Executive Officer Notice:

Biosimilar Policy - Update

July 17, 2024

The Ontario government is continuing the biosimilar policy regarding the funding of biologic products through the Ontario Drug Benefit (ODB) program. This Executive Officer (EO) Notice provides important information for pharmacy operators about the biosimilar policy. These changes continue to support the ministry's objectives of creating a modern and sustainable drug system that offers high-quality treatment, while allowing the government to fund more new drug therapies, encourage innovation in the health care system, and continue to support the delivery of better, connected patient care.

Biosimilar Policy

The biosimilar policy was introduced on March 10, 2023 and transitioned coverage for specific biologic products to their biosimilar versions.[1] Moving forward, ODB program recipients who are initiating therapy with a biologic drug are required to start on the biosimilar version, instead of the originator version (the "New Start Rule"). ODB program recipients already using the originator version of a biologic are required to transition to a biosimilar version in order to have the biologic covered under the ODB program, subject to certain exemptions (the "Transition Rule").

This biosimilar 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 to receive coverage under the ODB program from other coverage types, including private drug plans and prescriptions paid for out of pocket.

New Start Rule

All ODB program recipients who have not been treated with the biologic, will be required to initiate treatment with a biosimilar version in order to receive coverage for that biologic drug under the ODB program.

[1] The original biologic products that were being transitioned to their biosimilar versions in the original biosimilar policy were Copaxone®, Enbrel®, Humalog®, Humira®, Lantus®, NovoRapid®, Remicade®, and Rituxan®.

Transition Rule

All ODB program recipients who are using an originator biologic product under the ODB program are subject to the Transition Rule.

Upon the funding of a biosimilar version of an originator biologic under the ODB program, existing ODB program recipients established on the originator version will be **required** to transition to the biosimilar version by the end of the next transition period in order to receive coverage for that biologic drug under the ODB program, subject to certain exceptions further described below.

There are 2 transition periods annually, beginning in May and November for 6 months, subject to ministry discretion.

The transition period applicable to a biologic will be announced in advance. For example, if a new biosimilar is listed on the ODB Formulary in March and is subject to a 6-month transition period, then the transition period would start in May based on the twice annual transition dates (i.e., May and November) and last 6 months. At the end of 6 months, the originator biologic would no longer be funded under the ODB program, subject to certain exceptions.

During the transition period, pharmacists are encouraged to contact their patients to discuss transitioning to a biosimilar version of a biologic

Individuals transitioning from a private plan or another form of coverage to the ODB program during the transition period who have previously started therapy with the originator biologic are subject to the Transition Rule and are required to transition to the biosimilar before the end of the applicable transition period in order to receive coverage for the biologic, subject to certain exceptions. This means that if an individual transitions to coverage under the ODB program in the month of September during a 6-month transition period that began in May, that person must transition to the biosimilar before the end of the transition period in November.

Exceptions

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 LU code clinical criteria and authorization periods

on the Formulary. This exception may not apply if the biologic is not indicated for use in palliative care and/or pregnancy.

Medically necessary exemptions may be considered through the Exceptional Access Program (EAP). Requests are assessed on a case-by-case basis. The EAP request should be submitted through the Special Authorization Digital Information Exchange (SADIE) webportal for faster response. Prescribers must ensure that sufficient and appropriate evidence is provided to support the EAP request.

Note that recipients who have been established on an originator prior to the listing of a biosimilar version on the ODB Formulary are generally expected to trial at least two biosimilar versions of the biologic, where available, before a request to the EAP will be considered for approval. Prescribers are encouraged to submit EAP requests as soon as possible during the transition period to avoid a gap in coverage if a medical exemption is required.

Biosimilar Patient Support Fee

Pharmacies may submit a claim for a Biosimilar Patient Support Fee in the amount of $15 for assisting ODB program recipients to transition to a biosimilar alternative. This may include:

- When filling the first prescription for a biosimilar included in the biosimilar policy for a ODB program recipient who is subject to the Transition Rule. Along with filling the prescription, pharmacies are expected to provide such a recipient 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 prescribers).

The fee can be claimed **once per recipient per transition to a biosimilar version of a biologic**. 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.

The claim for the Biosimilar Patient Support Fee must include the PIN corresponding to the originator biologic from which the recipient is transitioning during the applicable transition period. A list of PINs will be made available in the transition EO Notice for the biologic

product. The claim for the fee **can be submitted starting on the day that the applicable transition period commences up to 1 year after the end of the transition period.**

The Biosimilar Patient Support Fee is not eligible for payment in the following circumstances:

- Recipients who are new to the ODB program on or after the start of the transition period;
- Prescriptions for biosimilars that were dispensed prior to start of a transition period
- 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 a biologic drug.

To qualify for the Biosimilar Patient 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. All other HNS rules and Ministry Policies respecting the submission of claims remain the same.

For purposes of post-payment verification, pharmacy records related to claims for the Biosimilar Patient 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:

- Documentation signed and dated by the pharmacy staff who assisted with the transition that includes the following information:
  - Confirmation of the originator biologic that the recipient was taking prior to their transition to a biosimilar; and

- When the originator biologic was last dispensed, if available; and
- Summary of the pharmacist-patient interaction and/or documentation of discussions with the prescriber including whether a new prescription is issued or whether further follow-up is required.

Ministry Policy

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

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