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Bulletin 241105 — Biosimilar policy update: Transition from originator biologics to biosimilars

Update on the biosimilar policy, transition period beginning November 29, 2024, and fee code – K900

To: All Physicians
Category: Physician Services; Primary Health Care Services
Written by: Drug Program Policy Strategy Branch, Health Programs and Delivery Division
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Overview

As an update to INFOBulletin 230302 (https://www.ontario.ca/document/ohip-infobulletins-2023/bulletin-230302-biosimilar-support-fee-code-k900a) , the Ontario government is continuing the biosimilar policy regarding the funding of biologics through the Ontario Drug Benefit (ODB) program. The Ministry of Health (the "ministry") is providing important information for physicians about the application of the biosimilar policy to Prolia® (denosumab) and Xgeva® (denosumab).

Biosimilar policy update for denosumab

Biosimilar versions of Prolia® and Xgeva® were listed on the Formulary as Limited Use

benefits on **August 30, 2024** and became subject to a **"New Start Rule"**. In accordance with this New Start Rule, ODB program recipients who are treatment naïve to denosumab will only receive coverage for the biosimilar versions, provided that they meet the applicable Limited Use criteria for the products.

ODB program recipients who are already using Prolia® or Xgeva® are subject to a **"Transition Rule"**. In accordance with this Transition Rule, treatment-experienced recipients will have 9 months to transition to a biosimilar version, subject to certain exceptions. This 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.

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 (LU) code on the Formulary. Please refer to the corresponding LU criteria for details. ODB program recipients who do not meet the LU 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

Prescribers of 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, may submit a request 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 demonstrating that the 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. Please note, currently, there is only one biosimilar available for Prolia® and one for Xgeva®. For up-to-date list of eligible ODB funded biosimilars please refer to the ODB Formulary. (https://www.formulary.health.gov.on.ca/formulary/)

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

For faster responses to EAP requests please process through the web-based portal, the Special Authorization Digital Information Exchange (SADIE). For more information about SADIE, or to register, please visit the SADIE website (http://www.ontario.ca/sadie) .

Requests by fax may be sent to 1-866-811-9908 (toll-free) or 416-327-7526 (Toronto area).

If authorized prescribers are unable to use SADIE or fax, EAP requests may be submitted by mail to the following address:

Exceptional Access Program
5700 Yonge Street — 3rd Floor
North York, Ontario M2M 4K5

Submission by mail may delay the receipt of the request by the ministry.

Discuss Transitioning to Biosimilar

Physicians are encouraged to contact their patients who are ODB program recipients and currently receiving treatment with Prolia® or Xgeva® to discuss transitioning to a biosimilar version of their medication, which will require a new prescription.

Table 1. ODB Program Coverage* (https://www.ontario.ca/document/ohip-infobulletins-2023/bulletin-230302-biosimilar-support-fee-code-k900a#1star)

Drug	Originator Biologic (ODB program recipients on an originator must transition to a biosimilar version on or before August 29, 2025, subject to certain exceptions)	Biosimilars Funded Under ODB Program	Indications
Denosumab	Prolia®	Jubbonti® Available as LU	• Increase bone mass in postmenopausal women with osteoporosis at high risk for fracture • Increase bone mass in men with osteoporosis

			at high risk for fracture
Denosumab	Xgeva®	Wyost® Available through EAP	• Treatment of bony metastases in patients with hormone refractory prostate cancer.

Biosimilar support fee to be continued

The ministry will be continuing the K900A Biosimilar Support Fee in recognition of the efforts required to contact patients and support patients through the transition to a biosimilar.

Physicians in Ontario who facilitate the transition of ODB program recipients from an originator biologic to a biosimilar version under the ministry's biosimilar policy may submit a claim for K900A. Please note that out-of-province prescribers are not eligible to be paid the Biosimilar Support Fee.

The Biosimilar Support Fee is only payable:

- To the physician prescribing the biologic.
- For patients who are ODB program recipients and are taking an originator biologic subject to the Biosimilar Policy.
    - Patients who are new to treatment with the biologic must start on a biosimilar version in order to receive ODB program coverage for the biologic. This remains unchanged and therefore the K900A cannot be billed for these

patients.

- Once per patient per biologic in the patient's lifetime.

The Biosimilar Support Fee includes payment for all support required to transition patients to biosimilars, including but not limited to, the following:

- Time spent identifying and contacting patients impacted by the policy
- Time spent researching or reviewing information relating to the biosimilar products subject to the policy
- In circumstances where no concurrent insured service is provided, the provision of prescriptions to impacted patients for the biosimilar products (as appropriate) and answering any questions the patient may have about the prescribed product
- Answering any questions the patient may have about the biosimilars policy and the transition from originator biologics to biosimilar versions
- Patient workup and review to determine whether the patient may meet an exemption requirement to remain on an originator version

The Biosimilar Support Fee will only be payable for support provided to patients who are ODB program recipients and transitioning to biosimilars. It will not be payable for patients who are not ODB program recipients, such as those whose medication expenses are covered by private insurers or paid for out-of-pocket.

