Update: Executive Officer Notice: Funding of Glatect®/Copaxone®/Glatiramer Acetate Injection under the Ontario Drug Benefit Program

September 2, 2025

Effective the August 2025 Formulary update, the Reason for Use (RFU) codes under the Ontario Drug Benefit (ODB) Program for Copaxone® and Glatiramer Acetate Injection will change to align with Glatect®. The Limited Use (LU) criteria for Glatect® will change to align with Copaxone® and Glatiramer Acetate Injection (text change in bold below), and RFU codes for all three products will be as follows. Please refer to the e-Formulary for the most up-to-date information.

Reason For Use Code 535: Relapsing Remitting Multiple Sclerosis (Previously LU/RFU 691 for Copaxone® and Glatiramer Acetate Injection)

As monotherapy for the treatment of patients with relapsing remitting multiple sclerosis (RRMS) meeting ALL the following criteria:

- Recent neurological examination consistent with the diagnosis of RRMS; AND
- Lesions typical of multiple sclerosis on brain magnetic resonance imaging (MRI); AND
- Experienced at least 2 clinical attacks in their lifetime with one attack occurring within the prior year; AND
- EDSS score less than or equal to 6.0 prior to start of treatment; AND
- Prescribed by a neurologist who is experienced in the treatment of Multiple Sclerosis.

Note: Transition from another Disease Modifying therapy (DMT) is permitted in those who are deemed to have met the above criteria prior to initiation of the other DMT and if **glatiramer acetate** is used as monotherapy.

LU Authorization Period: 1 year

Reason For Use Code 536: Clinically Isolated Syndrome (Previously LU/RFU 692 for Copaxone® and Glatiramer Acetate Injection)

As monotherapy for the treatment of patients who have experienced a single demyelinating event/ Clinically Isolated Syndrome (CIS) meeting ALL the following criteria:

- CIS occurred within the prior 12 months; AND
- Recent neurological examination; AND
- Lesions typical of CIS confirmed on brain magnetic resonance imaging (MRI); AND
- EDSS score less than or equal to 6.0 prior to start of treatment; AND
- Prescribed by a neurologist who is experienced in the treatment of Multiple Sclerosis

Note: Transition from another Disease Modifying therapy (DMT) is permitted in those who are deemed to have met the above criteria prior to initiation of the other DMT and if **glatiramer acetate** is used as monotherapy.

LU Authorization Period: 1 year

Reason For Use Code 537: Renewal of therapy for RRMS/CIS (Previously RFU 693 for Copaxone® and Glatiramer Acetate Injection)

Renewal of therapy for patients diagnosed with relapsing remitting multiple sclerosis (RRMS) or a single demyelinating event /Clinically Isolated Syndrome (CIS) who meet ALL the following criteria:

- Used as monotherapy for the treatment of RRMS or CIS; AND
- EDSS score less than or equal to 6.0; AND
- Disease activity is stabilized as determined by a neurological exam and the number of clinical relapses experienced while on treatment; AND
- Prescribed by a neurologist experienced in the treatment of Multiple Sclerosis (MS) OR a prescriber in consultation with a neurologist overseeing the patient's MS.

LU Authorization Period: 1 year

As of the August 2025 Formulary update, prescribers should ensure that prescriptions directing the dispensing of Glatect®, Copaxone® or Glatiramer Acetate Injection for ODB Program recipients who meet the above LU criteria, include the appropriate RFU code. When dispensers receive such prescriptions, they must submit a claim for payment with the corresponding RFU code.

The above RFU codes (535, 536 and 537) do not represent a change for Glatect®, so no transition issues are expected for ODB Program recipients who meet the LU criteria for Glatect®.

However, for Copaxone® and Glatiramer Acetate Injection, the RFU codes 535, 536 and 537 are new. To assist recipients in transitioning to these new RFU codes, RFU code 279 will be activated for Copaxone® and Glatiramer Acetate Injection. This transition RFU code may be temporarily used in claims for payment submitted by dispensers for supplying Copaxone® or Glatiramer Acetate Injection to ODB Program recipients who meet the applicable LU criteria, for a period of up to twelve (12) months after the August 2025 Formulary update. It is expected that after 12 months, all ODB Program recipients who meet the LU criteria for Copaxone® and Glatiramer Acetate will have a prescription with the correct RFU code. The transition code RFU 279 will be deactivated with the August 2026 Formulary update. The rules regarding the use of RFU code 279 are set out in the Ontario Drug Programs Reference Manual.

