Saskatchewan Biosimilars Initiative
Guide for Patients

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Overview

The Saskatchewan Biosimilars Initiative promotes the use of biosimilar versions of biologic medications by individuals who require these medications. The first phase of the Biosimilars Initiative was successfully completed in April 2024 and the second phase will be launched in February 2026.

Under the Biosimilars Initiative, patients receive Saskatchewan Drug Plan coverage for a biosimilar version of a biologic medication where one is available and listed on the Saskatchewan Formulary.

Using biosimilars present a significant opportunity for cost savings and long-term health system sustainability while providing safe and effective medication options. Continued expansion of the Biosimilars Initiative supports patient access to public drug plan coverage.

The Biosimilars Initiative will apply to future reference biologics as new biosimilars are added to the Saskatchewan Formulary. Updates will be communicated on an ongoing basis.

All provincial public drug plans across Canada have put similar policies in place to promote the uptake of biosimilar medications and many countries have also introduced measures to support biosimilar use.

About Biologic and Biosimilar Medications

Biologic medications are made from living organisms or their cells. Biologic medications differ from most other medications that are made solely from chemicals. Biologic medications include hormones, blood products, antibodies, genes, and vaccines. Biologics treat many different diseases, including Crohn's disease, ulcerative colitis, rheumatoid arthritis, diabetes, etc.

A **reference biologic or "originator" biologic medication** is the first version of a biologic medication to be made.

Biosimilar medications are the next versions of the biologic medication to be made after the reference biologic's patent expires. All biosimilars approved by Health Canada meet rigorous quality standards to confirm that they are as effective and safe as the reference biologic.

- Biosimilars are produced to the same quality as reference biologics but can be made at a much lower cost. Biosimilars cost less because they are based on work already done to develop the reference biologic medication.
- The expected therapeutic effect is the same for both a reference biologic and its biosimilar versions.

In Canada and internationally, there have not been any unexpected safety issues identified for biosimilars.

About the Saskatchewan Biosimilars Initiative

New Patients: Starting a Biosimilar Medication

- Patients who are newly starting an affected biologic medication will receive Saskatchewan Drug Plan coverage for a biosimilar version beginning on the Effective Date New Patients Must Use a Biosimilar shown in the List of Drugs Affected.

Existing Patients: Transitioning to a Biosimilar Medication

- Patients who are currently using an affected reference biologic medication will need to transition to a biosimilar version by the end of the announced transition period to maintain Saskatchewan Drug Plan coverage of their treatment. The announced transition period allows time for patients using an affected reference biologic medication to talk to their health care provider and get a new prescription for a biosimilar.
- Patients who may need to transition to a biosimilar medication to maintain their Saskatchewan Drug Plan coverage will be notified directly by letter.
- After the announced transition period, the Saskatchewan Drug Plan will no longer cover the reference biologic medication.

Prescriptions for Biosimilars

- Patients will need to obtain a new prescription for a biosimilar version of their affected reference biologic.
- Biosimilars are not listed as interchangeable with the reference biologic on the Saskatchewan Formulary. They cannot be substituted at the pharmacy level.

Exception Drug Status (EDS)

- Patients who have current EDS approval for an affected reference biologic will have EDS approval added for the biosimilar version(s) at the beginning of the transition period.
- Health care providers do not need to submit a new EDS application for their patients to transition to a biosimilar.

List of Drugs Affected by the Saskatchewan Biosimilars Initiative

The list of drugs affected shows the biologic medications currently included in the Biosimilars Initiative.

Drug Name	**Reference Biologic Brand Name** (switch from)	**Biosimilar Brand Name** (switch to)*	**Health Conditions**	**Effective Date New Patients Must Use a Biosimilar****	**Transition Period** (for affected patients)
Denosumab	Prolia®	Jubbonti® Stoboclo™	Osteoporosis	Dec. 1, 2025	Feb. 1, 2026 to Jan. 31, 2027
Omalizumab	Xolair®	Omlyclo®	Chronic idiopathic urticaria***		Feb. 1, 2026 to Jul. 31, 2026
Tocilizumab	Actemra®	Avtozma™ Tyenne®	Autoimmune conditions (giant cell arteritis, rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis)		
Ustekinumab	Stelara®	Jamteki™ Otulfi™ Steqeyma® Wezlana™	Autoimmune conditions (plaque psoriasis, psoriatic arthritis, Crohn's disease)		

*Please refer to the Saskatchewan Formulary for the most current listings.

