Ministry of Health
Drug Plan and Extended Benefits
2nd Floor, 3475 Albert Street
Regina, Canada S4S 6X6

May 1, 2023

Dear Health Care Providers:

RE: End of Saskatchewan Biosimilars Initiative Transition Period

Starting May 1, 2023, nine reference biologic drugs are no longer eligible for coverage under the Saskatchewan Drug Plan.

Humira (adalimumab)	**Enbrel** (etanercept)	**Lovenox** (enoxaparin)
Neupogen (filgrastim)	**Copaxone** (glatiramer acetate)	**Remicade** (infliximab)
NovoRapid (insulin aspart)	**Lantus** (insulin glargine)	**Rituxan** (rituximab)

Under the Saskatchewan Biosimilars Initiative announced October 20, 2022, patients receiving one of these reference biologic drugs must transition to a biosimilar version to maintain Saskatchewan Drug Plan coverage of their treatment after April 30, 2023.

Biosimilar options are listed on www.saskatchewan.ca/biosimilars and https://formulary.drugplan.ehealthsask.ca/SearchFormulary. **Prescriptions must clearly indicate the biosimilar brand to be dispensed by the pharmacy.**

IMPORTANT EXCEPTIONS: Coverage will continue to be available in the cases below until further notice. These patients will be notified if/when there is a change to their coverage.	
Individual Patient Exemptions	Patients who receive approval for an exemption from the Saskatchewan Biosimilars Initiative policy will continue to receive coverage of their reference biologic for an approved time period. Details are communicated directly to the prescriber and patient.
HUMALOG	The transition for **HUMALOG** is paused, until supply of the biosimilar (**ADMELOG**) has stabilized and demand can be met. The Drug Plan will be issuing communication and notification to patients and prescribers as more information becomes available.
Vials for NOVORAPID and LANTUS	These vials will remain covered until biosimilar(s) in a vial format are listed on the Saskatchewan Formulary. Existing vial users have ongoing coverage in place. Prescribers can request an exemption to the policy for new patients requiring a vial format.
Insulin Pump Users	Coverage of **NOVORAPID** and **HUMALOG** will continue to be available for patients who use vials for an insulin pump while the biosimilars undergo insulin pump certification, even if biosimilar(s) in a vial format are available.

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One-Time Fill of Reference Biologic Medications:

Starting May 1, 2023, patients who require an **urgent** refill of their reference biologic and do not have a prescription for a covered biosimilar may be eligible for a *one-time fill* of the reference biologic medication.

- A one-time fill is intended to prevent treatment gaps or delays related to the ability of a patient to obtain a biosimilar prescription before their next scheduled dose/infusion.
- If eligible for a one-time fill, the patient will pay for the reference biologic according to their usual co-payment and/or deductible. Patients will have until their next scheduled dose/infusion to coordinate a biosimilar prescription with their prescriber.
- **Pharmacists should call** the Biosimilars Initiative team at **1-800-667-2549, option 3**, to determine if their patient may be eligible for a one-time fill of a reference biologic medication.
- **Reminder – Pharmacy Biosimilar Insulin Transition Fee (BITF):** If a patient is using a reference biologic insulin, pharmacists can support patients to transition to a biosimilar insulin without a prescription. Pharmacists may be eligible to claim a BITF when supporting the initial transition to a biosimilar insulin. Please refer to www.saskatchewan.ca/biosimilars for more information.

Transitioning to a Biosimilar – Assessment of Unexpected Response:

- medSask has developed a tool for prescribers to assess unexpected responses to biosimilars (enclosed). Please refer to medsask.usask.ca for more details.
- Prescribers are encouraged to consider all contributing factors prior to submitting a request for an exemption to the Biosimilars Initiative policy.

