Executive Officer Notice:

Update to Biosimilar Policy

December 11, 2023

Effective December 29, 2023, Ontario's transition period for the Expanded Biosimilars Policy for the originator biologics Copaxone®[1], Enbrel®, Humalog®[2], Humira®, Lantus®, NovoRapid®, Remicade®, and Rituxan® through the ODB program will end, with limited exemptions (see below). Recognizing that this milestone comes during the holidays, the ministry will allow pharmacists to submit a claim for a limited quantity, one-time compassionate supply for an originator prescription dispensed between December 29, 2023, and January 30, 2024. This policy change is being made to ensure patients are able to access treatment over the holidays.

See Appendix A for a full listing of relevant LU Codes and changes.

Limited Use Products

Existing LU codes for the insulin products Humalog®[3] (599), Lantus® (614), NovoRapid® (388, 389, 390, 628, 644) will end as scheduled on December 28, 2023.

Existing LU codes for Humira® (417) and Enbrel® (418) for plaque psoriasis will be changed to new LU codes (660 for Humira® and 661 for Enbrel®), under which prescriptions can be issued if the LU criteria are deemed to be met by the prescriber. These new codes are only valid until January 30, 2024.

For originators under the EAP, patients with an approval expiring on or after December 1, 2023 and on or before December 28, 2023, will have their approval automatically extended for an additional month, ending on January 30, 2024.

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[1] Glatect® and Copaxone® are non-biologic complex drugs (NBCDs), however, the biosimilars 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®.

[2] 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.

[3] 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.

Limited Use Code 279 for LU Products

From December 29, 2023, to January 30, 2024, pharmacists can use LU Code 279 to provide a compassionate minimum supply of Humalog®, Lantus®, NovoRapid®, Enbrel or Humira if they are not able to contact a patient's prescriber to obtain a new prescription for a biosimilar. This will ensure patients do not go without their drug until they are able to contact their prescriber. The rules in this EO Notice regarding use of LU code 279 supersede the rules for using LU code 279 set out in the Ontario Drug Programs Reference Manual.

Patients who require originator versions of these products after January 30, 2024, will need to meet the funding criteria and be approved for a medically necessary exemption on a case-by-case basis through the Exceptional Access Program.

Exceptional Access Program (EAP) Products

Patients with EAP approvals for the originator biologics Copaxone®, Enbrel®, Humira®, Remicade® or Rituxan® expiring on or after December 1, 2023 and on or before December 28, 2023, will be automatically extended to January 30, 2024. The purpose of this extension is to grant a compassionate supply for patients on EAP approved originators who did not transition during the 9-month transition period of the biosimilar policy and have not been able to contact a patient's prescriber to obtain a new prescription for a biosimilar.

Compensation for Pharmacists

Pharmacists can continue to claim a Biosimilar 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 biosimilars policy for a transitioning ODB program recipient. Along with filling the prescription, pharmacists are expected to provide recipients 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 physicians).

The fee can be claimed **once per recipient per transition to a biosimilar product**.

The fee **can only be submitted for payment once for transitioning ODB program recipients to a biosimilar on or before January 30, 2024**.

Contacting a prescriber for LU code 660 for Humira® and 661 for Enbrel® or using the temporary transition LU code 279 for the prescribed biologic for a patient offers an opportunity for the pharmacist to remind the patient and the prescriber that the patient must transition to a biosimilar immediately for continuing eligibility for funding under the ODB program.

Please see the EO Notice regarding the Biosimilar Support Fee for more information: Update: Executive Officer Notice: Update to Biosimilar Policy

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

Ministry Policy

Any information about the Biosimilar Policy in this Notice from the Executive Officer and corresponding Q&A for Pharmacists constitutes a ministry policy that pharmacy operators must comply with when submitting claims for payment to the ministry for the Biosimilar 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 LU Code Changes

