UPDATED Executive Officer Notice:

Biosimilar Policy - Lucentis®, Stelara®, Lovenox®, Neupogen®

July 17, 2024

The Ontario government is continuing the biosimilar policy regarding the funding of biologics through the Ontario Drug Benefit (ODB) program. This Executive Officer (EO) Notice provides important information for pharmacy operators about the biosimilar policy[1]. 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.

Effective **July 31, 2024** Ontario will add four additional biologic drugs to the biosimilar policy: Lucentis® (Ranibizumab), Stelara® (Ustekinumab), Lovenox® (Enoxaparin), and Neupogen® (Filgrastim). Please note that additional transitions will follow the updated Biosimilar Policy as outlined in the EO Notice, titled Biosimilar Policy Update.

Biosimilar versions of the originator biologics are currently listed on the Formulary and treatment-naïve recipients (the "New Start Rule") should have been initiated on the biosimilar product. Under "the Transition Rule" recipients who have already initiated therapy with the originator biologic (treatment-experienced) will be required to transition to the biosimilar version of the biologic in order to continue to receive ODB program coverage 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 February 1, 2025, the originator biologics will not be funded under the ODB program, subject to certain exceptions.

<u>Exceptions</u>

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

[1] The biosimilar policy was introduced on March 10, 2023 and transitioned coverage for specific biologic products to their biosimilar versions. 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®.

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 this 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.

Biosimilar Patient Support Fee

Pharmacies are expected to assist treatment-experienced recipients in transitioning to a biosimilar version of the biologic during the 6-month transition period and may submit a claim to the ministry for the Biosimilar Patient Support Fee using the PINs in the table below, subject to the terms and conditions set out in this EO Notice and the accompanying Pharmacy FAQs.

Drug Product	Biosimilar Patient Support Fee PINs
Lucentis® (Ranibizumab)	09858337
Stelara ® (Ustekinumab)	09858338
Lovenox ® (Enoxaparin)	09858339
Neupogen ® (Filgrastim)	09858340

Pharmacies have until **January 30, 2026,** to submit a claim for payment for the Biosimilar Patient Support Fee for assisting treatment-experienced recipients in transitioning to a biosimilar version of one of the originator biologics listed above during the period of July 31, 2024 to January 31, 2025.

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

Terms and Conditions for Biosimilar Patient Support Fee

Pharmacies may claim for the Biosimilar Patient Support Fee in the amount of $15 when assisting ODB program recipients on an originator biologic transition to the 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 fee **can be submitted for payment for transitioning ODB program recipients to a biosimilar starting on the day that the applicable transition period commences up to 1 year after the end of the transition period.** It 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 patient'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 for payment 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 Support Fee in this EO Notice from the Executive Officer and corresponding FAQs for Pharmacies 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

APPENDIX A – List of Originators and Biosimilars

Drug Product	Biosimilars
Lucentis® (Ranibizumab)	• Byooviz® • Ranopto®
Stelara ® (Ustekinumab)	• Jamteki® • Wezlana®
Lovenox ® (Enoxaparin)	• Elonox® • Inclunox® • Noromby® • Redesca®
Neupogen ® (Filgrastim)	• Grastofil® • Nivestym® • Nypozi®

- *For up-to-date list of eligible ODB funded biosimilars please refer to the ODB formulary.*

APPENDIX B – List of LU Code Changes DIN/PIN

Drug Product	LU Codes
Lucentis® (Ranibizumab)	LU codes for pregnancy and/or palliative care exemptions are not provided and will not be considered as the product is intended for intravitreal injection with local action administered by a qualified ophthalmologist.
Stelara ® (Ustekinumab)	**LU Code: 680** For the treatment of Severe plaque psoriasis in patients who meet ALL the following criteria: • Patients who become pregnant during the transition period of July 31, 2024 to January 31, 2025. LU Authorization Period: 12 months from date of authorization
	LU Code: 681 For the treatment of Severe plaque psoriasis in patients who meet ALL the following criteria: • Patients who require palliative care during the transition period of July 31, 2024 to January 31, 2025. LU Authorization Period: 12 months from date of authorization
Lovenox ® (Enoxaparin)	**LU Code: 678** For the treatment of pulmonary embolism, deep vein thrombosis who meet ALL the following criteria: • Patients who become pregnant during the transition period of July 31, 2024 to January 31, 2025. LU Authorization Period: 12 months
	LU Code: 679 For the treatment of pulmonary embolism, deep vein thrombosis who meet ALL the following criteria: • Patients who require palliative care during the transition period of July 31, 2024 to January 31, 2025.

	LU Authorization Period: 12 months
Neupogen ® (Filgrastim)	**LU code: 682** For the treatment of low white blood cell count in patients who meet ALL the following criteria: • Patients who become pregnant during the transition period of July 31, 2024 to January 31, 2025. LU Authorization Period: 12 months from date of authorization **LU code: 683** For the treatment of low white blood cell count in patients who meet ALL the following criteria: • Patients who require palliative care during the transition period of July 31, 2024 to January 31, 2025. LU Authorization Period: 12 months from date of authorization