Questions and Support:

- Online courses about biosimilar medications are now available for patients/caregivers and health care providers (accredited). More information is available here or in the enclosed handouts.
- For support with the Saskatchewan Biosimilars Initiative policy and drug coverage:
  - Visit www.saskatchewan.ca/biosimilars.
  - Contact the Biosimilars Initiative team directly at sk.biosimilars@health.gov.sk.ca or 1-800-667-2549 (306-787-8744 in Regina), option #3.
- For clinical support from medSask:
  - Health care providers can contact medSask pharmacists directly at druginfo@usask.ca or 1-800-667-3425 (306-966-6340 in Saskatoon), or visit medsask.usask.ca/professional-practice/biosimilars-in-Saskatchewan.
  - Patients can contact medSask pharmacists directly at med.sask@usask.ca or 1-800-665-3784 (306-966-6378 in Saskatoon), or visit medsask.usask.ca/general-public/biosimilars-in-saskatchewan.

Transitioning To A Biosimilar: Assessment Of Unexpected Response

- **Biosimilars are demonstrated to be as effective and safe as the reference biologic. The unexpected response may not be related to the use of a biosimilar.**
- **When assessing an unexpected response: acknowledge and address patient concerns, use objective measures in addition to subjective information, and consider all potential factors.**

FACTORS	CONSIDERATIONS FOR REVIEW
Drug Storage **Deviations from manufacturer recommended storage may compromise efficacy.**	• Storage conditions ✓ Not exposed to temperature extremes (including during transport) ✓ Storage time at room temperature not exceeded ✓ Drug not expired
Drug Regimen **Non-adherence may lead to treatment failure resulting in unnecessary changes to or escalation of treatment.**	• Adherence ✓ Original reference biologic discontinued by patient ✓ Administered dose is the same as the reference biologic ✓ Dose given on time and as scheduled (i.e., no interruption of therapy)
Drug Administration **Improper use of the device could result in delivery of subtherapeutic dose.**	• Site of administration ✓ Appropriate and different from last site of administration • Dose delivery (as applicable) ✓ Plunger of prefilled syringe completely depressed ✓ Viewing window indicates complete drug delivery ✓ Autoinjector held in place at least 10 seconds ✓ Dose not accidently discharged (i.e., autoinjector button pressed too soon)

Drug Interactions
Concomitant medications or supplements may:
• **reduce efficacy of the biosimilar;**
• **increase side effects; or**
• **have side effects that mimic a disease flare.**
	• New use of:
	  • Prescription medications
	  • Over-the-counter medications
	  • Supplements
	  • Samples
	  • Products ordered on the internet or purchased outside of Canada

Clinical Status Of Condition Being Treated	• Natural disease progression • Possibility of disease flare

FACTORS	CONSIDERATIONS FOR REVIEW

Other Therapies Used To Manage Condition	• Adherence or recent changes to:
	  • Concomitant medications
	  • Nonpharmacologic management (e.g. physical therapy, psychotherapy, diet, exercise, sleep/rest, etc.)

Overall Health Status	• Change in physical health including comorbid conditions, injury, or new diagnosis • Change in mental, emotional, social health (e.g. financial instability, work stress, access to care, etc.)
Nocebo Effect **Negative expectations may influence treatment outcomes.**	• Patient knowledge about biosimilars and sources of information • Patient anxiety about transitioning to the biosimilar • Health care provider confidence in the quality, safety, and efficacy of biosimilars

Managing Injection Site Pain

The transition to a different product may result in a change to how the injection feels. Consider:

