Executive Officer Notice:

Biosimilar Policy

March 10, 2023

The Ontario government is expanding its biologic drug coverage policy to further promote the use of biosimilars funded through the Ontario Drug Benefit (ODB) program. As a key health system partner, the Ministry of Health ("the ministry") is seeking support from pharmacists in the implementation of this policy. These changes support the ministry's objectives of creating a modern and sustainable drug system that continues to offer 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.

What are the changes in drug coverage for biologics?

In general, effective March 31, 2023, the ODB program will start transitioning coverage for Copaxone®[1], Enbrel®, Humalog®[2], Humira®, Lantus®, NovoRapid®, Remicade®, and Rituxan® to their biosimilar versions. As new biosimilars enter the Canadian market, these biosimilars and their corresponding originator biologic drugs may be included as part of this policy change.

Effective December 29, 2023, coverage for these originator biologic drugs through the ODB program will not be available for patients and the ODB program will only provide coverage for the biosimilar version of these drugs for all ODB program recipients, with limited exemptions (see below). In general, for ODB program recipients who are already on these biologic drugs, there is up to a 9-month transition period (see below for more information).

[1] Glatect® and Copaxone® are non-biologic complex drugs (NBCDs), however, the biosimilars 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®.

[2] 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.

Note: The ministry is aware of the ongoing Admelog shortage. The ministry will continue to monitor the situation. Prescribers will be expected to transition patients once the supply issues are resolved. The ministry will continue to communicate with healthcare providers.

This biosimilars policy does not apply to coverage outside of the ODB program, including private drug plans and prescriptions paid out-of-pocket. However, the biosimilar policy will apply to patients transitioning from other coverage types to the ODB program; such patients who are on originator biologic drugs subject to the biosimilar policy will need to transition to a biosimilar version to receive coverage for these biologic drugs under the ODB program, with exemptions.

Health Canada undertakes a robust and rigorous approval process before approving biosimilars for patient use. To be approved in Canada, a biosimilar must be proven to be highly similar to an originator biologic, with no clinically meaningful differences in terms of safety and efficacy between them. All the biosimilars affected by this policy have all been approved by Health Canada and are already in widespread use.

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

Transition period

ODB program recipients on any of the drugs listed above will be required to transition to a biosimilar version to continue receiving coverage for their medication under the ODB program, unless they meet a medically necessary exemption. A transition period of up to nine months, beginning March 31, 2023, will be granted for ODB program recipients (including existing Exceptional Access Program (EAP) recipients) to provide an opportunity for patients and their health care professionals to discuss biosimilar transition.

EAP approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring between March 31, 2023, and June 29, 2023, will be extended to June 30, 2023. The purpose of this extension is to give prescribers adequate time to contact their patients and discuss the transition to the biosimilar version or to determine if the patient may require a medically necessary exemption.

Patients with EAP approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring *after* June 29, 2023, will be required to transition to a biosimilar by the expiry date of their EAP approval OR December 28, 2023, whichever is earlier, in order to continue receiving ODB program coverage for these biologics.

Prescribers are being asked to contact their patients to discuss transitioning to a biosimilar version of their medication and will need to write a new prescription. Prescribers should access the biosimilar for their patients on the ODB Formulary by using an eligible Limited Use (LU) code as applicable.

Medically Necessary Exemptions for Formulary Biologics

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[3] 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.

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.

Compensation 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.

[3] 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.

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

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.

For additional details on the list of affected drugs and indications, please refer to the accompanying Pharmacist FAQs.

Ministry Policy

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Additional Information:

For pharmacies:

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

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282

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