

Manitoba Biosimilars Initiative Guide for Prescribers

Overview

The Manitoba Biosimilars Initiative was implemented 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 ongoing access to public drug coverage and new drug benefits for Manitobans.

The Manitoba Biosimilars Initiative will transition provincial drug plan coverage of biologic medications to biosimilar versions, where they are available.

Patients will need to transition to a biosimilar version of their biologic medication, in order to maintain Pharmacare or other provincial drug plan coverage.

Manitoba has joined public drug plans across Canada, including those in British Columbia, Alberta, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, the Northwest Territories, and Yukon, in implementing a Biosimilars Initiative as part of responsible and sustainable drug plan management.

About the Biosimilars Initiative

The Biosimilars Initiative includes 10 drugs covered under Pharmacare and other provincial drug plans (see **Appendix 1**). It is anticipated that further drugs will be added to this list as new biosimilars become available.

Patients currently using reference biologic drugs (also called “originator” or “innovator” biologics) with an available biosimilar version will be required to transition to a biosimilar by the transition period end date, in order to maintain coverage under Pharmacare and other provincial drug plans.

From now until the transition period end date, patients will be eligible for coverage of both the reference biologic and any listed biosimilar option(s).

After the end of the transition period, the reference biologic drug will no longer be covered under Pharmacare and other provincial drug plans.

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

As trusted health care providers, we encourage you to prepare patients to transition to biosimilars prior to the transition end date to ensure there is sufficient time to:

- Address patient concerns
- Update the patient's prescription with the selected biosimilar
- Support the patient's enrollment in a biosimilar patient support program (if applicable).

Information about available biosimilar patient support programs can be found here:

<https://www.gov.mb.ca/health/pharmacare/docs/biosimilar-support-programs.pdf>

List of Affected Patients for Prescribers

The department will be mailing letters to all prescribers of patients with existing Exception Drug Status (EDS) coverage of reference biologics. These letters will include a list of affected patients who will need to start using a biosimilar in order to maintain Pharmacare and other provincial drug plan coverage.

Letters will not be sent to prescribers of patients using reference biologic insulin products; however, patients using reference biologic insulins with an available biosimilar version will also need to start using a biosimilar in order to maintain Pharmacare and other provincial drug plan coverage.

Prescriptions

A new prescription is required for your patient to start using a biosimilar.

At this time, biosimilars are not listed as interchangeable with the reference biologics on the Manitoba Interchangeability Formulary. Consequently:

- Biosimilars cannot be substituted at the pharmacy level.
- Prescriptions must clearly indicate the biosimilar brand to be dispensed by the pharmacy.

Existing Exception Drug Status (EDS) Coverage

A new EDS application is not required for your patient to start using a biosimilar.

Where applicable, EDS coverage for all listed biosimilars has now been added for patients with current EDS coverage for an affected reference biologic. **EDS coverage for the reference biologic will expire on the existing EDS coverage expiry date or on the transition period end date, whichever is sooner.**

Requests to renew existing coverage of reference biologic drugs during the transition period will be considered; however, if a request for renewal of EDS coverage for the reference biologic is

approved, extended coverage for the reference biologic will expire on the transition period end date, while coverage for the biosimilar versions will be for the standard approval period.

Exceptional Coverage of Reference Biologics

In limited circumstances, some patients may need to continue using the reference biologic for medical reasons. Exceptions to Manitoba's Biosimilars Initiative may be considered for individual clients to continue to receive coverage of a reference biologic after the transition period end date. Prescribers should submit an EDS application and supply clinical rationale for review on a case-by-case basis.

Patient Notification

The department will be mailing letters to affected patients (to the address on file with Manitoba Health, Seniors and Long-Term Care):

- Notifying them of the Biosimilars Initiative and any resulting EDS coverage updates (as applicable).
- Referring patients to the Manitoba Biosimilars Initiative webpage where additional information and resources are available:
<https://www.gov.mb.ca/health/pharmacare/biosimilars.html>

These letters will also direct patients to do the following before the transition period end date:

- Continue using their reference biologic according to the prescriber's instructions.
- Follow-up with the health care provider who prescribes their reference biologic at their next scheduled appointment, or contact their provider's office if they do not have an appointment booked before the transition period end date.
- Request a new prescription for a biosimilar version of their medication.
- Discuss their questions about biosimilars with their health care provider.

