**Economic Requirements Checklist**

**Instructions for Sponsors**

This checklist is required to ensure that the sponsor is undertaking a quality check of their application to minimize delays in the screening process. Please read the instructions below and consult the [Procedures for Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf) and Pharmaceutical Review Updates for any applicable information before completing the template. 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).

Completing the Template:

Please complete all sections of the template.

If a row or section, is not relevant for your submission, please select “NA”.

When the template is complete, delete this cover page with the instructions (including CDA-AMC document header). Please feel free to add company-specific elements such as a cover page, disclaimer, header, footer, etc. 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**

**Economic Requirements Checklist**

| **Component** | **Requirement** | **Included** | **Deviation approved by CDA-AMC a** |
| --- | --- | --- | --- |
| **Cost-Utility Analysis** | | | |
| Pharmaco-economic evaluation: technical report | **Submission or Resubmission:**   * Pharmacoeconomic evaluation reflects the full population identified in the Health Canada indication(s) to be reviewed * Scenario analysis of the population identified in the reimbursement request (if different from the population in the full indication) * Other relevant scenario analyses presented   **Reassessments:**   * Pharmacoeconomic evaluation reflects the scope of the reassessment:   + Population covered under the proposed revised reimbursement criteria   + Population covered under the current reimbursement criteria   + Relevant scenario analyses presented | Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA | Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA |
| * Have all relevant comparators have been included? | Yes / No / NA | Yes / No / NA |
| * If potentially relevant comparators were excluded, has a rationale been provided? | Yes / No / NA | Yes / No / NA |
| * Does the base case reflect the public health care payer perspective? | Yes / No / NA | Yes / No / NA |
| * If time horizon is longer than 1 year, has a 1.5% discount rate on costs and QALYs been used? | Yes / No / NA | Yes / No / NA |
| * Was the submitted price per smallest dispensable unit used? | Yes / No / NA | Yes / No / NA |
| * Were all submitted forms and strengths included? | Yes / No / NA | Yes / No / NA |
| * Are the base case results presented probabilistically? | Yes / No / NA | Yes / No / NA |
| * Are the base case results presented deterministically? | Yes / No / NA | Yes / No / NA |
| * Are results presented for all relevant analyses? | Yes / No / NA | Yes / No / NA |
| * Are QALYs, life-years and costs reported? | Yes / No / NA | Yes / No / NA |
| * Are results presented in disaggregated format? | Yes / No / NA | Yes / No / NA |
| * If relevant, has companion diagnostic test information been incorporated? | Yes / No / NA | Yes / No / NA |
| * Does the pharmacoeconomic evaluation technical report align with the economic model? | Yes / No / NA | Yes / No / NA |
| Economic model | * Has one economic evaluation been submitted? | Yes / No / NA | Yes / No / NA |
| * Has one economic model been submitted? | Yes / No / NA | Yes / No / NA |
| * Is the model programmed in Excel? | Yes / No / NA | Yes / No / NA |
| * Is the model fully unlocked and executable, and all code provided? | Yes / No / NA | Yes / No / NA |
| * Does the model functions in a standalone environment (i.e., does not require access to a web-based platform or links to other documents)? | Yes / No / NA | Yes / No / NA |
| * Do the probabilistic analyses run without error? | Yes / No / NA | Yes / No / NA |
| * Is the model flexible for CDA-AMC to easily vary any individual input and view calculation? | Yes / No / NA | Yes / No / NA |
| * Are the results of the probabilistic analysis stable and has a congruence test been provided? | Yes / No / NA | Yes / No / NA |
| * If used, is seeding easily disabled or modifiable? | Yes / No / NA | Yes / No / NA |
| * Does the model run treatments simultaneously and present the results of all comparators sequentially? | Yes / No / NA | Yes / No / NA |
