# Ontario Health Insurance Plan INFOBulletin

Biosimilar support fee code K900A

New Fee Schedule Code (FSC) to support the transition from originator biologics to biosimilars

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**To**: All Physicians

**Category**: Physician Services; Primary Health Care Services

**Written by**: Negotiations Branch, Ontario Health Insurance Plan Division

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# Contents

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# Biosimilar policy

The Ontario government is expanding its biologic drug coverage policy to further promote the use of biosimilars funded through the Ontario Drug Benefit (ODB) program. As a key health system partner, the Ministry of Health ("the Ministry") is seeking support from physicians in the implementation of this policy. These changes support the Ministry's objectives of creating a modern and sustainable drug system that continues to offer high-quality treatment, while allowing the government to fund more new drug therapies, bring innovation to the health care system and continue its work to deliver better, connected patient care.

The following drugs are included:

- Copaxone®
- Enbrel®
- Humalog®
- Humira®
- Lantus®
- NovoRapid®
- Remicade®
- Rituxan®

Effective December 29, 2023, coverage for these drugs through the ODB program will not be available for patients. The ODB program will only provide coverage for the biosimilar version of these drugs for all ODB recipients, with limited exemptions (see below).

For ODB recipients who are already on these biologic drugs, there is an up to 9-month transition period (see below for more information). As new biosimilars enter the Canadian market, additional biologic drugs may be included as part of this policy change.

Note: The ministry is aware of the current Admelog shortage. Physicians should switch their patients as soon as supply of the drug becomes available. The ministry will continue to monitor the situation.

Glatect® and Copaxone® are non-biologic complex drugs (NBCDs), however, the Biosimilar Policy will apply to their funding. As a result, in this document, references to an originator biologic include Copaxone® and references to a biosimilar include Glatect®.

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# Humalog®

Humalog® 200 units/mL KwikPen® 200U/mL Inj Sol-Pref Pen 5x3mL Pk (DIN 02439611) is excluded from the Biosimilar Policy. No biosimilar is available for this strength.

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# Enbrel® and Humira® will be removed from the formulary

As of December 29, 2023, access to Enbrel® and Humira® for plaque psoriasis will be removed from the Ontario Drug Benefit Formulary. Requests for patients requiring medically necessary exemptions to this policy for Enbrel® or Humira® for plaque psoriasis will need to be submitted to the Exceptional Access Program using the SADIE web-based portal or by fax.

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# Biosimilar 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 for more than 15 years and Ontario is the eighth Canadian jurisdiction to expand the use of biosimilar medications, following British Columbia, Alberta, New Brunswick, Quebec, Northwest Territories, Nova Scotia and Saskatchewan.

## Ontario Drug Benefit recipients on any drug identified

Ontario Drug Benefit (ODB) program recipients on any of the drugs listed above will be required to transition to a biosimilar version to continue receiving coverage for their medication under the ODB program, unless they meet a medically necessary exemption. A transition period between March 31, 2023 to December 28, 2023 will be granted for ODB program recipients (including existing Exceptional Access Program (EAP) recipients to provide an opportunity for patients and their health care professionals to discuss biosimilar transition.

## Patients with Exceptional Access Program approvals

Exceptional Access Program (EAP) approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring between March 31, 2023, and June 29, 2023, will be extended to June 30, 2023. The purpose of this extension is to give prescribers adequate time to contact their patients and discuss the transition to the biosimilar version or to determine if the patient may require a medically necessary exemption.

Patients with EAP approvals for Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring **after** June 29, 2023, will be required to transition by the expiry date of their EAP approval or December 28, 2023 (inclusive), whichever is earlier.

## Discuss transitioning to a biosimilar

Physicians are asked to contact their patients to discuss transitioning to a biosimilar version of their medication and will need to write a new prescription. The use of virtual tools such as video conference or telemedicine is encouraged where possible.

# Table 1. Ontario Drug Benefit Program Coverage*

| Drug | Originator Biologic (Patients must transition to the biosimilar version before December 29, 2023) | Biosimilars Funded Under ODB Program Effective March 31, 2023 | Indications |
|---|---|---|---|
| Adalimumab | Humira®<br>Funded only for exemptions under EAP*** | Abrilada®<br>Amgevita®<br>Hadlima®<br>Hulio®<br>Hyrimoz®<br>Idacio®<br>Simlandi®<br>Yuflyma®<br>Available as LU | Ankylosing Spondylitis<br>Crohn's Disease<br>Hidradenitis Suppurativa<br>Plaque psoriasis<br>Polyarticular Juvenile Idiopathic Arthritis<br>Psoriatic Arthritis<br>Rheumatoid Arthritis<br>Ulcerative Colitis<br>Uveitis |
| Etanercept | Enbrel®<br>Funded only for exemptions under EAP*** | Brenzys®<br>Available as LU<br>Erelzi®<br>Available as LU | Ankylosing spondylitis<br>Plaque psoriasis<br>Polyarticular juvenile Idiopathic arthritis<br>Psoriatic arthritis<br>Rheumatoid arthritis |
| Glatiramer acetate** | Copaxone®<br>Funded only for exemptions under EAP | Glatect™<br>Available as LU | Relapsing Remitting Multiple Sclerosis (RRMS) |

| | | | |
|---|---|---|---|
| Infliximab | Remicade®<br>Funded only for exemptions under EAP | Avsola®<br>Inflectra®<br>Renflexis®<br>Available as LU | Ankylosing spondylitis<br>Crohn's Disease<br>Plaque psoriasis<br>Psoriatic arthritis<br>Rheumatoid arthritis<br>Ulcerative Colitis |
| Insulin aspart | NovoRapid®<br>exemptions funded as LU Benefit | Kirsty®<br>Trurapi®<br>Available as GB | Diabetes (Type 1 and 2) |
| Insulin glargine | Lantus®<br>exemptions funded as LU Benefit | Basaglar®<br>Semglee®<br>Available as GB | Diabetes (Type 1 and 2) |
| Insulin lispro | Humalog®<br>exemptions funded as LU Benefit**** | Admelog®<br>Available as GB | Diabetes (Type 1 and 2) |
| Rituximab | Rituxan®<br>Funded only for exemptions under EAP | Riximyo®<br>Ruxience™<br>Truxima™<br>Available as LU | Rheumatoid Arthritis<br>Granulomatosis with Polyangiitis (GPA or Wegener's Granulomatosis)<br>Microscopic Polyangiitis (MPA) |

