Resubmission

for the

Alberta Drug Benefit List

Version 7: October 2012

As stated on Page 1 of the Resubmission Form, only the completed form (i.e. maximum of 10 pages, excluding the *Budget Impact Assessment Form*) will be provided to the Expert Committee on Drug Evaluation and Therapeutics for review of the resubmitted product.

The Expert Committee reserves the right to request further information relating to the resubmission, and to defer the resubmission pending receipt of the requested information which will be subject to the submission deadlines.

Alberta Government

Points for Consideration:

This form must be used when a pharmaceutical manufacturer wishes to make a resubmission to request reconsideration of a previously submitted drug product to the Alberta Drug Benefit List (ADBL).

This applies to those drug products that have been reviewed by the Alberta Health Expert Committee on Drug Evaluation and Therapeutics and a decision has been made by the Minister of Health to:

- not add the drug product to the ADBL,
- add the drug product to the ADBL as a special authorization or restricted benefit, or
- maintain the criteria for coverage of a special authorization or restricted benefit drug product despite the manufacturer's request for a change.

The pharmaceutical manufacturer must make a resubmission of the drug product in order for it to be reconsidered for addition, a change in benefit status or a change in criteria for coverage by the Expert Committee. In addition to the completed Resubmission Form, the manufacturer is also required to provide a Consent Letter, a Letter Confirming Ability to Supply and an updated *Budget Impact Assessment Form* (i.e., if economic information has changed).

Only **new information, data and reference materials that have not previously been provided** in the original submission should be provided in the resubmission. Therefore, the onus is on the pharmaceutical manufacturer to specifically and succinctly address the Expert Committee's concerns as communicated in the decision letter to the manufacturer in the resubmission.

Please Note:

1. The information requested in this form is intended to assist the Alberta Health Expert Committee on Drug Evaluation and Therapeutics and the Minister of Health in the review of a recommendation and reconsideration of a decision pertaining to the status of a drug product on the ADBL.
2. Only the completed form will be provided to the Expert Committee. However, the Expert Committee reserves the right to request further information relating to the submission, and to defer the submission pending receipt of the requested information which will be subject to the submission deadlines.
3. The completed form should not exceed 10 pages in length. Completed forms that are longer than 10 pages in length will be deemed incomplete and will not be submitted to the Expert Committee for review until completed. Text must be in 11-point font and margins must be set at one inch or greater.
4. If new economic information is provided in support of a resubmission, a revised *Budget Impact Assessment for the ADBL* form must be completed that incorporates the new economic information. The *Budget Impact Assessment for the ADBL* form is not counted toward the 10-page limit. Please note that copies of the *Budget Impact Assessment* form can be obtained by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross at Phone: (780) 498-8098 or Fax: (780) 498-8040.
5. Submission requirements for resubmitted products are published in the ADBL. Please be advised that only those resubmissions meeting all of the submission requirements (i.e. including Consent Letter, Letter Confirming Ability to Supply and *Budget Impact Assessment Form*) will be submitted to the Expert Committee. All fields must be completed. If sections are not applicable, please enter "N/A". Incomplete forms will be deemed incomplete submissions and will not be submitted to the Expert Committee for review.

Directions for Use:

Section 1: Background:

- Indicate the date of the original submission to the ADBL as well as the date(s) of any previous resubmissions to the ADBL, in addition to the product-specific information requested.
- State the rationale provided in the decision letter to the pharmaceutical manufacturer as to why the drug product was originally not added to the ADBL and (if applicable) the rationale provided in subsequent decision letter(s) as to why a previous resubmission(s) was/were not successful.
- State the current special authorization or restricted benefit criteria (if applicable) provided in the decision letter(s) to the pharmaceutical manufacturer.

Section 2: Justification for the Resubmission:

- State the rationale for why the resubmission is being made and list the new evidence to justify that a reconsideration of the previous recommendation/decision not to add the drug product to the ADBL is warranted. If the resubmission is being made to request a change in the current special authorization or restricted benefit status of a drug product or to request a change in current criteria for coverage, the rationale and new evidence to justify reconsideration is also required.

