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| BiosimilarSummary Form*for the* *Alberta Drug Benefit List*  |

*Version 2: July 2020*

**As stated on Page 1 of the Biosimilar Summary Form, only the completed form will be provided to the Expert Committee on Drug Evaluation and Therapeutics for review of the submitted product.**

**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.**



**Points for Consideration:**

This form must be used when a pharmaceutical manufacturer wishes to make a biosimilar submission to request consideration of their drug product for listing on the *Alberta Drug Benefit List (ADBL).*

The information requested in this form is intended to assist the Alberta Health Expert Committee on Drug Evaluation and Therapeutics in their review, and the Minister of Health in their decision, pertaining to the status of a drug product on the *ADBL*.

Submission requirements for submitted products are published in the *ADBL*. For more information refer to submission guidelines: <https://idbl.ab.bluecross.ca/idbl/DBL/dbl_sec1_drug.pdf>

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. Examples of additional information that may be requested include pharmacokinetic (PK) and/or pharmacodynamic (PD) studies, clinical efficacy trials, safety and immunogenicity comparisons, and the rationale for authorization of all indications approved by Health Canada.

Completing the Biosimilar Summary Form:

* All sections must be completed by the Manufacturer. If sections are not applicable, please enter “N/A” and the reason the section is not applicable. Incomplete forms will be deemed incomplete submissions and will not be submitted to the Expert Committee for review.
* Section 4.2 “Summary of Comparative Clinical Trials” should only include information from the Biosimilar’s Health Canada-approved Product Monograph. Sample tables, headings, and text have been provided and should be modified as necessary to align with the Product Monograph.
* References must be provided in the following format:
* In-text citations must be numbered in order of appearance.
* A numbered reference list must be provided in the Citing Medicine format at the end of the document in the References section.
* Save the completed template as a Word document using the following file name structure: BrandName\_BiosimilarForm.

The completed Biosimilar Summary Form should be saved as a Word document, as noted above, and incorporated as part of the submission requirements for Biosimilars.

**Section 1: Biosimilar Product Information:**

|  |  |
| --- | --- |
| **Biosimilar (Brand Name)** |  |
| **Active Pharmaceutical Ingredient** |  |
| **Manufacturer** |  |
| **DIN(s) / Strength(s) / Dosage Form(s) / Route of Administration(s)**  |  |
| **Health Canada-Approved Indication(s) submitted** |  |
| **Health Canada-Approved Reference Product Indications Not Being Sought by the Manufacturer****(if applicable)** |  |
| **NOC date(s)a** |  |

aPlease provide NOC date(s) according to submitted indication.

NOC = notice of compliance.

DIN = Drug Identification Number.

**Section 2: Reference Product Information:**

|  |  |
| --- | --- |
| **Reference Product (Brand Name)** |  |
| **Active Pharmaceutical Ingredient** |  |
| **Manufacturer** |  |
| **DIN(s) / Strength(s) / Dosage Form(s) / Route of Administration(s)**  |  |
| **Health Canada-Approved Reference Product Indications** |  |

**Section 3: Manufacturer’s Reimbursement Request:**

|  |  |
| --- | --- |
| **Manufacturer’s Reimbursement Request** |  |

**Section 4: Health Canada’s Assessment of (Biosimilar) for Market Authorization:**

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| 4.1 Authorized Indications |
| **Indications:** Indications have been granted on the basis of similarity between *<Biosimilar>* and the reference biologic drug, *<Reference Product>.* Further details can be found in the Health Canada-approved product monographs for *<Biosimilar>* and *<Reference Product>*:* *<Biosimilar>*: *<Insert Weblink to Product Monograph on Health Canada’s website>*
* *<Reference Product>*: *<Insert Weblink to Product Monograph on Health Canada’s website>*

**Authorization of Indications (if applicable):** Randomized clinical trials have not been conducted to compare *<Biosimilar>* to *<Reference Product>* in patients with *<indication(s)>. <Please provide a short summary regarding the basis of Health Canada approving indications for which no clinical trial(s) was (were) conducted. Please include the rationale for any extrapolation of data to other indications for which no clinical trial(s) was (were) conducted and Health Canada’s conclusions regarding the extrapolation of such data to other indications.>* |
| 4.2 Summary of Comparative Clinical Trials (Based only on information from the Health Canada-approved Biosimilar Product Monograph – Section 15) |
| **4.2.1 Comparative Clinical Trial Design and Patient Demographics**Clinical trials conducted to support similarity between <*Biosimilar*> and the reference biologic drug *<Reference Product>* included:* *<Please provide a short statement describing the trial design and patient population of each study; add a separate bullet point for each study>*

An overview of the trial design(s) and demographic characteristics of patients enrolled in each clinical study are presented in Table 1.Table *<#>:* Comparative Clinical Trial Design and Patient Demographics

