Ontario

Ministry of Health
Health Programs and Delivery Division

Update to Biosimilar Policy: Q&A for Pharmacists

December 11, 2023

1. How can pharmacists help with the transition from the originator biologic to the biosimilar at the pharmacy level?

Pharmacists can help the transition by contacting the prescriber on the ODB program recipient's behalf and requesting a new prescription for the biosimilar, by educating recipients when they fill their new prescription for a biosimilar, and by answering any questions they may have.

2. Are the existing LU codes no longer valid?

Existing LU codes for the insulin products Humalog®[1] (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 LU codes are only valid until January 30, 2024.

3. What is LU 279 used for?

After December 28, 2023, to January 30, 2024, pharmacists can use LU Code 279 to submit a claim for dispensing certain originator biologics as a one-time compassionate supply (for a maximum quantity of 1 month supply) without obtaining a new prescription with the new LU code or an existing exemption **LU code for the insulin products. This will ensure the patient does not go without their** drug until they are able to obtain a new prescription for the biosimilar from their prescriber. Please refer to the EO Notice for more information.

LU Code 279 should **not** be used in lieu of attempting to contact the prescriber and facilite a switch to the biosimilar. The purpose of this code is as a backup in urgent situations over the holidays where the prescriber cannot be reached.

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[1] 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.

4. **Are the originator products funded under ODB after December for patients who have not transitioned?**

During the period of December 29, 2023 to January 30, 2024, pharmacists can use LU Code 279 to submit a claim for dispensing certain originator biologics with an existing valid prescription as a one-time compassionate supply without obtaining a new prescription with the LU code 279. This will ensure the patient does not go without their drug over the holidays Pharmacists still require a new prescription to dispense the biosimilar and should make the prescriber for the patient aware the patient still needs to be transitioned. Please refer to the EO Notice for more information.

5. **How long is the new temporary LU code 279 valid?**

The new temporary LU code 279 can be applied for dispensing Humalog®, Lantus®, NovoRapid®, and Enbrel or Humira for plaque psoriasis if they are not able to contact a patient's prescriber to obtain a new prescription for a biosimilar for one additional prescription dispensation until January 30, 2024. Please refer to the EO Notice for more information.

6. **If patients are using the insulin vials and are unable to use the cartridges or prefilled pens of the new biosimilar versions, would the LU code be valid after Dec 28, 2023?**

For patients who are using Lantus® vials and meet the Limited Use exemption code 644 (patient requires insulin therapy and is unable to use the insulin pen) will continue to have coverage beyond December 28, 2023 and do not require a new prescription. LU code 279 is not required in these circumstances.
The Ministry will only consider removing Limited Use code 644 if, in the future, the biosimilar manufacturers begin to market a vial of the biosimilars insulin glargine. Any changes to the formulary will be published in the monthly Ontario Drug Benefit Formulary update.

7. **Do Exceptional Access Program (EAP) approvals for patients end in December?**

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 an additional one time 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 their prescriber to obtain a new prescription for a biosimilar.

8. Can a pharmacist claim the Biosimilar Support Fee if the pharmacy contacts the prescriber to discuss the transition, but the discussion does not result in a new prescription for the biosimilar?

There is no requirement to obtain the prescription in order to claim the Biosimilar Support Fee. Making the contact is sufficient to claim the fee. The Biosimilar Policy states that 'Contacting the prescriber on behalf of one or more ODB program recipients to discuss their transition to the biosimilar product and obtaining new prescriptions for the recipients (e.g., providing to the prescriber a list of ODB program recipients who are patients of the prescriber and who need to transition to biosimilars under the Biosimilar Policy)'.