Biosimilar Policy: Q&A for Pharmacists

1. Why is coverage for biologic drugs changing?

Every year, the Ontario Drug Benefit (ODB) program covers new treatments to ensure that Ontarians 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.

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 ODB recipients will continue receiving the same high-quality treatment, while allowing the government to fund more new drug therapies, bring innovation to the health care system and continue its work to deliver better, connected patient care.

Biosimilars have been used in the European Union for more than 15 years and a number of Canadian jurisdictions, including British Columbia, Alberta, New Brunswick, Quebec, Northwest Territories, Nova Scotia and Saskatchewan, have expanded the use of biosimilar medications.

2. 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.

3. Which biologic products are being transitioned?

This change will impact patients that are taking any of the following originator biologic drugs: Enbrel® (etanercept), Humalog® (insulin lispro), Humira® (adalimumab), Lantus® (insulin glargine), NovoRapid® (insulin aspart), Remicade® (infliximab), or Rituxan® (rituximab). This change will also impact Copaxone® (glatiramer), which is a non-biologic complex drug (NBCD).

Patients taking any of the medications mentioned above, may require a new prescription to continue to receive ODB program coverage for medication(s). This new prescription would allow them to transition from the originator biologic drug they are currently on to a biosimilar version.

Patients are encouraged to speak to their healthcare professional to discuss this transition.

As new biosimilars enter the Canadian market, additional biologic drugs may be included as part of this policy change. The ministry will update materials online as additional biologic drugs are included under the policy.

Drugs Included in the Biosimilars Policy

Table 1: ODB Program Coverage*

Drug	Originator Biologic (Patients must transition to the biosimilar version **before** December 29, 2023)	Biosimilars Funded Under ODB Program Effective March 31, 2023	Indications
Adalimumab	Humira® Funded only for exemptions under EAP***	Abrilada® Amgevita® Hadlima® Hulio® Hyrimoz® Idacio® Simlandi® Yuflyma® Available as LU	Ankylosing Spondylitis Crohn's Disease Hidradenitis Suppurativa Plaque Psoriasis Polyarticular Juvenile Idiopathic Arthritis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis Uveitis
Etanercept	Enbrel® Funded only for exemptions under EAP***	Brenzys® Available as LU Erelzi® Available as LU	Ankylosing Spondylitis Plaque Psoriasis Polyarticular Juvenile Idiopathic Arthritis Psoriatic Arthritis Rheumatoid Arthritis

Glatiramer acetate**	Copaxone® Funded only for exemptions under EAP	Glatect™ Available as LU	Relapsing Remitting Multiple Sclerosis (RRMS)
Infliximab	Remicade® Funded only for exemptions under EAP	Avsola® Inflectra® Renflexis® Available as LU	Ankylosing Spondylitis Crohn's Disease Plaque Psoriasis Psoriatic Arthritis Rheumatoid Arthritis Ulcerative Colitis
Insulin aspart	NovoRapid® exemptions funded as LU Benefit	Kirsty® Trurapi® Available as GB	Diabetes (Type 1 and 2)
Insulin glargine	Lantus® exemptions funded as LU Benefit	Basaglar® Semglee® Available as GB	Diabetes (Type 1 and 2)
Insulin lispro	Humalog® exemptions funded as LU Benefit	Admelog® Available as GB	Diabetes (Type 1 and 2)
Rituximab	Rituxan® Funded only for exemptions under EAP	Riximyo® Ruxience™ Truxima™ Available as LU	Rheumatoid Arthritis Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis) Microscopic Polyangiitis (MPA)

NOTES

GB = General Benefit on the ODB Formulary
LU = Limited Use product; reimbursement criteria must be met
EAP = Exceptional Access Program; reimbursement criteria must be met
* As new biosimilars enter the Canadian market, additional originator biologics will be transitioned. This table will also be updated accordingly.
** Copaxone® and Glatect® are non-biologic complex drugs (NBCDs), however, the biosimilar policy will apply to their funding. As a result, in this document, references to an originator biologic include Copaxone® and references to a biosimilar include Glatect®.
*** See section above entitled "Medically Necessary Exemptions for Formulary Biologics".
****Humalog® 200 units/mL KwikPen® 200U/mL Inj Sol-Pref Pen 5x3mL Pk (DIN 02439611) is excluded from the biosimilar policy. No biosimilar is available for this strength.

For patients with current EAP approvals for an originator biologic for other indications not listed above:

- Patients with current EAP approvals for the originator biologic for indications that are not listed above will automatically have the corresponding biosimilar(s) added to their EAP approval for the same duration. A new EAP request for the biosimilar versions will not

be required until the current approval period expires. Please note that a new prescription for the biosimilar must be written.
- New patients starting on therapy for indications not on the ODB Formulary or not meeting the limited use criteria will require an EAP request for the biosimilar to be submitted for consideration of funding.
- Patients with current EAP approvals for the originator biologic for an indication that is listed above will also automatically have the corresponding biosimilar added to their EAP approval until its expiry date. If the EAP approval expiry date is after December 28, 2023, the EAP approval will not apply to the originator biologic after December 28, 2023 but will continue to apply to the biosimilar until the EAP approval expiry date. It should be noted that physicians can access the biosimilar for their patients on the ODB Formulary by using an eligible Limited Use (LU) code; however, access to the biosimilar through EAP will be maintained for existing patients to avoid an unintended treatment gap. Please note that a new prescription is required when changing to a biosimilar.

4. Will there be other drug products added to this policy?

As new biosimilars or similar versions of non-biologic complex drugs enter the Canadian market, additional drug products may be included as part of this policy change. The ministry will update materials online as additional drug products are included under the policy.