Claim processing

Only physicians with an OHIP billing number in the range of 000001 to 299999 are eligible to submit K900A.

The K900A FSC must be submitted alone on a claim to ensure payment.

Claims for K900A must be submitted within 3 months of the date of service.

K900A may only be billed once per biologic transition and has a limit of 6 services per patient per 365-day period. Services in excess of this maximum will pay at $0.00 with explanatory code 'M1-Maximum fee allowed or maximum number of service has been

reached same/any provider'

K900A can only be provided under payment program Health Claims Payment (HCP).

K900A is not eligible to be submitted through Reciprocal Medical Billing (RMB). K900A submitted as an RMB claim will reject to the provider's error report with error code 'R04-Service Excluded from RMBS'.

K900A is not eligible to be submitted through the Workplace Safety and Insurance Board (WSIB) payment program. K900A submitted as a WSIB claim will reject to the provider's error report with error code 'VW1-Invalid WCB Service'.

K900A and primary care

Providers practicing in Primary Care Patient Enrolment Models (PEM) are eligible to receive the full Biosimilar Support Payment for both enrolled and non-enrolled patients. Eligible PEMs include:

- Blended Salary Model
- Comprehensive Care Model
- Family Health Group
- Family Health Network
- Family Health Organization
- General Practitioner Focus-HIV
- General Practitioner Focus-Care of the Elderly 1
- General Practitioner Focus-Care of the Elderly 2
- General Practitioner Focus-Palliative Care
- Group Health Centre
- Rural & Northern Physician Group Agreement
- Sioux Lookout Regional Physician Services

- Saint Joseph's Health Centre
- Weeneebayko Area Health Authority
- Aboriginal Family Health Team
- Family Health Team Specialist Sessionals
- Inner City Health Associates
- Sherbourne Physicians Group
- Shelter Health Network
- Toronto Palliative Care Associates

K900A will be added to the list of allowable fee-for-service codes for physicians enrolled in the Income Stabilization program.

K900A will not contribute to the fee for service ceiling cap.

K900A will not contribute to After-Hours thresholds for the following groups:

- General Practitioner Focus-Care of the Elderly 1
- General Practitioner Focus-Palliative Care
- General Practitioner Focus-HIV
- Toronto Palliative Care Associates

K900A will be exempt from the Northern Specialist Reduction.

Alternate Payment Plan (Emergency Department Alternate Funding Agreement, Academic Health Science Centre, or other Alternate Payment Program)

Providers practicing in all alternative payment plans (APP), alternative funding plans, and alternative funding agreements are eligible to receive the full Biosimilar Support Payment when K900A is billed with AAXX range group numbers, H005, H006, H007,

H008, H300, H001, H900, and H8XX range group numbers.

Relationship to insured service claims submitted to OHIP

K900A is payable in addition to insured services that may be rendered to the patient and that would otherwise be eligible for payment in accordance with the *Health Insurance Act* and the Schedule of Benefits for Physician Services.

In instances where the only services provided are transition elements described as components of K900A, no additional insured services are eligible for payment.

Recovery of ineligible payments

If any of the above requirements or rules are not met, the K900A Biosimilar Support Fee is not eligible for payment. Ineligible payments are subject to recovery.

Additional information

Information regarding Ontario's Exceptional Access Program (http://health.gov.on.ca/en/pro/programs/drugs/eap_mn.aspx) can be found on the ministry website.

For information about SADIE or to register for SADIE access please visit the SADIE website (http://www.ontario.ca/sadie) .

Inquiries regarding physician billing should be directed to the Service Support Centre at 1-800-262-6524.

Inquiries regarding exemptions should be directed to the Exceptional Access Program at 416-327-8109 or 1-866-811-9893. All other inquiries regarding the biosimilar policy should be directed to DrugProgramsDelivery@ontario.ca

(mailto:DrugProgramsDelivery@ontario.ca)

Keywords/Tags

Biosimilar; Ontario Drug Benefit Program; ODB; Biologics; Exceptional Access Program; EAP; K900A

Contact information

Do you have questions about this INFOBulletin? Email the Service Support Contact Centre (mailto:SSContactCentre.MOH@ontario.ca) or call 1-800-262-6524. Hours of operation: 8:00 a.m. to 5:00 p.m. Eastern Monday to Friday, except holidays.

Previous **(https://www.ontario.ca/document/ohip-infobulletins-2024/bulletin-241104-reminder-use-updated-forms-and-contact-email)**

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