| * If relevant, is the model flexible to assess all parametric distributions tested by the sponsor; and have the Kaplan-Meier and parametric curves been presented graphically to allow visual inspection of fit concurrently, within one graph for each outcome? | Yes / No / NA | Yes / No / NA |
| * Has a Markov or event-time trace been provided via formulas within the Excel workbook (and not via VBA)? | Yes / No / NA | Yes / No / NA |
| * Is the model run time no more than 1 business day (8 hours) | Yes / No / NA | Yes / No / NA |
| * Does the economic model require CDA-AMC to agree to terms and conditions or have a legal disclaimer? | Yes / No / NA | Yes / No / NA |
| **Cost-Minimization Analysis** | | | |
| Pharmacoeconomic evaluation: technical report | * Drug is a new treatment in an existing therapeutic class in which there are treatments already reimbursed | Yes / No / NA | Yes / No / NA |
| * Drug under review demonstrates similar clinical effects compared with the most appropriate comparator(s) | Yes / No / NA | Yes / No / NA |
| * Drug under review is anticipated to result in equivalent or lesser costs to the health system | Yes / No / NA | Yes / No / NA |
| **Submission or Resubmission:**   * Pharmacoeconomic evaluation reflects the full population identified in the indication(s) to be reviewed * Scenario analysis of the population identified in the reimbursement request (if different from the population in the full indication)   **Reassessments:**   * Pharmacoeconomic evaluation reflects the scope of the reassessment:   + Population covered under the proposed revised reimbursement criteria   + Population covered under the current reimbursement criteria | Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA | Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA  Yes / No / NA |
| * Have all relevant comparators have been included? | Yes / No / NA | Yes / No / NA |
| * If potentially relevant comparators were excluded, has a rationale been provided? | Yes / No / NA | Yes / No / NA |
| * Does the base case reflect the public health care payer perspective? | Yes / No / NA | Yes / No / NA |
| * If time horizon is longer than 1 year, has a 1.5% discount rate on costs been used? | Yes / No / NA | Yes / No / NA |
| * Was the submitted price per smallest dispensable unit used? | Yes / No / NA | Yes / No / NA |
| * Were all submitted forms and strengths included? | Yes / No / NA | Yes / No / NA |
| * Have all results been presented probabilistically or rationale provided for absence of parameter uncertainty to support deterministic analysis? | Yes / No / NA | Yes / No / NA |
| * Are results presented in disaggregated format? | Yes / No / NA | Yes / No / NA |
| * Does the pharmacoeconomic evaluation technical report align with the cost calculation workbook? | Yes / No / NA | Yes / No / NA |
| Cost calculations | * Has one economic evaluation been submitted? | Yes / No / NA | Yes / No / NA |
| * Is an excel workbook provided? | Yes / No / NA | Yes / No / NA |
| * Is the workbook fully unlocked and all calculations provided? | Yes / No / NA | Yes / No / NA |
| * Does the model function in a standalone environment (i.e., does not require access to a web-based platform or links to other documents)? | Yes / No / NA | Yes / No / NA |
| * Is the model flexible for CDA-AMC to easily vary any individual input and view calculation? | Yes / No / NA | Yes / No / NA |
| * If probabilistic, do the analyses run simultaneously for all comparators without error, and results are stable over multiple runs? | Yes / No / NA | Yes / No / NA |
| * Is the model run time no more than 1 business day (8 hours) | Yes / No / NA | Yes / No / NA |
| * Does the economic model require CDA-AMC to agree to terms and conditions or have a legal disclaimer? | Yes / No / NA | Yes / No / NA |
| **Supporting documentation for the Pharmacoeconomic Evaluation** | | | |
| Supporting documentation | * Has an economic model user guide been submitted? | Yes / No / NA | Yes / No / NA |
| * Have all unpublished studies or analyses used to inform the pharmacoeconomic evaluation, including technical report(s) of the indirect comparison(s), utility studies, etc., been provided to CDA-AMC in a folder labelled “Unpublished references”? Does the numbering of these references align with the numbering in the pharmacoeconomic evaluation report reference list? | Yes / No / NA | Yes / No / NA |
