Manitoba
Health, Seniors and Long-Term Care

Manitoba Biosimilars Initiative
Frequently Asked Questions – Patients

What is a biologic drug?

- Biologic drugs are made from living organisms or their cells.
- They differ from most other drugs in that they are not made by chemical synthesis, and instead consist of larger and more complex molecules.
- Examples of biologic drugs include insulins, blood products, antibodies, and growth hormones.
- Biologic drugs treat many different conditions, including Crohn's and colitis, diabetes, and rheumatoid arthritis.

What is a reference biologic?

- The first version of a biologic drug to be produced is called the reference biologic drug (or sometimes an **originator** or **innovator** biologic drug).

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 costly.

Are biosimilar drugs the same as generics?

- No. A generic drug is a simpler molecule and is an exact copy of the original brand name medication.
- Biologic drugs are made from live cells and are more complex than traditional drugs.
- Biosimilar drugs are highly similar to their reference biologic and will work in the same way as the reference biologic.
- Each batch of a biologic drug can have minor variations. These minor changes can happen with each batch of a reference biologic and with biosimilar drugs, but do not change the effect or safety of the drug.

Is a biosimilar drug as effective as a reference biologic?

- Yes. Biosimilars work in the same way as the reference biologic.
- Patients can expect the same clinical results from biosimilars as from 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?

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

What is the Biosimilars Initiative?

- Manitoba's Biosimilars Initiative replaces coverage of reference biologic medications with coverage of biosimilar versions of these products.
- Patients are required to transition to a biosimilar version of their medication, in order to maintain Pharmacare or other provincial drug plan coverage.
- Biosimilars present a significant opportunity for cost savings and health system sustainability while providing safe and effective medication options.
- The Biosimilars Initiative supports ongoing access to public drug coverage and new drug benefits for Manitobans.

Does the Biosimilars Initiative apply to all patients?

- The Biosimilars Initiative applies to patients receiving Pharmacare or other provincial drug plan coverage for a reference biologic drug on the list of products included in the initiative: https://www.gov.mb.ca/health/pharmacare/biosimilars.html
- 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.
- Your prescriber can submit a request and supply clinical rationale for review on a case-by-case basis.
- Please note, patients will continue to be able to access coverage of their reference biologic medication if a suitable biosimilar format is not available.

Why is a Biosimilars Initiative needed?

- Manitoba has joined public drug plans across Canada in implementing a Biosimilars Initiative as part of responsible and sustainable drug plan management.
- Biosimilar drugs present a significant opportunity for cost savings and health system sustainability while providing safe and effective medication options.
- The Biosimilars Initiative supports ongoing access to public drug coverage and new drug benefits for Manitobans.

How do I find out if I need to switch to a biosimilar?

- When a product is added to the Biosimilars Initiative, patients are contacted directly by letter if they need to start using a biosimilar version of their medication to maintain their Pharmacare or other provincial drug plan coverage. This letter is mailed to the patient's mailing address on file with Manitoba Health.
- Patients using a reference biologic drug on the list of drugs affected by the Biosimilars Initiative will need to start using a biosimilar version before the end of the transition period in order to maintain their drug plan coverage.
    - A list of products included in the Biosimilars Initiative and their associated transition period(s) can be found here: https://www.gov.mb.ca/health/pharmacare/biosimilars.html
- After the end of the announced transition period, the reference biologic drug will no longer be covered under Pharmacare and other provincial drug plans.
- Patients should contact their health care provider with questions about their treatment or about biosimilar medications.

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

- Patients should check the list of products included in the Biosimilars Initiative to see if they need to use a biosimilar to be eligible for continued coverage of their biologic medication.
    - A list of products included in the Biosimilars Initiative and their associated transition period(s) can be found here: https://www.gov.mb.ca/health/pharmacare/biosimilars.html
- Patients are encouraged to follow up with the health care provider who prescribes their biologic medication at their next scheduled appointment. Please contact your prescriber if you do not have a scheduled appointment before the transition period end date associated with your reference biologic.
- Patients should talk to their health care provider about available biosimilar options and get a new prescription for a biosimilar. A new prescription is required to start receiving the biosimilar at a pharmacy or clinic.
- Patients may have the option to enrol in a new biosimilar patient support program. Your health care provider can help with this process.
- After the completion of the transition period, reference biologic drugs will no longer be covered under Pharmacare or other provincial drug plans.