## *Table notes

GB = General Benefit on the ODB Formulary

LU = Limited Use product; reimbursement criteria must be met

EAP = Exceptional Access Program; reimbursement criteria must be met

* As new biosimilars enter the Canadian market, additional originator biologics will be transitioned. This table will also be updated on the ministry's website

** Copaxone® and Glatect® are non-biologic complex drugs (NBCDs), however, the Biosimilar Policy will apply to their funding. As a result, in this INFOBulletin, references to an originator biologic include Copaxone® and references to a biosimilar include Glatect®.

*** See section above entitled "Medically Necessary Exemptions for Formulary Biologics".

****Humalog® 200 units/mL KwikPen® 200U/mL Inj Sol-Pref Pen 5x3mL Pk (DIN 02439611) is excluded from the Biosimilar Policy. No biosimilar is available for this strength.

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## For patients with current EAP approvals for an originator biologic for other indications not listed above

Patients with current EAP approvals for the originator biologic for indications that are not listed above will automatically have their EAP approval extended to the corresponding biosimilar(s) for the same duration. A new EAP request for the biosimilar versions will not be required until the current approval period expires. Please note that a new prescription for the biosimilar must be written.

Patients with current EAP approvals for the originator biologic for an indication that is listed above will also automatically receive EAP approval for all the biosimilar versions. If the EAP approval expiry date is after December 28, 2023, the EAP approval for the originator biologic will end on December 28, 2023 but the approval for the biosimilars will continue until the EAP approval expiry date. It should be noted that as of March 31, 2023, physicians can access the biosimilar for their patients on the ODB Formulary by using an eligible LU code; however, access to the biosimilar through EAP will be maintained for existing patients during the transition period to avoid an unintended treatment gap. Please note that a new prescription is required when changing to a biosimilar.

New patients starting on therapy for indications not on the ODB Formulary or not meeting the Limited Use (LU) criteria will require an EAP request for the biosimilar to be considered of funding.

Medically necessary exemptions to this policy may be granted on a case-by-case basis through the EAP. Note that patients are generally expected to trial at least two biosimilars of the originator biologic before a request to the EAP will be considered to resume funding of their originator product.

Where an originator biologic only has one biosimilar, a patient would only be required to trial one biosimilar before an EAP request for the originator biologic would be considered. **EAP requests from Ontario 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.

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

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# Medically necessary exemptions for formulary biologics

During the transition period of March 31, 2023 to December 28, 2023, prescribers with patients requiring medically necessary exemptions to this policy for Lantus®, NovoRapid®, and Humalog® may include the corresponding temporary Limited Use codes on their prescriptions, but only if the patient is currently established on the originator. These temporary Limited Use codes will be available for medically necessary exemptions until the effective date of the December 2024 Formulary update, and any medically necessary exemptions for Lantus®, NovoRapid®, and Humalog® will need to be submitted to the EAP for case-by-case consideration. Physicians are encouraged to submit EAP requests as soon as possible during the transition period to avoid a gap in coverage.

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# Expect a fax

All physicians who have ODB program recipients with an EAP approval since **March 31, 2022** (for Remicade®, Enbrel®, and Humira® and Copaxone®) and **September 30, 2021** (for Rituxan®), will receive by fax an individualized letter. The letter will include a list of their patients who may need to be transitioned to a biosimilar to maintain ODB program coverage for that biologic. Letters will **not** be sent to physicians identifying ODB program recipients on Lantus®, NovoRapid®, or Humalog®. The ministry will provide all patients, including patients on Lantus®, NovoRapid®, or Humalog®, with an information letter to facilitate the transition to a biosimilar.

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# Biosimilar support fee to be introduced

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 introducing a Biosimilar Support Fee in recognition of the efforts required to contact patients and support patients through the transition to a biosimilar.

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# Requirements for payment of biosimilar support fee

Effective March 31, 2023, physicians in Ontario who facilitate the transition of ODB program recipients from an originator biologic to a biosimilar version (and from Copaxone® to Glatect®) under the Biosimilar Policy may submit a claim for K900A to receive a support payment of $61.20. 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.
  - Currently patients who are new to treatment must start on a biosimilar in order to receive public funding. This remains unchanged and therefore the K900A cannot be billed for these patients.
- Once per patient per drug 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 described within 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 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 to resume the ODB coverage for originator biologics that are subject to the Biosimilar Policy will only be considered for patients who 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 Ontario Drug Benefit 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.

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# 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 (WCB) payment program. K900A submitted as a WCB claim will reject to the provider's error report with error code 'VW1-Invalid WCB Service'.

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# 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 be added to the list of allowable fee-for-service codes for physicians enrolled in the New Graduate Entry 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.

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# 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.

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# 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.

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# Additional information

Information regarding Ontario's Exceptional Access Program can be found on the ministry website. For information about SADIE or to register for SADIE access please visit the SADIE website.

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

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# Keywords/Tags

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

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# Contact Information

Do you have questions about this INFOBulletin? Email the Service Support Contact Centre or call 1-800-262-6524.