| * Have all other supporting documentation (i.e., references) used and/or cited in the pharmacoeconomic evaluation been provided within one folder labelled “Published references”? Does the numbering of these references align with the numbering in the pharmacoeconomic evaluation report reference list? | Yes / No / NA | Yes / No / NA |
| * If relevant, has documentation summarizing key sources of information for the companion diagnostic test been provided within a folder labelled “Companion diagnostic information”? Does the numbering of these references align with the numbering in the pharmacoeconomic evaluation report reference list? | Yes / No / NA | Yes / No / NA |
| **Tailored Review** | | | |
| Tailored Review Template | * Was the economic section of the template completed? | Yes / No / NA | Yes / No / NA |
| * Was the submitted price per smallest dispensable unit used? | Yes / No / NA | Yes / No / NA |
| * Were all submitted forms and strengths included? | Yes / No / NA | Yes / No / NA |
| **Budget Impact Analysis** | | | |
| Budget impact analysis: technical report | * Does the base case reflects pan-Canadian (national) drug program perspective (excluding Quebec)? | Yes / No / NA | Yes / No / NA |
| * If the submission is a plasma protein review, has an analysis from the Canadian Blood Services perspective been provided? | Yes / No / NA | Yes / No / NA |
| * If the submission is for cell and gene therapies, products administered partially or solely in hospital, or infusion therapies, has a scenario that considers the Canadian health system perspective been provided? | Yes / No / NA | Yes / No / NA |
| * Does the population(s) assessed in the base case and scenarios align with the economic evaluation? | Yes / No / NA | Yes / No / NA |
| * Does the base-case analysis use a 1-year baseline period and three-year forecast period? | Yes / No / NA | Yes / No / NA |
| * Have all relevant comparators been included (i.e., aligns with the economic evaluation)? | Yes / No / NA | Yes / No / NA |
| * Was the submitted price per smallest dispensable unit used? | Yes / No / NA | Yes / No / NA |
| * Were all submitted forms and strengths included? | Yes / No / NA | Yes / No / NA |
| * Have the results been presented deterministically? | Yes / No / NA | Yes / No / NA |
| * Have the results been presented for each specified jurisdiction before being aggregated to derive the pan-Canadian results? | Yes / No / NA | Yes / No / NA |
| * Does the report include (at minimum) a description of the decision problem, methods, assumptions and results? | Yes / No / NA | Yes / No / NA |
| * Does the budget impact analysis technical report align with the budget impact model? | Yes / No / NA | Yes / No / NA |
| Budget impact model | * Is the model programmed in Excel? | Yes / No / NA | Yes / No / NA |
| * Is the model fully unlocked and executable, and has all code been provided? | Yes / No / NA | Yes / No / NA |
| * Does the model functions in a standalone environment (i.e., does not require access to a web-based platform or links to other documents)? | Yes / No / NA | Yes / No / NA |
| * Is the model flexible for CDA-AMC to easily vary individual parameters, view the calculations, and run the model to generate results? | Yes / No / NA | Yes / No / NA |
| * Does the model allow assessment of each specified individual drug program? | Yes / No / NA | Yes / No / NA |
| * Does the model present a breakdown of costs by perspective? | Yes / No / NA | Yes / No / NA |
| * Does the budget impact model require CDA-AMC to agree to terms and conditions or have a legal disclaimer? | Yes / No / NA | Yes / No / NA |
| **Supporting documentation for the Pharmacoeconomic Evaluation** | | | |
| Supporting documentation | * Have all unpublished studies or analyses used to inform the budget impact analysis, including market share, forecasting studies, etc., been provided to CDA-AMC in a folder labelled “Unpublished references”? Does the numbering of these references align with the numbering in the budget impact analysis report reference list? | Yes / No / NA | Yes / No / NA |
| * Have all other supporting documentation (i.e., references) used and/or cited in the budget impact analysis been provided within one folder labelled “Published references”? Does the numbering of these references align with the numbering in the budget impact analysis report reference list? | Yes / No / NA | Yes / No / NA |