**Sponsor’s Executive Summary**

**Instructions for Sponsors**

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the application 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 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:

The executive summary should provide a high-level summary of the application. Required headings and subheadings have been provided in the template; however, additional sections may be added, as needed. The amount of space used for each section is at the discretion of the applicant.

Complete the appropriate section of the template:

* Section 1 if filing a submission
* Section 2 if filing a resubmission or a reassessment

Use 11-point Arial font for text outside of tables and 10-point Arial font for text inside of tables.

The completed template must not exceed five pages for standard and tailored reviews and six pages for complex reviews, excluding the reference list.

References must be provided in the following format:

* In text citations must be numbered in ordered of appearance.
* A numbered reference list must be provided in the JAMA Oncology format.

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, etc. as required.

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.

**Section 1: Executive Summary for a Standard or Tailored review Submission**

**Brand name (non-proprietary name)**

**Executive Summary**

**1. Brief Description of the Drug**

**2. Place in Therapy**

**3. Summary of Clinical Evidence**

3.1 Overview of Studies:

3.2 Efficacy Results:

3.3 Safety Results:

**4. Summary of Pharmacoeconomic Evidence**

**5. Requested Reimbursement Criteria**

5.1 Requested Reimbursement Criteria:

5.2 Rationale for Requested Reimbursement Criteria:

**6. Conclusions**

**References**

**Section 2: Executive Summary for a Resubmission** **or Reassessment**

**Brand name (non-proprietary name)**

**Executive Summary**

**1. Brief Description of the Drug**

**2. Place in Therapy**

**3. Rationale for Filing the Resubmission or Reassessment**

**4. Summary of New Clinical Evidence**

4.1 Overview of New Studies:

4.2 New Efficacy Results:

4.3 New Safety Results:

**5. Summary of New Pharmacoeconomic Evidence**

**6. Requested Reimbursement Criteria**

6.1 Requested Reimbursement Criteria:

6.2 Rationale for Reimbursement Criteria:

**7. Conclusions**

**References**