UPDATED Executive Officer Notice: Biosimilar Policy – Denosumab (Prolia® and Xgeva®)

November 19, 2024

The Ontario government is continuing to expand the biosimilar policy 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 **November 29, 2024,** Ontario has added two additional biologic drugs to the biosimilar policy: Prolia® (denosumab) and Xgeva® (denosumab). Please note that future transitions will continue to follow the policy described in the EO Notice: Biosimilar Policy dated July 17, 2024.

Biosimilar versions of Prolia® and Xgeva® were listed on the Formulary as Limited Use benefits on **August 30, 2024,** and became subject to the **New Start Rule**. In accordance with the New Start Rule, ODB program recipients who are treatment naïve to Prolia® and Xgeva® will only receive coverage for the biosimilar versions, provided they meet the applicable Limited Use criteria for the products.

With respect to the **Transition Rule**, ODB program recipients who are already using Prolia® or Xgeva® will have nine (9) months to transition to a biosimilar version, subject to certain exceptions. This nine (9) month transition period **begins on November 29, 2024, and ends on August 29, 2025**. At the end of this transition period, Prolia® and Xgeva® will not be funded under the ODB program, subject to certain exceptions.

The Transition Rule also applies to individuals receiving coverage for Xgeva® through the New Drug Funding Program (NDFP).

[1] The biosimilar policy was introduced on March 10, 2023 and transitioned coverage for specific originator biologic products to their biosimilar versions. The originator biologic products subject to this policy in March 2023 were Copaxone®, Enbrel®, Humalog®, Humira®, Lantus®, NovoRapid®, Remicade®, and Rituxan®.

Exceptions

Length of Transition Period for Recipients on Xgeva®

ODB program recipients who have coverage for Xgeva® through the Exceptional Access Program (EAP) will be required to transition to a biosimilar version by the expiry date of their existing EAP approval or August 29, 2025, whichever is earlier, unless their continued coverage for Xgeva® is approved through the EAP based on a medically necessary exemption (see below).

Palliative Care Exceptions

ODB program recipients who are using Prolia® and undergoing palliative care may be eligible for a 12-month extension of coverage for Prolia® through a Limited Use code on the Formulary. Please refer to the corresponding Limited Use criteria for details. ODB program recipients who do not meet the Limited Use criteria are required to transition to a biosimilar version in order to maintain coverage for denosumab, unless a medically necessary exemption applies (see below).

ODB program recipients who are using Xgeva® and undergoing palliative care may be eligible for a 12-month extension of coverage for Xgeva® through the EAP. Prescribers of such recipients must submit a request for this extended coverage to the EAP. Requests will be assessed on a case-by-case basis. ODB program recipients who do not receive EAP approval for this palliative care exemption are required to transition to a biosimilar version in order to maintain coverage for denosumab, unless a medically necessary exemption applies (see below).

Medically Necessary Exemptions

ODB program recipients who are using Prolia® or Xgeva® and require continued coverage of that product after the end of the transition period on August 29, 2025, must have their prescriber apply to the EAP for a medically necessary exemption. Requests for medically necessary exemptions are assessed on a case-by-case basis. Prescribers are encouraged to apply for such medically necessary exemptions during the 9-month transition period to avoid an unintended gap in coverage.

Requests for a medically necessary exemption must include documentation that a recipient has tried up to two biosimilar versions (where applicable) and has experienced an adverse effect that is documented and submitted on the Health Canada side effect reporting form. A copy of each Health Canada side effect reporting form must be included in the EAP request.

Medically necessary exemptions will not be considered for ODB program recipients who are subject to the New Start Rule.

Biosimilar Patient Support Fee

Pharmacies are expected to assist treatment-experienced recipients in transitioning to a biosimilar version of the biologic during the 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
Prolia®	09858346
Xgeva®	09858347

Pharmacies have until **August 29, 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 from November 29, 2024, to August 29, 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 ODB program recipients transitioning 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 recipient's initial transition to a biosimilar;
- Recipients who are not enrolled in the ODB program and pay out-of-pocket or receive drug coverage through 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 list of PINs on *page 3*
- 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 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
Prolia®	Jubbonti®
Xgeva®	Wyost®

- *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

Prolia®	**LU Code: 690**
	
	Only for a patient who is established on Prolia (denosumab) therapy prior to November 29, 2024, and who is or becomes palliative requiring end-of-life care during the biosimilar transition period between November 29, 2024, to August 29, 2025.
	
	Patient must also meet the following criteria:
	
	- The patient is a postmenopausal female or male with osteoporosis and Prolia (denosumab) is being used to increase the bone mass in the patient;
	- The patient is at high risk* for fracture; and
	- One of the following applies to the patient:
	  ○ The patient has failed other available osteoporosis therapy (i.e., fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels) despite adherence to the therapy for one year; or
	  ○ bisphosphonates are contraindicated for the patient due to hypersensitivity, abnormalities of the esophagus (e.g., esophageal stricture or achalasia), or inability to stand or sit upright for at least 30 minutes.
	
	*High risk of fracture is defined as one of the following:
	
	- a prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%) based on the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the Fracture Risk Assessment (FRAX) tool;
	- a high 10-year fracture risk (greater than or equal to 20%) based on the CAROC or FRAX tool; or
	- where a patient's 10-year fracture risk based on the CAROC or FRAX tool is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture.
	
	Note: Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.

	Funded duration: One period of up to 12 months beginning on the date of the first prescription with RFU code 690 is dispensed for the patient. NOTE: In all cases, patients receiving Prolia must not be receiving concomitant bisphosphonate therapy. The recommended dose of PROLIA (denosumab) is a single SC injection of 60 mg, once every 6 months.