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Bulletin 240803 — Biosimilar Policy Update: Transition from originator biologics to biosimilars

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 changes to the biosimilar policy. Effective July 31, 2024, four new drugs are included in the Biosimilar Policy:

- Lucentis® (ranibizumab)
- Stelara® (ustekinumab)

- Lovenox® (enoxaparin)
- Neupogen® (filgrastim)

Biosimilar policy

Effective July 31, 2024, biosimilar versions of the originator biologics listed above will be designated as benefits on the ODB Formulary and result in funding changes for ODB program recipients who have not yet initiated therapy with the biologics, also known as "treatment-naïve patients" (the "New Start Rule") and ODB program recipients who have already initiated therapy with the originator biologic, also known as "treatment-experienced patients" (the "Transition Rule"). Under the New Start Rule, treatment-naïve patients will be required to initiate therapy with a biosimilar version of the biologic in order to receive ODB program coverage for the biologic. Under the Transition Rule, treatment-experienced recipients will have 6 months (from July 31, 2024 to January 31, 2025) to transition to a biosimilar version of the biologic in order to receive ODB program coverage for the biologic, subject to certain exceptions. The purpose of the 6-month transition period is to provide an opportunity for patients and their health care professionals to discuss transitioning to a biosimilar. At the end of the 6-month transition period on January 31, 2025, the originator biologics will not be funded under the ODB program, subject to certain exceptions.

As new biosimilars enter the Canadian market, additional biologic drugs may become subject to the biosimilar policy.

Exceptions

Treatment-experienced patients who are pregnant during the 6-month 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. These patients may continue receiving ODB program coverage for the originator biologic, in accordance with the Limited Use (LU) clinical criteria and authorization periods on the ODB Formulary. However, this exception does not apply to Lucentis® as it is not indicated for use in palliative care and pregnant patients.

Treatment-experienced patients who require ODB program coverage for an originator biologic during or after the 6-month 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.

Authorized prescribers who believe that their patient meets a medically necessary exemption to stay on their originator product must submit a request for exemption to the EAP.

ODB program coverage for Stelara® (ustekinumab) is limited to the treatment of plaque psoriasis. As such, requests for medically necessary exemptions to **have Stelara®** funded for treatment-experienced patients under EAP will only be considered for the indication of plaque psoriasis. If a treatment-experienced patient requires ustekinumab for other indications, then they may receive ODB program coverage for a biosimilar version, provided that they meet any applicable LU clinical criteria on the ODB Formulary. If a patient does not meet the applicable Limited Use clinical criteria for a biosimilar, then funding for the biosimilar may be requested under the EAP.

EAP requests from Ontario authorized prescribers may be submitted through EAP's web-based portal, the Special Authorization Digital Information Exchange (SADIE) or by fax. 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.

Biosimilars use in Canada and abroad

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, with no clinically meaningful differences in terms of safety and efficacy compared to the originator biologic. 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 and a number of Canadian jurisdictions have expanded the funding of biosimilar medications.

Discuss Transitioning to Biosimilar

Physicians are encouraged to contact their treatment-experienced patients 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 (Treatment-experienced patients must transition to the biosimilar version before January 31, 2025)**	**Biosimilars Funded Under ODB Program**	**Indications**
Ranibizu	Lucentis®	Byooviz®	Age-related macular degeneration (AMD), diabetic macular edema

mab		Ranopto® Available as LU	(DME), branch retinal vein occlusion (BRVO), central retinal vein occlusion (CRVO) or choroidal neovascularization
Ustekinumab	Stelara®	Jamteki® Wezlana® Available as LU	Severe plaque psoriasis
Enoxaparin	Lovenox®	Elonox® Incluno x® Noromby® Redesca®	Prevention and treatment of deep venous thrombosis Treatment of pulmonary embolism
(Filgrastim)	Neupogen ®	Grastofil® Nivestym®	Prevention and treatment of neutropenia

		Nypozi ®	

Biosimilar support fee to be continued

The ministry acknowledges the critical role physicians have in explaining to patients the safety and efficacy of biosimilar products as well as the implications this policy has on everyday practices. For this reason, 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
- If required, submitting a request to EAP on behalf of the ODB program recipient to receive ODB program coverage for an originator biologic as an exception. These requests may be submitted through EAP's web-based portal, the Special Authorization Digital Information Exchange (SADIE), or by fax.
    - EAP requests for originator biologics that are subject to the biosimilar policy will only be considered for patients who were originally established on the originator biologic under the ODB program prior to the New Start Rule for the biologic, and have trialed at least two (2) available biosimilar versions and have experienced an adverse drug reaction to the biosimilar. Where an originator biologic only has one biosimilar, a patient would only be required to trial one biosimilar before an EAP request to resume coverage for the originator biologic would be considered.

The Biosimilar Support Fee will only be payable for those enrolled in the ODB program who are transitioning to biosimilars. It will not be payable for patients who are not enrolled in the ODB program or 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.

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