Saskatchewan Biosimilars Initiative Guide for Patients

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Overview

The Saskatchewan Biosimilars Initiative was announced on October 20, 2022, to improve the uptake of biosimilar drugs.

Biosimilars present a significant opportunity for cost savings and health system sustainability while providing safe and effective medication options. The Biosimilars Initiative will support patient access to public drug coverage and new drug benefits.

The Biosimilars Initiative means that coverage will only be available for a biosimilar version of a biologic medication.

About Biologic and Biosimilar Drugs

<u>Biologic drugs</u> are made from living organisms or their cells. They differ from most other drugs in that they are not made by chemicals. Biologic drugs include hormones, blood products, antibodies, genes, and vaccines. Biologics treat many different diseases, including Crohn's and colitis, rheumatoid arthritis, and diabetes.

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

<u>Biosimilar drugs</u> are the next versions of the biologic drug to be made after the reference biologic's patent expires. You can be confident that biosimilars are as effective and safe as reference biologics.

- Biosimilars work in the same way as the reference biologic, but are less expensive.
- You can expect the same results from biosimilars as the reference biologic you are familiar with.

Biosimilars are regulated and monitored by Health Canada. Clinical studies show that biosimilars have the same efficacy and safety as the reference biologic drug.

Several public drug plans across Canada, including Alberta, British Columbia, New Brunswick, Nova Scotia, Quebec, and the Northwest Territories, have already implemented similar policies to increase uptake of biosimilar drugs. Several countries have also implemented policies to encourage the use and transition to biosimilars. In Canada and internationally, there have not been any unexpected safety issues identified for biosimilars.

About the Saskatchewan Biosimilars Initiative

If you are starting or already using a reference biologic drug in the table on the second page <u>and</u> you receive Saskatchewan Drug Plan coverage for this medication, you may be affected by the Saskatchewan Biosimilars Initiative.

If you are already using a reference biologic with an available biosimilar version, you will need to start using a biosimilar by **April 30, 2023**, in order to maintain your Saskatchewan Drug Plan coverage. From now until the end of the transition period on April 30, 2023, you will be eligible for coverage of both the reference biologic drug and any listed biosimilar(s), to allow for time to talk to your health care provider and get a new prescription for the biosimilar. After the transition period, the Saskatchewan Drug Plan will no longer cover the reference biologic drug.



List of Drugs Affected by the Biosimilars Initiative

Drug name	Reference biologic brand name (switch from)	Biosimilar brand name (switch to)	Health conditions	End of transition period
Adalimumab	Humira®	Abrilada® Amgevita™ Hadlima® Hulio® Hyrimoz® Idacio® Simlandi™ Yuflyma™	Auto-immune conditions, including: Ankylosing spondylitis Crohn's disease Hidradenitis suppurativa Juvenile idiopathic arthritis Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis Uveitis	April 30, 2023
Enoxaparin	Lovenox®	Inclunox® Noromby® Redesca™	Prevention and treatment of venous thromboembolic events	April 30, 2023
Etanercept	Enbrel®	Brenzys® Erelzi®	Auto-immune conditions, including: Ankylosing spondylitis Juvenile idiopathic arthritis Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis	April 30, 2023
Filgrastim	Neupogen®	Grastofil® Nivestym™	Low white blood cell count (non-cancer related)	April 30, 2023
Glatiramer (a non-biologic complex drug)	Copaxone®	Glatect™	Multiple sclerosis	April 30, 2023
Infliximab	Remicade®	Avsola™ Inflectra® Renflexis™	Auto-immune conditions, including: Ankylosing spondylitis Crohn's disease Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis	April 30, 2023
Insulin aspart	NovoRapid®	Trurapi [®]	Diabetes	April 30, 2023
Insulin glargine	Lantus®	Basaglar™	Diabetes	April 30, 2023
Insulin lispro	Humalog [®]	Admelog®	Diabetes	April 30, 2023
Rituximab	Rituxan®	Riximyo® Ruxience™ Truxima™	Auto-immune conditions listed in Appendix A of the Saskatchewan Formulary	April 30, 2023

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.



Transitioning to a Biosimilar

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

- Follow up with the health care provider who prescribes your reference biologic at your next scheduled appointment. Contact their office if you do not have an appointment before April 30, 2023.
- Get a new prescription for the biosimilar version of your medication (a new prescription is required to start the biosimilar at your pharmacy or clinic).
- 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. Your health care provider can help you with this.