If I keep using the reference biologic even though a biosimilar version is available, will Pharmacare (or other provincial drug plans) cover the cost of the reference biologic up to the cost of the biosimilar?

- No. After the end of a transition period, reference biologic drugs are no longer covered under Pharmacare or other provincial drug plans.
- Patients will be responsible for the full cost of their reference biologic medications unless an exception request has been approved in advance by the department.

What if I have private coverage?

- The Biosimilars Initiative applies only to Pharmacare or other provincial drug plan coverage of reference biologic drugs on the list of products included in the initiative: https://www.gov.mb.ca/health/pharmacare/biosimilars.html
- Contact your private insurance provider with questions about your private drug coverage and how the Manitoba's Biosimilars Initiative may affect these benefits.

Will my medication costs change when I start using a biosimilar?

- The cost you may need to pay for your medication will vary based on the product and your annual income-based Pharmacare deductible.
- For questions related to drug coverage, please contact Pharmacare at:

    Phone: 204-786-7141
    Toll free: 1-800-297-8099
    FAX: 204-786-6634
    TTY/TDD Relay Service: 204-774-8618
    outside Winnipeg: 711 or 1-800-855-0511
    E-mail: pharmacare@gov.mb.ca

When do I need to start using a biosimilar?

- If you have Pharmacare or other provincial drug plan coverage for one of the reference biologics affected by the Biosimilars Initiative, you will need to start using a biosimilar version before the end of the announced transition period.

    - A list of products included in the Biosimilars Initiative and their associated transition period(s) can be found here: https://www.gov.mb.ca/health/pharmacare/biosimilars.html
- Until the end of the announced transition period, you will be eligible for coverage of both the reference biologic drug and any listed biosimilar(s).
- After the end of a transition period, the reference biologic drug will no longer be covered unless an exception request has been approved in advance by the department.

What if I can't use a biosimilar?

- 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 individuals to continue to receive coverage of a reference biologic after the transition period end date.
- Your prescriber can submit a request and supply clinical rationale for review on a case-by-case basis.
- Patients will continue to be able to access coverage of their reference biologic medication if a suitable biosimilar format is not available.

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

- It is understandable to have questions about changes to your treatment.
- Biosimilars work in the same way as the reference biologic; there are no clinically meaningful differences between the two drugs.
- 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 clinical results 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, you can:
    - Recognize the possibility of the nocebo effect.
    - Find trustworthy information about biosimilars; see the Resources available here: https://www.gov.mb.ca/health/pharmacare/docs/biosimilars-resources.pdf
    - Speak to your health care provider about your biosimilar questions and options.
    - Keep a neutral or positive outlook and acknowledge the rigorous process that goes into the development of these drugs.
    - Be confident 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.

What supports are available?

- Patients may contact their health care provider with questions about their treatment or about biosimilar medications.
- Many biosimilar manufacturers have Patient Support Programs (PSPs) and services to assist patients starting and transitioning to a biosimilar drug.
    - Information on biosimilar PSPs is available here: https://www.gov.mb.ca/health/pharmacare/docs/biosimilar-support-programs.pdf
- For trustworthy information on biosimilars, patients can refer to the Resources available here: https://www.gov.mb.ca/health/pharmacare/docs/biosimilars-resources.pdf

- For general questions about the Manitoba Biosimilars Initiative, please contact Pharmacare at:

  Phone: 204-786-7141
  Toll free: 1-800-297-8099
  FAX: 204-786-6634
  TTY/TDD Relay Service: 204-774-8618
  outside Winnipeg: 711 or 1-800-855-0511
  E-mail: pharmacare@gov.mb.ca

Who was consulted as part of the implementation of the Biosimilars Initiative?

- Manitoba Health, Seniors and Long-Term Care (MHSLC) consulted with health care providers, drug manufacturers, patient groups, and health system stakeholders as part of the implementation of the Biosimilars Initiative.
- The department also works closely with other public drug plans that have implemented Biosimilars Initiatives.
- The MHSLC is committed to continuing to work with patients, prescribers, and other stakeholders to address any concerns related to the Biosimilars Initiative.

Are cancer drugs included and will cancer patients need to switch?

- The Biosimilars Initiative affects reference biologics covered under Pharmacare and other provincial drug plans; it does not include those covered through CancerCare Manitoba (CCMB).

Please also see Guide for Patients, available here:
https://www.gov.mb.ca/health/pharmacare/docs/patient-guide.pdf