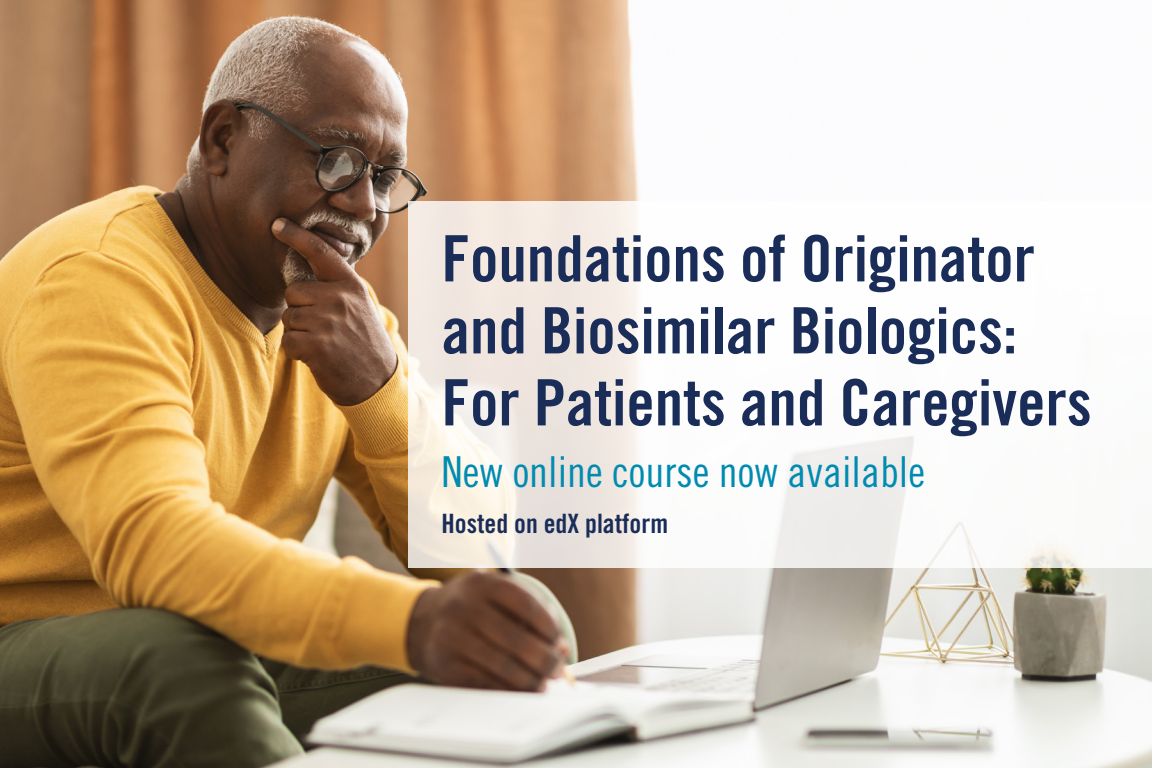
- Product formulation factors: excipients, pH, volume, temperature, viscosity
- Device features: needle length and gauge
- Injection technique: injection speed and movement during injection
- Patient factors: low body weight, female sex, mental health status, disease severity, expectations of pain

Unexpected and severe adverse effects should be reported to Health Canada:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

Who to contact with questions or concerns:

- Saskatchewan Biosimilars Initiative: email sk.biosimilars@health.gov.sk.ca or call 1.800.667.2549 (306.787.8744 in Regina), option 3.
- medSask: email druginfo@usask.ca or call 1.800.667.3425 (306.966.6340 in Saskatoon)



Foundations of Originator and Biosimilar Biologics: For Patients and Caregivers

New online course now available

Hosted on edX platform

Created by health professionals and patients, this course will help you learn more about:

- How biosimilar biologic medications are made
- How these medications are approved for sale and use in Canada
- How to ask questions and lead discussions with your health care provider
- Available for free in the course audit stream

Scan to register!

Register at edx.org

UNIVERSITY OF TORONTO
LESLIE DAN FACULTY OF PHARMACY

Professional Certificate in Originator and Biosimilar Biologics: For Patients and Healthcare Providers

New online course for health professionals

Hosted on edX platform

Enhance your knowledge and skills related to using biosimilar or biologic medicines in professional practice settings.

Accredited professional certificate stream available for $200 CAD.

- Improve patient-provider communication and perceptions of biosimilar use
- Learn about best practice implementation of biosimilar medications
- Progress at your own speed through self-paced learning model
- Earn CE credits for pharmacy, nursing, medicine

Scan to register!

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Register at edx.org