**The effective date reflects the listing date of the first biosimilar version.

***Omlyclo is also listed on the Saskatchewan Formulary as an Exception Drug Status (EDS) benefit for other conditions.

Please note that patients will continue to be able to access Saskatchewan Drug Plan coverage of their reference biologic medication if a suitable biosimilar format is not available.

Patients using Humalog® (insulin lispro), NovoRapid® (insulin aspart), and Lantus® (insulin glargine)

- Coverage of Humalog® 200 units/mL will continue to be available for patients who need a higher concentration formula, as there is no equivalent biosimilar format at this time.
- Lantus® vials will remain covered at this time, until biosimilar(s) in a vial format are listed on the Saskatchewan Formulary. Existing Lantus® vial users have ongoing coverage in place. Prescribers can request an exemption to the policy for new patients requiring a vial format.
- Lantus® cartridges will remain an Exception Drug Status (EDS) benefit for pediatric patients who require a half-unit pen device to administer insulin glargine.
- NovoRapid® vials will remain an EDS benefit for patients who use insulin pumps while the biosimilar(s) are certified for use with insulin pumps. A biosimilar insulin aspart vial is also listed on the Saskatchewan Formulary.
- Individuals with questions about insulin compatibility with specific insulin pump models are encouraged to contact the insulin pump manufacturer or their health care provider.

Concluded Transition Periods

The transition periods for the following reference biologic medications have concluded. Patients are required to use a biosimilar version to be eligible for Saskatchewan Drug Plan coverage of these medications unless they have an approved exemption.

- March 31, 2024 – Drug(s) affected: Humalog® 100units/mL
- April 30, 2023 – Drug(s) affected: Humira®, Lovenox®, Enbrel®, Neupogen®, Copaxone®, Remicade®, NovoRapid® (cartridge), Lantus® (cartridge, pre-filled pen), Rituxan®

Transitioning to a Biosimilar

If you are using a reference biologic medication included in the Biosimilars Initiative and you receive Saskatchewan Drug Plan coverage for this medication, you should:

- Check the List of Drugs Affected to see if you need to use a biosimilar to maintain Saskatchewan Drug Plan coverage of this medication.
- At your next appointment, talk to the health care provider who prescribed your current biologic medication. If you don't have an appointment scheduled before the transition period ends, call their office to book one.
- You will need a new prescription for the biosimilar version of your medication because your pharmacy or clinic can only start the biosimilar with a new prescription.
- Discuss your questions about biosimilars with your doctor, nurse, or pharmacist.
- In some cases, you may have the option to enroll in a biosimilar patient support program (PSP). If applicable and appropriate, your health care provider can help you with this.

Exemptions

Exemptions for a patient to maintain coverage of a reference biologic will be considered for those who cannot use a biosimilar for a medical reason. Your prescriber may submit an Exemption Request Form for review by the Drug Plan on a case-by-case basis. Prescribers and patients will be notified of exemption decisions directly by letter. Please note that patients will continue to be able to access Saskatchewan Drug Plan coverage of their reference biologic medication if a suitable biosimilar format is not available.

Additional Information

Comparing Biosimilar and Generic Medications

- A generic medication is a simpler molecule and is an exact copy of the original brand name medication.
- Biologic medications are made from live cells and are more complex than traditional medications.

Comparing Biosimilar and Reference Biologic Medications

- Biosimilar medications are highly similar to their reference biologic. The biosimilar will work in the same way as the reference biologic.
- The expected therapeutic effect is the same for both a reference biologic and its biosimilar versions.

- Biosimilar manufacturers submit studies to Health Canada to prove that their biosimilar works as well and is as safe as the reference biologic.
- Each batch of a biologic medication can have minor variations from the first biologic that was made. These minor changes can happen with each batch of a reference biologic and with the biosimilar copies, but do not change the effect or safety of the medication.

Biosimilar Medication Safety

- Health Canada monitors and regulates all medications, including biosimilars.
- All biosimilars approved by Health Canada meet rigorous quality standards to confirm that they are as effective and safe as the reference biologic.
- Biosimilars are produced to the same quality as reference biologic medications.
- In Canada and internationally, there have not been any unexpected safety issues identified for biosimilars.

Patients Affected by the Biosimilars Initiative

- The Biosimilars Initiative applies to patients who:
  - are newly starting, OR currently using a biologic medication on the List of Drugs Affected, AND
  - receive Saskatchewan Drug Plan coverage for this biologic medication.
- Please note that patients will continue to be able to access Saskatchewan Drug Plan coverage of their reference biologic medication if a suitable biosimilar format is not available.

