UPDATE - Biosimilar Policy: FAQs for Pharmacies

1. Why is coverage for biologic drugs changing?

Every year, the Ontario Drug Benefit (ODB) program covers new treatments to ensure that eligible recipients have access to new and innovative drug therapies. Currently, ODB program recipients have access to coverage for over 5,000 safe and effective medications through the ODB Formulary with over 1,400 that require approval through the Exceptional Access Program (EAP).

Biologic medicines have improved the treatment of many disabling and life-threatening diseases. A biosimilar is a biologic drug that is highly similar to an originator biologic drug that was already authorized for sale.

Expanding the use of biosimilar versions of biologic drugs ensures that ODB program recipients will continue receiving the same high-quality treatment, while allowing the government to fund more new drug therapies. This will encourage innovation in the health care system and support the delivery of better, connected patient care.

Biosimilars have been used in the European Union and a number of Canadian jurisdictions, including British Columbia, Alberta, New Brunswick, Quebec, Northwest Territories, Nova Scotia, Saskatchewan, Prince Edward Island and Newfoundland and Labrador.

2. What is the difference between a biosimilar and generic product?

Generic drugs are made from chemical synthesis, while biosimilars are biologic drugs that are made from living organisms. Generic products are smaller molecules that can be synthesized chemically to be an exact chemical copy of its brand name or reference drug. Biologics are larger and more complex molecules that are made in living cells. Biosimilars, also referred to as subsequent entry biologics or follow-on biologics, are biologics that are similar to an originator biologic, and would enter the market after the patents or data protection rights for an originator biologic have expired. They are made in living cells, so while they are highly similar to their originator biologic, they are not identical. Due to the complexity of the larger molecules and variability of the living cells that are used to produce biologic drugs, there are batch-to-batch variabilities within the same brand.

Both generics and biosimilars undergo extensive Health Canada evaluations to confirm that there are no clinically meaningful differences in safety and efficacy between them and their original reference products. However, due to differences in manufacturing and the complexity of biologics, biosimilars are not designated as interchangeable with the innovator reference biologic.

3. What clinical evidence supports the claim that transitioning from an originator biologic to a corresponding biosimilar is safe and efficacious?

Biosimilar biologics must fulfill rigorous regulations and testing requirements imposed by Health Canada to prove they are as safe and effective as the originator biologic. Health Canada has definitively stated that its rigorous standards for authorization mean that patients and health care providers can have the same confidence in the quality, safety and efficacy of a biosimilar as the originator biologic.

Clinical trials and registry data findings are regularly reported at annual scientific meetings around the world that indicate that transitioning from an originator biologic to a biosimilar is safe and effective. There are now more than 100 research studies in rheumatology, gastroenterology, dermatology and other diseases, which collectively show little to no clinical differences between biosimilars and originator biologics.

The Ministry of Health will be carefully monitoring drug usage and feedback from ODB program recipients and healthcare practitioners both during and after the implementation of this funding policy regarding biosimilars.

4. Which biologic products are subject to the transition rule under biosimilar policy starting on November 29, 2024?

Prolia® (denosumab) and Xgeva® (denosumab) will be subject to the transition rule under the biosimilar policy effective as of November 29, 2024. Please refer to the accompanying EO Notice.

5. How long is the transition period?

The transition period is 9 months beginning November 29, 2024, until August 29, 2025. Please refer to the accompanying EO Notice.

6. Will Xgeva be covered for eligible patients receiving it from a hospital or cancer centre?

No, effective November 29, 2024, individuals receiving Xgeva® coverage through the New Drug Funding Program will also be required to transition to the biosimilar.

7. Will other drug products be added to the biosimilar policy?

Yes. As new biosimilars or similar versions of non-biologic complex drugs (NBCDs) enter the Canadian market, additional drug products may be included as part of the biosimilar policy.

