Saskatchewan Biosimilars Initiative
Exemption Request Form

Drug Plan and Extended Benefits Branch
3475 Albert Street
REGINA SK S4S 6X6
Phone: 1-800-667-2549 (306-787-8744 in Regina), option 3
Fax: 306-798-1089
Email: sk.biosimilars@health.gov.sk.ca

Prescribers complete this form to request an exemption to the Saskatchewan Biosimilars Initiative policy for a patient who cannot use a biosimilar due to a medical reason.

Note: Submission of a complete form, with supporting clinical evidence or rationale, initiates the review process for the exemption request. A submission does NOT mean the request will be automatically approved.

Complete each section to avoid potential delays in review.

Section 1 – Prescriber Information

Prescriber First Name:

Prescriber Last Name:

Prescriber Mailing Address (Street, City/Town, Province, Postal Code):

Prescriber Email Address:

Prescriber Phone Number:

Prescriber Fax Number:

Section 2 – Patient Information

Patient First Name:

Patient Last Name:

Health Services Number:

Date of Birth:

Section 3 – Saskatchewan Biosimilars Initiative Exemption Request and Clinical Information

*Type of Request (check **one**):*

- ☐ Initial request
- ☐ New/additional information (request for reconsideration)
- ☐ Exemption renewal request

Reference Biologic Drug Requested (trade/brand name):	Device (e.g., pre-filled syringe, pre-filled pen, etc.):

Diagnosis:

Current Dosing Regimen:

Approximate Start Date of the Reference Biologic:

*Clinical Reason(s) Patient Cannot Use a Biosimilar (complete **one** of the two options below):*

1. ☐ Current pregnancy – please provide the anticipated due date: _____/_____/_____ (MM / DD / YYYY)

2. ☐ Other clinical reason – complete the appropriate sections below.

***INSTRUCTIONS:** Complete **SECTION A** if the patient **has NOT tried** a biosimilar.*

A. **If a trial with a biosimilar has not occurred, please explain why a biosimilar is not appropriate.**

***INSTRUCTIONS:** Complete **SECTION B** if the patient **has tried** a biosimilar.*

B. **List the biosimilar brand(s) tried, including the dates/duration of and response to the biosimilar trial(s).**
***Where possible**, before ruling out all biosimilar options, there should be a trial with **more than one** biosimilar brand.*

BIOSIMILAR BRAND	APPROXIMATE DATES OF TRIAL	RESPONSE TO BIOSIMILAR TRIAL

Why is the patient not able to continue using a biosimilar version?

Indicate how non-drug factors that may have contributed to this response have been ruled out:

- Changes to dosing regimen?

- Gaps in therapy?

- Administration technique reviewed, if applicable?

- Drug interactions?

- Non-clinical influences on symptoms and disease progression?
  Examples: Natural disease progression or disease flare; adherence or recent changes to nonpharmacologic management (physical therapy, psychotherapy, diet, exercise, sleep/rest, etc.); changes in physical, mental, emotional, or social health (injury, new diagnosis, financial instability, work stress, access to care, etc.); nocebo effect (negative expectations, patient knowledge or anxiety about biosimilars, etc.).

Clinical status prior to initiation of biosimilar(s):

Relevant laboratory results or assessments PRIOR TO and AFTER biosimilar trial(s).
Attach laboratory results or assessments to this request or complete the table below.

Relevant clinical investigations will vary depending on the drug and condition. For example, HbA1C and blood glucose testing, inflammatory markers, anti-drug antibody levels, other symptom/disease indicators, clinic assessments, quality of life impacts, etc.

☐ Laboratory results or assessments are attached to this request.

LAB/TEST/ASSESSMENT	RESULTS **PRIOR TO** TRIAL/DATE	RESULTS **AFTER** TRIAL/DATE
	Results:	Results:
	Date:	Date:
	Results:	Results:
	Date:	Date:
	Results:	Results:
	Date:	Date:
	Results:	Results:
	Date:	Date:

INSTRUCTIONS: *Complete* ***SECTION C*** *for* ***all*** *requests.*

C. Provide patient's clinical status and history.

- Current clinical status and treatments being used to manage this condition:

- Relevant medical history and other therapies tried:

INSTRUCTIONS: *Complete* ***SECTION D****, if applicable.*

D. Provide clinical evidence to support this request.

Please note: A copy of the journal article(s), the electronic link(s), or the complete citation(s) MUST be provided. The clinical evidence submitted should align with the request for this treatment, condition, and patient.

Section 4 – Prescriber Signature

Prescriber Signature: Date Signed:

SEND COMPLETED FORM BY EMAIL TO sk.biosimilars@health.gov.sk.ca OR FAX TO 306-798-1089
OR MAIL TO 3475 ALBERT STREET, REGINA SK S4S 6X6