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 another 1,000 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 and Newfoundland and Labrador, have expanded the funding of biosimilar medications.

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 biosimilar policy starting on July 31, 2024?

Effective **July 31, 2024** Ontario will add four additional biologic drugs to the biosimilar policy: Lucentis® (Ranibizumab), Stelara® (Ustekinumab), Lovenox® (Enoxaparin), and Neupogen® (Filgrastim). This will involve listing biosimilar versions of the originator biologics on the Formulary and implementing funding rules for treatment-naïve recipients (the “New Start Rule”) and recipients who have already initiated therapy with the originator biologic (the “Transition Rule”). Under the New Start Rule, treatment-naïve recipients will be required to initiate therapy with a biosimilar version of a biologic in order to receive ODB program coverage for the biologic. Under the Transition Rule, treatment-experienced recipients will have 6 months (from July 31, 2024 to January 31, 2025) to transition to a biosimilar version of a biologic in order to receive ODB program coverage for the biologic, subject to certain exceptions. At the end of the 6-month period on January 31, 2025, the originator biologics will not be funded under the ODB program, subject to certain exceptions.
Transitioning from an originator biologic to a biosimilar version will require a new prescription from a prescriber.

ODB program recipients taking one of the originator biologics listed above are encouraged to speak to their healthcare professional to discuss this transition.

5. How long is the transition period?

The transition period is 6 months beginning July 31, 2024 until January 31, 2025.

6. 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 this policy framework.

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

Recipients who are pregnant during the transition period or who require palliative care during the transition period are temporarily exempt from the requirement to transition to a biosimilar version of an originator biologic. This only applies to existing and established ODB patients. These recipients may continue receiving ODB program coverage for the originator biologic, in accordance with the Limited Use clinical criteria and authorization periods on the Formulary, and as set out in Appendix "B" to the accompanying Executive Officer (EO) Notice. This exception may not apply if the biologic is not indicated for use in palliative care and/or pregnancy.

Recipients who require ODB program coverage for an originator biologic during or after the transition period may ask their prescriber to submit a request for a medically necessary exemption to the ministry's Exceptional Access Program (EAP). The request should include documentation confirming that the recipient has experienced an adverse reaction to two or more biosimilars (where available). Requests are assessed on a case-by-case basis.

8. How can prescribers submit Exceptional Access Program exemption requests?

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.

9. 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 help the transition by educating ODB 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.

10. 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.

11. 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 Transition Rule. This may include:

- When filling the first prescription for a biosimilar included in the biosimilar policy for a transitioning ODB program recipient. Along with filling the prescription, pharmacies are expected to provide recipients with the information they need to assist with their transition to a biosimilar, which could include educating the recipient on the safety and efficacy of the product and answering any questions they have; OR
- Contacting the prescriber on the ODB program recipient's behalf to discuss the transition to the biosimilar product and obtaining a new prescription (e.g., generating lists of patients on an originator biologic for physicians).

The fee can be claimed **once per recipient per transition to a biosimilar product**. For clarity, if a recipient transitions to more than one biosimilar version of a biologic, then only one Biosimilar Patient Support Fee is payable for the transitions.

Pharmacies also have the flexibility to submit a claim for a Biosimilar Patient Support Fee when they undertake activities to support a recipient's transition to a biosimilar, such as contacting a prescriber to obtain the ODB program recipient's first prescription for a biosimilar as part of their transition from the originator biologic, subject to any terms and conditions set out in the accompanying EO Notice. Where an ODB program recipient obtains their first prescription for the biosimilar directly from the prescriber *without* pharmacy involvement, the pharmacy may continue to submit a claim for the Biosimilar Patient Support Fee when filling the prescription for the first time. The purpose of the Biosimilar Patient Support Fee is to help ensure a smooth and timely transition for ODB program recipients to biosimilar products. The fee is only available once per recipient per transition to a biosimilar product.

For the latest phase of the Transition Rule, which is between July 31, 2024 to January 30, 2025, the Biosimilar Patient Support Fee for the 4 products included in this phase can be submitted for payment in respect of ODB program recipients transitioning to a biosimilar version from July 31, 2024 to January 30, 2026 (i.e., the claim submission window is the start of the transition period for these 4 products to 1 year after the end of the transition period). It is <u>not</u> eligible for payment in the following circumstances:

- Recipients who are new to the ODB program on or after July 31, 2024;
- Prescriptions for biosimilars that were dispensed prior to July 31, 2024,
- Subsequent prescriptions for a biosimilar product, after the recipient's initial transition to a biosimilar;
- Recipients who are not enrolled in the ODB program and pay out-of-pocket or are reimbursed by a third-party payer (e.g., private insurer); or
- Recipients who are treatment-naïve to the biologic originator or the biosimilar drug.

12. 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 to a biosimilar.

13. 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.

14. 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