitor for adverse events

​​[ ]  No

If applicable, please list the test(s) that are required or recommended.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Diagnostic or other test** | **Required or Recommended** | **Purpose of the test** | **Timing/Frequency of testing** | **Test setting**  |
| State the test | State if required or recommended | State the purpose of the test (e.g., evaluate clinical response; monitor for adverse events [state the specific events]) | State the number of tests required, the interval of when testing should be performed, and if testing is required to reinitiate treatment after treatment discontinuation | Please indicate where the test is typically performed (e.g., imaging clinic, blood lab, specialist clinic)  |
| Add rows as required |  |  |  |  |