Section 3: A List of Decisions in Other Canadian Jurisdictions:

- Provide a summary of the benefit status of the drug product at the time of the resubmission in all other provincial/territorial jurisdictions and include all criteria for coverage for the drug product if applicable. If areas within the table are left blank, it is assumed that coverage has not been obtained in the jurisdiction in question.

Section 4: Reference Materials:

- List in bullet form all new information that has **not previously been provided in the original submission or previous resubmissions** that is being included in this resubmission.
- If projections made in previous budget impact assessments or pharmacoeconomic evaluations differ from those put forth in the original submission or in previous resubmissions, updated economic information is required by including a revised *Budget Impact Assessment for the ADBL* form. **The *Budget Impact Assessment for the ADBL Form* will not be counted toward the 10-page limit.**

Section 5: Appended Reference Materials:

- Append all references that have been cited within the *Resubmission Form*. The inclusion of cited references will be confirmed during the screening process. If cited references are not appended, the resubmission will be deemed incomplete and will not be submitted to the Committee for review.
- **The appended reference materials will not be counted toward the 10-page limit.**

Section 1: Background:

Current Benefit Status	
Date of Original Submission to the ADBL	
Date(s) of Any Previous Resubmissions to the ADBL	
Drug Identification Numbers (DINs) for all Resubmitted Strengths	
Current Prices for all Resubmitted Strengths	
Current Patent Status [i.e. expiry date(s) of all Canadian patent(s)]	
NOC date of product being submitted	

- Indicate the date of the original submission to the ADBL as well as the date(s) of any previous resubmissions to the ADBL in addition to the product-specific information requested

Complete the following sections as applicable to the specific resubmission:

Rationale for why the Drug Product was not Added to the ADBL Following the Original Submission:	
Rationale for why the Drug Product was not Added to the ADBL Following Previous Resubmission(s):	
Current Special Authorization Criteria	
Current Restricted Benefit Criteria	

- State the rationale provided in the decision letter to the pharmaceutical manufacturer as to why the drug product was originally not added to the ADBL and (if applicable) the rationale provided in subsequent decision letter(s) as to why a previous resubmission(s) were not successful
- State the current special authorization or restricted benefit criteria (if applicable) provided in the decision letter(s) to the pharmaceutical manufacturer

Section 2: Justification for the Resubmission:

Justification and Rationale for the Resubmission

- State the rationale for why the resubmission is being made and list the new evidence to justify that a reconsideration of the previous recommendation/decision not to add the drug product to the ADBL is warranted. If the resubmission is being made to request a change in the current special authorization or restricted benefit status of a drug product or to request a change in current criteria for coverage, the rationale and new evidence to justify reconsideration is also required.

Section 3: List of Decisions in Other Canadian Jurisdictions:

Province/Territory	Decision (If applicable, all Criteria for Coverage MUST be provided in addition to the Decision. If areas are left blank, it is assumed that coverage has not been obtained in the jurisdiction in question.)	Interchangeability Status
British Columbia		
Saskatchewan		
Manitoba		
Ontario		
Quebec		
Prince Edward Island		
New Brunswick		
Nova Scotia		
Newfoundland		
NWT		
Yukon		
Non-Insured Health Benefits (NIHB)		

- Provide a summary of the benefit status of the drug product at the time of the resubmission in all other provincial/territorial jurisdictions **and include all criteria for coverage for the drug product if applicable**.

Section 4: Reference Materials:

- List in bullet form all new information that has **not previously been provided in the original submission or previous resubmissions** that is being referenced in this resubmission.
- The updated *Budget Impact Assessment for the ADBL Form* should be appended to this section, if applicable. **The *Budget Impact Assessment for the ADBL Form* will not be counted toward the 10-page limit.**

Reference Materials

Section 5: Appended Reference Materials:

- Append all references that have been cited within the *Resubmission Form*. The inclusion of cited references will be confirmed during the screening process. If cited references are not appended, the resubmission will be deemed incomplete and will not be submitted to the Committee for review.
- **The appended references will not be counted toward the 10-page limit.**