5. What are the criteria for exemptions and how will they be determined?

Medically necessary exemptions to this policy may be granted on a case-by-case basis through the EAP. Note that patients are generally expected to trial at least two[1] biosimilars of the originator biologic before a request to the EAP will be considered to resume funding of the originator product.

During the transition period of March 31, 2023 to December 28, 2023, prescribers with patients requiring medically necessary exemptions to this policy for Lantus®, NovoRapid®, and Humalog® may include the corresponding temporary LU codes on their prescriptions, but only if the patient is currently established on the originator. These temporary LU codes will be available for medically necessary exemptions until the effective date of the December 2024 Formulary update, and any medically necessary exemptions for Lantus®, NovoRapid®, and Humalog® will need to be submitted to the EAP for case-by-case consideration. Physicians are encouraged to submit EAP requests as soon as possible during the transition period to avoid a gap in coverage.

[1] Where an originator biologic only has one biosimilar, a patient would only be required to trial one biosimilar before an EAP request for the originator biologic would be considered.

As of December 29, 2023, access to Enbrel® and Humira® for plaque psoriasis will be discontinued and that indication will be removed from the ODB Formulary. Requests for patients requiring medically necessary exemptions to this policy for Enbrel® or Humira® for plaque psoriasis will need to be submitted to the EAP.

The ministry will continue to make other case-by-case decisions as requests are submitted for consideration. For complicated requests, EAP will consult with external specialists.

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

Medically necessary exemptions to this policy may be granted on a case-by-case basis through the Exceptional Access Program. **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).

7. 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. As such, a pharmacist will not be able to adapt prescriptions to biosimilars.

Pharmacists can help the transition by educating Ontario Drug Benefit recipients when they fill their new prescription for a biosimilar or similar NBCD, and by answering any questions they may have.

8. How should I approach patient discussions?

Pharmacists can help the transition by educating Ontario Drug Benefit 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;
- Are available at nearby infusion centres, though it may be a different infusion centre than they currently attend (applies to infliximab and rituximab); and
- Are well-studied and that transition programs have been successful around the world.

9. What is the support fee for pharmacists?

Pharmacists may claim a Biosimilar Support Fee in the amount of $15 when filling the first prescription for a biosimilar included in the biosimilars policy for a transitioning ODB recipient. Along with filling the prescription, pharmacists are expected to provide patients with the information they need to assist with their transition to a biosimilar, which could include educating the patient on the safety and efficacy of the product and answering any questions they have.

The fee can be claimed **once per patient per drug transitioned to a biosimilar product**. Claims for the support fee will only be paid during the transition period for eligible patients.

Note that the fee **can only be claimed for transitioning ODB recipients between March 31, 2023 and December 28, 2023**. It is not eligible to be claimed for:

- Recipients who are new to ODB on or after March 31, 2023;
- Prescriptions for biosimilars that were dispensed prior to March 31, 2023 or after December 28, 2023;
- Subsequent prescriptions for a biosimilar product, after the patient's initial transition to that drug product;
- Recipients who are not enrolled in the ODB program and pay out-of-pocket or are reimbursed by a third-party insurer; or
- Treatment-naïve recipients.

In order to be reimbursed for the Biosimilar Support Fee, pharmacies must follow the normal process for submitting claims to the Health Network System (HNS) (See Section 5 of the Ontario Drug Programs Reference Manual ("Manual")), with the following additional information:

- Intervention code 'PS': (Professional Care Services)
- PIN: see Table below for list of PINs
- Valid Pharmacist ID

New PINs will be added if the policy is expanded to include new biosimilars. The claim for the Biosimilar Support Fee must be submitted on the same day as the initial claim submission for the biosimilar. All other HNS rules and Ministry Policies remain the same.

For purposes of post-payment verification, pharmacy records related to claims for the Biosimilar Support Fee must be maintained in a readily available format for the purpose of ministry inspection for a minimum of 10 years from the last recorded pharmacy service provided to the individual, or until 10 years after the day on which the individual reached or would have reached the age of 18 years, whichever is longer.

Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacy records must include the following:

- A valid prescription;
- Signed and dated documentation, that includes but is not limited to the following:
  - Cross-referencing to the biosimilar claim to which the support fee relates; and
  - Confirmation of the originator biologic that the patient was taking; and
  - When the originator biologic was last dispensed, if available; and
  - Summary of the pharmacist-patient interaction.

Drug Product	Biosimilar Patient Support Fee PINs
Adalimumab	09858133
Etanercept	09858104
Glatiramer acetate	09858107
Infliximab	09858105
Insulin aspart	09858238
Insulin glargine	09858108
Insulin lispro	09858132
Rituximab	09858106

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

All other inquiries regarding the biosimilar policy should be directed to DrugProgramsDelivery@ontario.ca

Any information about the Biosimilar Support Fee in this document and the accompanying Notice from the Executive Officer constitutes a ministry policy that pharmacy operators must comply with when submitting claims for payment to the ministry for the Biosimilar Support Fee. Compliance with all ministry policies is required under section 3.2 of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators.

10. Will patients have to go to different infusion centres?

Patients who take Remicade® or Rituxan®, as part of the biosimilar transition may have to go to a new infusion centre to receive their infliximab or rituximab infusion.

The Ministry of Health has been working closely with our health care partners to support access to an infusion clinic that can deliver the biosimilar. Infusion clinics in Ontario are ready to support ODB program recipients with their transition to a biosimilar.

11. 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.

12. Where can I get more information?

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

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

For any further inquiries regarding the biosimilars policy, please contact the Exceptional Access Program within the Ministry of Health 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
- Arthritis Consumer Experts Biosim Exchange
- Canadian Digestive Health Foundation: What's Health Canada Saying about Biosimilars? (Youtube)