Details regarding these RFU codes and LU criteria for Glatect®, Copaxone® and Glatiramer Acetate Injection will also be posted in the August 2025 Formulary update which can be found on the ministry's website at:

http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx

Glatiramer Frequently Asked Questions

1. **What is the difference between Copaxone®, Glatect® and Glatiramer Acetate Injection?**

   Copaxone® (glatiramer acetate), Glatect® (glatiramer acetate) and Glatiramer Acetate Injection are all Health Canada-approved versions of glatiramer acetate manufactured by various drug manufacturers for the treatment of multiple sclerosis. Copaxone® is the brand innovator product, Glatiramer Acetate Injection is a generic interchangeable version of Copaxone ®, and Glatect® is a subsequent-entry non-biologic complex drug that has not been designated as interchangeable with Copaxone® or Glatiramer Acetate Injection.

2. **What was the previous funding status of Copaxone®, Glatect® and Glatiramer Acetate Injection, and what has changed as of the August 2025 Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (Formulary) Update?**

As of the December 2024 Formulary update (effective December 30, 2024), Copaxone® and Glatiramer Acetate Injection are designated on the Formulary as LU benefits. Glatiramer Acetate Injection continues to be designated as interchangeable with Copaxone®. Glatect® continues to be designated on the Formulary as a LU benefit. As of the August 2025 Formulary update , Glatect®, Copaxone® and Glatiramer Acetate Injection will share the same LU/RFU codes and clinical criteria on the Formulary.

3. **Is the Ministry requiring ODB program recipients to switch from Glatect® to Copaxone® or Glatiramer Acetate Injection?**

   No. There will not be any requirements for recipients currently using Glatect® to switch to Copaxone® or Glatiramer Acetate Injection. Recipients currently using Glatect® in accordance with the LU criteria on the Formulary may continue to do so. However, prescribers and dispensers should refer to Q6 for more information on different prescribing and dispensing scenarios relating to all three products.

4. **How will these changes impact ODB program recipients and those with an EAP approval for Copaxone®?**

   ODB program recipients with existing EAP approvals for Copaxone® may continue to receive coverage for their established therapy, and transition to receive coverage through applicable LU criteria on the Formulary by the expiry date of their existing EAP approval.

5. **How will these changes impact prescribers and dispensers?**

   As of the August 2025 Formulary update, Copaxone® and Glatiramer Acetate Injection will share the same LU criteria and LU/RFU codes as Glatect®. Pharmacies must submit claims using the drug identification number (DIN) of the product dispensed and the applicable RFU code. The applicable RFU code must be documented on the prescription, which may require prescribers to issue new prescriptions. Until a prescription with the new LU/RFU code can be obtained, an existing valid prescription may be dispensed temporarily using RFU code 279 at the discretion of the pharmacist.

   The following rules are applicable to both glatiramer-naïve and glatiramer-experienced recipients. Any reference to a “prescription” in the rules below shall be interpreted as a prescription containing the applicable LU/RFU code corresponding to the LU criteria met by the recipient, subject to the allowance described in this document regarding the temporary use of RFU code 279:

i. If a prescription directs “Copaxone” to be dispensed to an ODB program recipient meeting the LU criteria with no substitution (i.e., “NO SUB”), the pharmacist shall dispense Copaxone®. The ministry would pay the drug benefit price of Glatiramer Acetate Injection and the applicable mark-up on that price, unless the recipient has a documented adverse reaction to Glatiramer Acetate Injection, in which case the drug benefit price of Copaxone® and applicable mark-up on that price would be paid. If the ministry does not pay the drug benefit price and mark-up for Copaxone®, then the recipient can be charged the difference between the sum of the drug benefit price and mark-up for Copaxone® and the sum of the drug benefit price and mark-up for Glatiramer Acetate Injection.

ii. If a prescription directs “Copaxone” to be dispensed to an ODB program recipient meeting the LU criteria but is silent on whether it can be substituted with an interchangeable product (e.g., prescription says “Copaxone” but does not say “NO SUB”), the pharmacist may dispense Glatiramer Acetate Injection. The pharmacist must not dispense Copaxone® without informing the ODB program recipient or person presenting the prescription of the right to request Glatiramer Acetate Injection, unless Copaxone® is being supplied pursuant to a repeat of the prescription or the pharmacy is not charging more for Copaxone® than it would charge for supplying Glatiramer Acetate Injection if Glatiramer Acetate Injection is available in the pharmacy’s inventory. The ministry would pay the drug benefit price of Glatiramer Acetate Injection and the applicable mark-up on that price, regardless of whether Copaxone® or Glatiramer Acetate Injection is dispensed. If Copaxone® is dispensed at the request of the recipient or the person presenting the prescription, then they could be charged the difference between the sum of the drug benefit price and mark-up for Copaxone® and the sum of the drug benefit price and mark-up for Glatiramer Acetate Injection.

