|  |
| --- |
| Resubmission*for the* *Alberta Drug Benefit List*  |

*Version 8: October 2023*

**As stated on Page 1 of the Resubmission Form, only the completed form (with a maximum of 10 pages for Section 3) 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.**



**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 or Devices 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 or Device to the *ADBL*,
* add the Drug Product or Device to the *ADBL* as a special authorization or restricted benefit, or
* maintain the benefit status of a Drug Product or Device despite the manufacturer’s request for a change or,
* maintain the criteria for coverage of a special authorization or restricted benefit Drug Product or Device despite the manufacturer’s request for a change.

The pharmaceutical manufacturer must make a resubmission of the Drug Product or Device 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 or if applicable, in previous resubmission(s), will be reviewed by the Expert Committee. 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 or Device 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. Section 3 of the completed form should not exceed 10 pages in length. Completed forms that exceed the maximum 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 by email: submissions@ab.bluecross.ca or by Phone: (780) 498-8098.
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:**

1. 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.
2. State the rationale provided in the decision letter to the pharmaceutical manufacturer as to why the Drug Product or Device 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.
3. State the current special authorization or restricted benefit criteria (if applicable) provided in the decision letter(s) to the pharmaceutical manufacturer.

**Section 2: A List of Decisions in Other Canadian Jurisdictions:**

1. Provide a summary of the benefit status of the Drug Product or Device at the time of the resubmission in all other provincial/territorial jurisdictions and include all criteria for coverage for the Drug Product or Device 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 3: Justification for the Resubmission:**

1. State the rationale for the resubmission and provide a summary of any new evidence that is provided to justify a reconsideration of the previous recommendation/decision. Only include information that has **not previously been provided in the original submission or previous resubmissions.** If you are writing in support of product listing or a revision to the criteria for coverage, please provide a concise summary of the evidence in support of your comments from the peer-reviewed scientific literature, if applicable. **There is a 10 page limit for this section and ONLY information provided in this section will be considered during the review process.**

**Section 4: Reference Materials:**

1. Provide a bulleted or numbered list of the references that were mentioned in section 3 and append all FULL references or provide links to open-source references. The inclusion of cited references (or links to open-source references) will be confirmed during the screening process. If cited references are not provided, the resubmission will be deemed incomplete and will not be submitted to the Expert Committee for review.
2. If projections made in 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.

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

1. State the rationale provided in the decision letter to the pharmaceutical manufacturer as to why the Drug Product or Device 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.
2. State the current special authorization or restricted benefit criteria (if applicable) provided in the decision letter(s) to the pharmaceutical manufacturer.

**Section 2: 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** |  |  |
| **Northwest Territories** |  |  |
| **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 or Device if applicable**.

**Section 3: Justification for the Resubmission:**

|  |
| --- |
| **Justification and Rationale for the Resubmission** |
| State the rationale for the resubmission and provide a summary of any new evidence that is provided to justify a reconsideration of the previous recommendation/decision. Only include information **not previously been provided in the original submission or previous resubmissions.** If you are writing in support of product listing or a revision to the criteria for coverage, you must provide summarized evidence in support of your comments from the peer-reviewed scientific literature. **There is a 10 page limit for this section.** |

**Section 4: Reference Materials:**

* Provide a bulleted or numbered list of the references that were mentioned in section 3.
* The updated *Budget Impact Assessment for the ADBL Form* should be appended to this section, if applicable.

|  |
| --- |
| **Reference Materials** |
|  |