A Guide for Patients is available to provide information for patients on biosimilars and the Manitoba Biosimilars Initiative:

<https://www.gov.mb.ca/health/pharmacare/docs/patient-guide.pdf>

Efficacy and Safety of Biosimilar Drugs

All biosimilars approved by Health Canada meet rigorous quality standards to confirm they are as effective and safe as the reference biologic. Patients and providers should not expect a difference in therapeutic effect whether a patient receives a reference biologic or a biosimilar version.

Patients place significant trust in their health care provider's advice and opinions. Your patients may be anxious or concerned about using a biosimilar version of their medication. We encourage you to approach patient questions with evidence-based information to help build patient confidence in the robust data supporting biosimilar use and transition. Biosimilar

Resources are available here: <https://www.gov.mb.ca/health/pharmacare/docs/biosimilars-resources.pdf>

Additional Information

For additional information on the Manitoba Biosimilars Initiative, please visit:
<https://www.gov.mb.ca/health/pharmacare/biosimilars.html>

Answers to Frequently Asked Questions regarding the Biosimilars Initiative can be found here:
<https://www.gov.mb.ca/health/pharmacare/docs/prescriber-faq.pdf>

Appendix 1 – Products Included in the Manitoba Biosimilars Initiative

Drug Name	Reference Biologic (Switch from)	Biosimilar (Switch to)	Health Conditions*	Transition Period End Date
Adalimumab	Humira	Abrilada Amgevita Hadlima Hulio Hyrimoz Idacio Simlandi Yuflyma	Ankylosing Spondylitis Crohn's Disease Hidradenitis Suppurativa Plaque Psoriasis Polyarticular Juvenile Idiopathic Arthritis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis	January 31, 2025
Enoxaparin	Lovenox	Elonox Elonox HP Inclunox Inclunox HP Noromby Noromby HP Resdesca Resdesca HP	Prevention and treatment of venous thromboembolic events	January 31, 2025
Etanercept	Enbrel	Brenzys Erelzi	Ankylosing Spondylitis Plaque Psoriasis Polyarticular Juvenile Idiopathic Arthritis Psoriatic Arthritis Rheumatoid Arthritis	January 31, 2025
Filgrastim	Neupogen	Grastofil Nivestym Nypozi	Prevention and treatment of neutropenia	January 31, 2025

Drug Name	Reference Biologic (Switch from)	Biosimilar (Switch to)	Health Conditions*	Transition Period End Date
Glatiramer (a non-biologic complex drug)	Copaxone	Glatect	Multiple Sclerosis	January 31, 2025
Infliximab	Remicade	Avsola Inflectra Renflexis	Ankylosing Spondylitis Crohn's Disease Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis	January 31, 2025
Insulin aspart	NovoRapid	Kirsty Trurapi	Diabetes	January 31, 2025
Insulin glargine	Lantus	Basaglar Semglee	Diabetes	January 31, 2025
Insulin lispro (100 units/mL)	Humalog	Admelog	Diabetes	January 31, 2025
Rituximab	Rituxan	Riximyo Ruxience Truxima	Granulomatosis with Polyangiitis Microscopic Polyangiitis Rheumatoid Arthritis	January 31, 2025

**Transition also applies for other conditions, funded on a case-by-case basis, which may not appear in the above list.*

Updates to this product list will be posted online here:
<https://www.gov.mb.ca/health/pharmacare/biosimilars.html>

An overview of reference biologic insulin products and covered biosimilar versions can be found here: <https://www.gov.mb.ca/health/pharmacare/docs/ref-insulin-chart.pdf>

Please note:

- 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 version available at this time.
- Coverage of Lantus cartridges will continue to be available for pediatric patients who require a half-unit pen device to administer insulin glargine.
- Coverage of NovoRapid vials will continue to be available for patients who use vials for an insulin pump, while biosimilars undergo insulin pump certification, and until these biosimilar(s) in a vial format are available / listed on the Manitoba Drug Benefits Formulary.
- Admelog is compatible with various insulin pump models from Insulet (Omnipod), Medtronic, Tandem, and Ypsomed.
- Individuals with questions about insulin compatibility with specific insulin pump models are encouraged to contact the insulin pump manufacturer.