8. What are the exceptions to the Transition Rule and how will they be applied?

During the transition period, existing and established ODB patients undergoing palliative care may be eligible to receive up to a 12-month coverage to remain on originator Prolia® through a Limited Use code on the formulary. Palliative patients on Xgeva ® funded under the ODB program may continue receiving ODB program coverage for the originator biologic by applying to the Exceptional Access Program (EAP) program for a palliative care exemption of up to 12 months.

Recipients of Prolia® and Xgeva® who require ODB program coverage to remain on an originator biologic for a medically necessary exemption can have their prescriber submit a request to the ministry's EAP. Please refer to the accompanying EO Notice for details.

Please note, currently there is only one biosimilar available for Prolia ® and one for Xgeva®. For an up-to-date list of eligible ODB funded biosimilars please refer to the ODB formulary.

9. How can prescribers submit Exceptional Access Program requests for exemptions under the biosimilar policy?

For faster responses prescribers are encouraged to submit EAP requests through EAP's web-based portal, the Special Authorization Digital Information Exchange (SADIE), which can be found at www.ontario.ca/sadie. Requests may also be sent by fax to 1-866-811-9908 (toll-free) or 416-327-7526 (Toronto area). If authorized prescribers are unable to use SADIE or fax, EAP requests may be submitted by mail to the following address:

Exceptional Access Program
5700 Yonge Street — 3rd Floor
North York, Ontario M2M 4K5

Submission by mail may delay the receipt of the request by the ministry.

10. How can I help with the transition from the originator biologic to the biosimilar at the pharmacy level?

Health Canada recommends that a transition from an originator biologic to a biosimilar be undertaken by the prescriber after discussion with the patient.

Pharmacies can assist with the transition by educating ODB program recipients when they fill their new prescription for a biosimilar or similar NBCD, and by answering any questions they may have. Pharmacies can also help by contacting the prescriber on the ODB program

recipient's behalf to discuss the transition to the biosimilar product and obtaining a new prescription.

11. How should I approach patient discussions?

Pharmacies can help the transition by educating ODB recipients when they fill their new prescription for a biosimilar, and by answering any questions they may have.

Treatment-naïve patients started on a biosimilar tend to accept biosimilars without issues. Treatment-experienced, stable patients using an originator biologic may need more support.

As healthcare professionals, pharmacists are trusted to be a source of information, expertise, and experience. It's important when talking to patients, to set a neutral or positive tone for the transition. Some critical information patients need to know is that biosimilars:

- Are safe and effective;
- Work the same way as their current medication;
- Add no increased risk of adverse reactions;
- Don't involve major changes to their routines or dosing;
- May have additional services provided by a patient support program; and
- Are well-studied and have been used successfully around the world.

12. What is the support fee for pharmacies?

Pharmacies may claim a Biosimilar Patient Support Fee in the amount of $15 when assisting ODB program recipients on an originator biologic transition to the biosimilar alternative in accordance with the biosimilar policy. Please refer to the accompanying EO Notice for more information, including the terms and conditions for the Biosimilar Patient Support Fee.

13. Some originator biologics have generic interchangeable versions. Can I claim a biosimilar support fee for transitioning patients from originators to the generic version instead of a biosimilar?

No, the Biosimilar Patient Support Fee can only be claimed when transitioning a recipient from an originator biologic to a biosimilar biologic.

14. What patient support programs are available for biosimilars?

Some biosimilar manufacturers are providing patient support programs (PSP) and services, along with access to infusion centres similar to those of the originator biologic. If applicable and appropriate, prescribers can help initiate the enrolment process into a PSP.

15. Where can I get more information?

For more information and reading materials, see the resources below.

For claims processing inquiries, call the ODB Pharmacy Help Desk at: 1-800-668-6641.

For any further inquiries regarding medical exemptions related to the biosimilars policy, please contact the Exceptional Access Program within the Ministry of Health by emailing the program at EAPFeedback@ontario.ca or by calling us at

416-327-8109 or 1-866-811-9893.

ADDITIONAL INFORMATION FOR HEALTH CARE PROFESSIONALS AND PATIENTS

- Health Canada—Biosimilar biologic drugs in Canada: Fact Sheet
- CADTH Biosimilar Drugs: Health care provider hand-out