DIN/PIN	Product Name Strength and Format	Limited Use code changes in the Formulary Update effective as of December 29, 2023	Valid LU code on December 29, 2023
9857294	Humira (adalimumab) 40mg/0.8mL Inj Sol-Pref Pen Pk	Removing: 417 - for severe plaque psoriasis (will be replaced by code 660) Adding: 660 - for severe plaque psoriasis, expires January 30, 2024	279 - for one-time compassionate supply 660 - for severe plaque psoriasis, expires January 30, 2024 (prescription required).
2258595	Humira (adalimumab) 40mg/0.8mL Inj Sol-Pref Syr Pk		
2242903	Enbrel (etanercept) 25mg/Vial Inj Pd-Vial Pk	Removing: 418 - for severe plaque psoriasis (will be replaced by code 661) Adding: 661 - for severe plaque psoriasis, expires January 30, 2024	279 - for one-time compassionate supply 661 - for severe plaque psoriasis, expires January 30, 2024 (prescription required).
2274728	Enbrel (etanercept) 50mg/mL Inj Pref Syr		
9857394	Enbrel (etanercept) SureClick 50mg/mL Pref AutoInj		
2245397	NovoRapid (insulin aspart) 100U/mL Inj Sol-10mL Pk	Removing: 388 - For the treatment of patients with Type 1 diabetes mellitus 389 - For the treatment of patients with Type 2 diabetes mellitus 390 - For the treatment of patients with Type 2 diabetes mellitus who are either experiencing recurrent hypoglycemia OR are unable to achieve adequate post-prandial glucose control while on a less intensive regimen of regular insulin (1-2 injections per day). 644 - Patient requires insulin therapy and is unable to use the insulin pen.	279 - for one-time compassionate supply No Changes to the exemption codes below: 642 - Patient established on therapy prior to March 31, 2023, who is or has become pregnant during the biosimilar transition period between March 31, 2023, to December 28, 2023. 643 - Patient established on therapy prior to March 31, 2023, who is or becomes palliative requiring end-of-life care during the biosimilar transition period between March 31, 2023, to December 28, 2023. 646 - Patient uses an insulin pump that has not been declared compatible with a funded biosimilar version by the insulin pump manufacturer's product labeling.

2244353	NovoRapid (insulin aspart) Penfill 100U/mL Inj Sol-5x3mL Pk	Removing: 628 - For the treatment of diabetes mellitus for only those patients currently established on NovoRapid (insulin aspart) therapy	279 - for one-time compassionate supply 642 - pregnancy exemption expires Dec 2024 643 - palliative exemption expires Dec 2024
2377209	NovoRapid (insulin aspart) FlexTouch 100U/mL Inj Sol-Prefil 5X3mL Pk Disposable Pen		
2245689	Lantus (insulin glargine) 100U/mL Inj Sol-10mL Vial Pk		642 – pregnancy exemption expires Dec 2024 643 – palliative exemption expires Dec 2024 644 – Patient requires insulin therapy and is unable to use the insulin pen
2294338	Lantus (insulin glargine) Solostar 100U/mL Inj Sol-5x3mL Pk	Removing: 614 – For the treatment of diabetes mellitus for only those patients currently established on Lantus (insulin glargine) therapy.	279 - for one-time compassionate supply 642 - Patient established on therapy prior to March 31, 2023, who is or has become pregnant during the biosimilar transition period between March 31, 2023, to December 28, 2023. 643 - Patient established on therapy prior to March 31, 2023, who is or becomes palliative requiring end-of-life care during the biosimilar transition period between March 31, 2023, to December 28, 2023.
2251930	Lantus (insulin glargine) 100U/mL Inj Sol-5x3mL Pk (Cartridge)		
2229704	Humalog (insulin lispro) 100U/mL Inj Sol-10mL Pk	Removing: 599 – For the treatment of diabetes mellitus for only those patients currently established on Humalog therapy.	279 - for one-time compassionate supply 642 - Patient established on therapy prior to March 31, 2023, who is or has become pregnant during the biosimilar transition period between March 31, 2023, to December 28, 2023. 643 - Patient established on therapy prior to March 31, 2023,

			who is or becomes palliative requiring end-of-life care during the biosimilar transition period between March 31, 2023, to December 28, 2023. 646 - Patient uses an insulin pump that has not been declared compatible with a funded biosimilar version by the insulin pump manufacturer's product labeling.
9853715	Humalog (insulin lispro) 100U/mL Inj Sol-5x3mL Pk	Removing: 599 - For the treatment of diabetes mellitus for only those patients currently established on Humalog therapy.	279 - for one-time compassionate supply 642 - Patient established on therapy prior to March 31, 2023, who is or has become pregnant during the biosimilar transition period between March 31, 2023, to December 28, 2023. 643 - Patient established on therapy prior to March 31, 2023, who is or becomes palliative requiring end-of-life care during the biosimilar transition period between March 31, 2023, to December 28, 2023.
2403412	Humalog Kwikpen 100U/mL Inj Sol-5x3mL Pk		
2470152	Humalog (insulin lispro) 100U/mL Inj Sol-Pref Pen 5x3mL Pk (Junior KwikPen)		