Medications Affected by the Biosimilars Initiative

- Please see the List of Drugs Affected for the reference biologic medications currently affected by the Saskatchewan Biosimilars Initiative.
- The Biosimilars Initiative also applies to biologic medications included in previous transition period(s) (see Concluded Transition Periods).

Saskatchewan Drug Plan Coverage for Biosimilar Medications

- Patients who have Saskatchewan Drug Plan coverage for a reference biologic medication on the List of Drugs Affected will need to start using a biosimilar version before the end of the announced transition period.
- During the announced transition period, patients who are already using an affected reference biologic drug will have Saskatchewan Drug Plan coverage of both the reference biologic and biosimilar(s) listed on the Formulary.
- After the announced transition period, the Saskatchewan Drug Plan will no longer cover the reference biologic medication unless a patient has an approved exemption.
- The cost of medication will vary based on an individual's coverage, deductible and/or copayment.
- Please note that the Drug Plan will not cover up to the cost of the biosimilar if patients keep using the reference biologic after the end of the transition period. Patients will be responsible for the full cost of their reference biologic treatment unless they have an approved exemption.
- For questions related to drug coverage, contact the Drug Plan at 1-800-667-7581 or 306-787-3317 (Regina) or DPEB@health.gov.sk.ca.

Private Drug Coverage for Biosimilar Medications

- The Biosimilars Initiative applies to patients receiving Saskatchewan Drug Plan coverage of a reference biologic medication on the List of Drugs Affected and to biologic medications included in previous transition period(s) (see Concluded Transition Periods).
- Your private insurance provider may coordinate your benefits with the Saskatchewan Drug Plan.
- Contact your private insurance provider with questions about your private drug coverage benefits and how the Saskatchewan Biosimilars Initiative may apply to your private benefits.

Preventing the Nocebo Effect

- Biosimilars work in the same way as the reference biologic; there are no clinically meaningful differences between the two medications.
- Biosimilar manufacturers submit studies to Health Canada and go through a rigorous process to prove that their biosimilar works as well and is as safe as the reference biologic.
- Patients can, therefore, expect the same therapeutic effect from biosimilars as the reference biologic.
- Science tells us that sometimes, our mindsets can influence our symptoms and sense of well-being. When negative expectations influence treatment outcomes, this is called the nocebo effect. Misinformation from a variety of sources can contribute to the nocebo effect.
- To prevent a nocebo effect, patients can:
    - Recognize the possibility of the nocebo effect
    - Find trustworthy information on biosimilars (see the Resources and Studies section)
    - Speak to their doctor, nurse, or pharmacist about biosimilar questions and options
    - Know that a growing number of patients around the world are safely using biosimilar treatments
    - Trust that your health care team is available if you have any questions or concerns about your treatment

Patient Supports

- Patients may contact their doctor, nurse, or pharmacist with questions about their treatment or about biosimilar medications.
- Many biosimilar manufacturers provide patient support programs (PSPs) and services similar to those of the reference biologic manufacturer to assist patients starting and transitioning to a biosimilar medication. See Patient Support Programs (PSPs) for more information.
- Patients can refer to the Information about Biologic and Biosimilar Medications, Saskatchewan Biosimilars Initiative: Information for Patients, and the Resources and Studies sections of the Saskatchewan Biosimilars Initiative website for trustworthy information on biosimilar medications.
- medSask is a drug information service that provides accurate, evidence-based information on medications and medication therapy to the general public, healthcare providers, and other collaborators. medSask is available to support patients and health care providers with questions about biosimilar drugs. To contact medSask, patients may:
    - visit medsask.usask.ca/general-public/biosimilars-in-saskatchewan, or
    - email med.sask@usask.ca, or
    - call 1-800-665-3784 (306-966-6378 in Saskatoon).

- For general questions about the Saskatchewan Biosimilars Initiative, patients can contact the Drug Plan at sk.biosimilars@health.gov.sk.ca or call 1-800-667-2549 (306-787-8744 in Regina), and press 2, then 2, or visit our website at www.saskatchewan.ca/biosimilars.

Biosimilar Medications for Cancer Treatment

- The Biosimilars Initiative impacts biologics and biosimilars listed on the Saskatchewan Drug Plan Formulary and does not include those covered through the Saskatchewan Cancer Agency.
- The Saskatchewan Cancer Agency is already using several biosimilar medications to treat various cancers.