CADTH

Revised Submission Guidelines for Category 2 Requirements

Effective for all CDR applications targeting the April 2016 CDEC meeting and onward, the category 2 requirements below replace sections 5.2 and 7.2 of the *Submission Guidelines for the CADTH Common Drug Review* (August 2014) for submissions and resubmissions, respectively.

Category 2 Requirements

Category 2 requirements are used by the drug plans and are not considered as part of the review or recommendation process of CDR. CADTH provides secretariat support to the drug plans by ensuring that category 2 requirements have been filed. CADTH does not screen category 2 requirements for completeness. When CADTH notifies a manufacturer that category 2 requirements have been received, it does not imply that the provided information meets the requirements of the individual drug plans. If any of the drug plans have questions regarding the filed category 2 requirements, they will contact manufacturers directly.

Category 2 requirements may be filed concurrently with category 1 requirements, when available. If not provided at the same time as category 1 requirements, one copy of the category 2 requirements must be provided to CADTH as a single package in electronic format on a CD, DVD, or USB flash drive, organized as specified in Appendix 9: Electronic File Structure and Naming Format. This single package of category 2 requirements for submissions or resubmissions must be provided to CADTH *at least* 20 business days before the targeted CDEC meeting at which the submission or resubmission will be considered. Delayed filing of category 2 requirements will not preclude a CDR review from being placed on the agenda of the targeted CDEC meeting; however, the embargoed CDEC recommendation will not be issued until category 2 requirements are received.

The manufacturer must also provide a copy of the category 2 requirements to all drug plans requiring "copies of requirements", as indicated in the "What to Send" column of table 19 in Appendix 1. Please note: The manufacturer is responsible for ensuring that appropriate copyright permissions have been obtained for electronic copies of all supporting documentation included in category 2 requirements of a submission or resubmission, to be shared among the drug plans.

Category 2 requirements are as follows for all submission types:

a) Cover Letter

The following letter is required for all submissions where category 2 requirements were not provided at the same time as category 1 requirements:

- A signed cover letter (an electronic signature is acceptable) from the applicant, providing the following information:
  - a clear description of the submission being filed (e.g., category 2 requirements for a new drug submission filed on a pre-NOC basis)
  - confirmation that all of the category 2 requirements have been provided

b) Budget Impact Analyses and Supporting Documentation

- BIAs for all of the following jurisdictions' drug plans, in accordance with their individual requirements: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New

Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits Program. When data specific to Prince Edward Island are unavailable, the BIA for Prince Edward Island is to be based on Nova Scotia data.
- Copies of all supporting documentation used and/or cited in the BIAs.
  - As specified in Appendix 9: Electronic File Structure and Naming Format, the first file in the folder must be a reference list of the documents included in the folder.

The base unit price used in the BIAs must be the same as the price submitted in the category 1 requirements and must be clearly identified in each BIA. Jurisdiction-specific markups or discounts can then be applied, if applicable.

c) Certified Product Information Document

- A completed and approved copy of the Certified Product Information Document (CPID). In lieu of the CPID, the Master Formula and Final Product Specifications documents are required.

Category 2 requirements for <u>resubmissions</u> are as follows:

a) Cover Letter

The following letter is required for all resubmissions where category 2 requirements were not provided at the same time as category 1 requirements:

- A signed cover letter (an electronic signature is acceptable) from the applicant, providing the following information:
  - a clear description of the resubmission being filed (e.g., category 2 requirements for a resubmission based on new cost information)
  - confirmation that all of the category 2 requirements have been provided.

b) Budget Impact Analyses and Supporting Documentation

- BIAs for all of the following jurisdictions' drug plans, in accordance with their individual requirements: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and Non-Insured Health Benefits Program. When data specific to Prince Edward Island are unavailable, the BIA for Prince Edward Island is to be based on Nova Scotia data.
- Copies of all supporting documentation used and/or cited in the BIAs.
  - As specified in Appendix 9: Electronic File Structure and Naming Format, the first file in the folder must be a reference list of the documents included in the folder.

The base unit price used in the BIAs must be the same as the price submitted in the category 1 requirements and must be clearly identified in each BIA. Jurisdiction-specific markups or discounts can then be applied, if applicable.