Exemptions

Some patients may need to continue using the reference biologic for medical reasons. Exemptions to the Saskatchewan Biosimilars Initiative policy may be considered for an individual patient to continue their Saskatchewan Drug Plan coverage of a reference biologic. Your prescriber can submit a request and supply clinical rationale for review on a case-by-case basis.

Frequently Asked Questions

What is a biologic drug?

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

What is a reference or originator biologic?

The first version of a biologic drug to be produced is called the reference or originator.

What is a biosimilar drug?

- Biosimilar drugs are the next versions of the biologic drug produced after patent expiry of the reference biologic drug.
- Biosimilars work in the same way as the reference biologic drug, but are less expensive.
- You can expect the same results from biosimilars as the reference biologic you are familiar with.

Is a biosimilar drug as effective as a reference biologic?

- Biosimilars work in the same way as the reference biologic.
- You can expect the same results from biosimilars as the reference biologic.
- Biosimilar manufacturers submit studies to Health Canada to prove that their biosimilar works as well and is as safe as the reference biologic.

Are biosimilar drugs safe?

- Health Canada monitors and regulates all drugs, including biosimilars.
- Health Canada ensures biosimilar drugs are as effective and safe as their reference biologic version.
- Biosimilars are produced with the same regulatory standards as reference or originator biologic drugs.
- In Canada and internationally, there have not been any unexpected safety issues identified for biosimilars.



How do I keep my coverage if I need to switch?

- Check the table on the second page to see if you may need to use a biosimilar to be eligible for Saskatchewan Drug Plan coverage.
- Between now and the end of the transition period, you are encouraged to contact the health care provider who prescribes your biologic medication.
- Talk to your health care provider about the available biosimilar options and get a new prescription for the biosimilar. A new prescription is required to start receiving the biosimilar at a pharmacy or clinic.
- In some cases, you may have the option to enroll in a biosimilar patient support program. Your health care provider can help you with this.
- After the transition period, the Saskatchewan Drug Plan will no longer cover the reference biologic drug.

What if I have private coverage?

- The Biosimilars Initiative will apply to patients receiving Saskatchewan Drug Plan coverage of a reference biologic drug in the table on the second page.
- 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.

What if I don't think a biosimilar will work?

- Biosimilars work in the same way as the reference biologic.
- 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.
- You can expect the same results from biosimilars as the reference biologic.
- A "nocebo effect" can happen if you think a biosimilar might not work or that it might cause new side effects. Even though biosimilars are proven to work as well as the reference biologic, simply having negative expectations can influence your symptoms when you start to use a biosimilar.
- To prevent a nocebo effect, you can:
 - Recognize the chance that your concerns can create a nocebo effect
 - Find trustworthy information on biosimilars (resources are available online at www.saskatchewan.ca/residents/health/prescription-drug-plans-and-health-coverage/extended-benefits-and-drug-plan/biosimilars)
 - Speak to your doctor, nurse, or pharmacist about your biosimilar questions and options
 - Know that a growing number of patients around the world are safely using biosimilar treatments to control their diseases
 - Trust that your health care team is available if you have any questions or concerns about your treatment

What if I can't use a biosimilar?

- Your prescriber can help determine if you need to remain on the reference biologic for medical reasons.
- Your prescriber can submit a request for your situation to be reviewed on a case-by-case basis by the Saskatchewan Drug Plan.

Where can I find more information and support?

- Go to our webpage: www.saskatchewan.ca/residents/health/prescription-drug-plans-and-health-coverage/extended-benefits-and-drug-plan/biosimilars
- Contact your doctor, nurse, or pharmacist with questions about biosimilar medications.
- medSask is a drug information service with pharmacists available to support you with questions about your biologic drug treatment. Visit medsask.usask.ca or call 1-800-665-3784.
- Many biosimilar manufacturers have Patient Support Programs and services to assist patients starting and transitioning to a biosimilar drug. Find the Patient Support Programs section on our webpage.



Contact Us

For general questions about the Saskatchewan Biosimilars Initiative, please contact sk.biosimilars@health.gov.sk.ca or call 1-800-667-2549 (306-787-8744 in Regina), option #3.

Information is also available online at www.saskatchewan.ca/residents/health/prescription-drug-plans-and-health-coverage/extended-benefits-and-drug-plan/biosimilars.

For questions related to drug coverage, contact the Drug Plan at 1-800-667-2549 or 306-787-8744 (Regina) or DPEB@health.gov.sk.ca.