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Number  | Trial Design | Patient Population | Dosage, Route of Administration, and Duration | Number of Subjects or Patients | Mean Age (range) | Sex |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

abb = abbreviations4.2.2 Comparative Clinical Trial Results<*Please provide a short narrative of the results of each comparative clinical trial (including pharmacokinetics, pharmacodynamics, efficacy, safety and immunogenicity results), with reference to the results in table form as per Section 15.1 (Comparative Clinical Trials) of the Health Canada-approved biosimilar product monograph.*>Table *<#>:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Parameter |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

abb = abbreviations |
| 4.3 Summary of Evidence for Switching Between the Biosimilar and Reference Biologic Drug (Optional) |
| <*Please provide a summary of all clinical trial evidence available for switching from the Reference Biologic Drug to the Biosimilar and if available, from the Biosimilar to the Reference Biologic Drug or another Biosimilar of the Reference Biologic Drug.>* |

**Section 5: Cost Overview:**

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| 5.1 Cost Comparison  |
| Table: Cost Comparison of Biosimilar and the Reference Product for *<Indication>*a

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Drug / Comparator** | **Strength** | **Dosage Form** | **Price ($)c** | **Recommended****Dosed** | **Average Monthly Drug Cost ($)** |
| **Canadian Costs** |
| <*Biosimilar under review*>b |  |  | $X.XXXX |  |  |
| *<Reference product*>b |  |  | $X.XXXX |  |  |
| *<Other Biosimilars>* |  |  | $X.XXXX |  |  |

a Please add separate cost tables for each indication where the dosage of the biosimilar product or the relevant comparators vary by indication.b Please rename these row headings with brand names of the biosimilar and the reference product.c Provide sources for price information. d Provide sources for the dosage information; please also include a statement if the biosimilar has a fixed dosing schedule or a weight-based dosing schedule for the requested indication(s) and the rationale, where applicable. |

**Section 6: Implementation Considerations:**

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| 6.1 Patient and Provider Support Programs  |
| Will a patient support program be made available by the manufacturer? [ ]  Yes or [ ]  NoWill a health care provider support program be made available by the manufacturer? [ ]  Yes or [ ]  NotionalOverview of the Patient and Provider Support Programs*<Please provide details of the support programs>*  |
| **6.2 Delivery Device for the Biosimilar (Optional)** |
| Is there a delivery device for this biosimilar? [ ]  Yes or [ ]  NoWhat is the evidence for similarity between the biosimilar delivery device and the reference biologic product delivery device?*<Please provide details of the evidence, if available>*  |

**Section 7: Reimbursement Status for Reference Product and Biosimilars:**

For each indication that is approved by Health Canada for the biosimilar, please provide the publicly available reimbursement status and criteria for the reference product and other biosimilars, if applicable. Alberta Blue Cross may update the information provided by the manufacturer with new information provided by the participating jurisdictions, as required.

**Step 1:** Use the following abbreviations to complete the table. Use a separate row for each indication and add more rows if necessary.

|  |  |
| --- | --- |
| **Abbreviation** | **Description** |
| **EX** | Exception item for which coverage is determined on a case-by-case basis |
| **FB** | Full benefit |
| **NB** | Not a benefit |
| **RES** | Restricted benefit with specified criteria (e.g., special authorization, exception drug status, limited use benefit) |
| **UR** | Under review |
| **‒** | Information not available |

Listing Status for *<name of reference product>*

|  |  |
| --- | --- |
| Indication(s) | Provincial Drug Plan Formularies  |
| **BC** | **AB** | **SK** | **MB** | **ON** | **QC** | **NB** | **NS** | **PE** | **NL** | **YK** | **NT** | **NIHB** |  |
| ***<Indication 1>*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 2*>** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 3*>** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 4>*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

AB = Alberta; BC = British Columbia; MB = Manitoba; NB = New Brunswick; NIHB = Non-Insured Health Benefits Program; NL = Newfoundland and Labrador;
NS = Nova Scotia; NT = Northwest Territories; ON = Ontario; PE = Prince Edward Island; QC = Quebec; SK = Saskatchewan; YK = Yukon.

Listing Status for *<name of biosimilar>*

|  |  |
| --- | --- |
| Indication(s) | Provincial Drug Plan Formularies  |
| **BC** | **AB** | **SK** | **MB** | **ON** | **QC** | **NB** | **NS** | **PE** | **NL** | **YK** | **NT** | **NIHB** |  |
| **<*Indication 1>*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 2>*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 3*>** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***<Indication 4>*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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**Step 2:** For all restricted benefit or special authorization entries, please state the criteria used by each drug plan. Use a separate table for each indication and add or delete rows as necessary.

Restricted Benefit or Special Authorization Criteria for *<name of reference product>* for the treatment of *<state the indication>*

|  |  |
| --- | --- |
| Drug Plan | Criteria for Restricted Benefit |
| ***<Add name>***  | *<State the exact criteria>*  |
| ***<Add name>***  | *<State the exact criteria>*  |
| ***<Add name>***  | *<State the exact criteria>*  |

Restricted Benefit or Special Authorization Criteria for *<name of biosimilar>* for the treatment of *<state the indication>*

|  |  |
| --- | --- |
| Drug Plan  | Criteria for Restricted Benefit |
| ***<Add Name>*** |  *<State the exact criteria>* |
| ***<Add Name>*** |  *<State the exact criteria>* |
| ***<Add Name>*** |  *<State the exact criteria>* |

Section 8: References:

* **List all references that have been cited within the Biosimilar Submission Form**.
* **The appendices are for reference only and any new information contained in this section may not be reviewed**.