iii. If a prescription directs “glatiramer acetate” to be dispensed to an ODB program recipient meeting the LU criteria without identifying a specific product name or manufacturer, the pharmacist shall dispense the Glatiramer Acetate Injection, in accordance with section 5 of the *Drug Interchangeability and Dispensing Fee Act* (DIDFA). The ministry would pay the drug benefit price of Glatiramer Acetate Injection and the applicable mark-up on that price. If a pharmacist has concerns about whether Copaxone® or Glatect® should be dispensed in this scenario, then the pharmacist can consult the prescriber and obtain a new prescription to dispense the intended therapy, if necessary.

iv. If there is a documented shortage of Glatiramer Acetate Injection, and a prescription directs the dispensing of “Copaxone” or “glatiramer acetate” to an ODB program recipient meeting the LU criteria, then the pharmacist may dispense Copaxone® with the “MI” (cost-to-operator) intervention code. The ministry would

pay the pharmacy's acquisition costs for Copaxone®. If there is a documented shortage of Glatect®, the pharmacist can consult the prescriber and obtain a new prescription to dispense a suitable alternative.

v. If a prescription directs "Glatect" to be dispensed to an ODB program recipient meeting the LU criteria with no substitution (i.e., with "NO SUB"), the pharmacist shall dispense Glatect®; the pharmacist could not dispense either Copaxone® or Glatiramer Acetate Injection unless the recipient receives a new prescription. The ministry would pay the drug benefit price of Glatect® and the applicable mark-up on that price.

vi. If a prescription directs "Glatect" to be dispensed to an ODB program recipient meeting the LU criteria but does not specify no substitutions (e.g., prescription says "Glatect" but does not say "NO SUB"), the pharmacist may dispense Glatect®, Copaxone® or Glatiramer Acetate Injection. Glatect® has not been designated as interchangeable with either Copaxone® or Glatiramer Acetate Injection, and the pharmacist may still dispense Copaxone® or Glatiramer Acetate Injection in its place in this scenario because Copaxone® and Glatiramer Acetate Injection contain glatiramer acetate in the same amounts of the same active ingredients in the same dosage form as Glatect®. In accordance with subsection 4(5) of DIDFA, pharmacists are permitted to select Copaxone® or Glatiramer Acetate Injection in such a scenario but are not required to. Pharmacists would use their professional judgment when selecting the product to dispense and may consult the recipient's prescriber.

If Glatect® is dispensed in this scenario, then the ministry would pay the drug benefit price of Glatect® and the applicable mark-up on that price.

If Glatiramer Acetate Injection is dispensed in this scenario, then the ministry would pay the drug benefit price of Glatiramer Acetate Injection and the applicable mark-up on that price.

If Copaxone® is dispensed in this scenario, then the ministry would pay the drug benefit price of Glatiramer Acetate Injection and the applicable mark-up on that price, unless there is a documented shortage of Glatiramer Acetate Injection, in which case the ministry would pay the pharmacy's acquisition costs for Copaxone®.

Note: If there is any discrepancy between the information in this response and the *Ontario Drug Benefit Act* (ODBA) or DIDFA, then the legislation prevails. If pharmacists have questions about their professional obligations, they should consult the Ontario College of Pharmacists (OCP) for further guidance.

For dispensers: For recipients with existing and valid EAP approvals for Copaxone®, pharmacies/pharmacists can continue to submit claims for Copaxone®, as applicable, using the appropriate DINs:

Table 1

DIN	Brand Name	Generic Name	Strength & Dosage Form	MFR
02245619	Copaxone®	glatiramer acetate	20 mg/mL, 1 mL prefilled syringe	Teva Canada Innovations G.P.-S.E.N.C.

There will not be any requirements for ODB program recipients currently using Glatect® to switch to Copaxone® or Glatiramer Acetate Injection. Recipients currently using Glatect® in accordance with the LU criteria on the Formulary may continue to do so. However, prescribers and dispensers should refer to Q5 for more information on different prescribing and dispensing scenarios relating to all three products.

6. **Is the Ministry requiring ODB program recipients to have a new prescription for Copaxone® or Glatiramer Acetate®?**

   A new prescription will be required with an updated RFU/LU code for Copaxone® or Glatiramer Acetate following the August 2025 Formulary update. However existing prescriptions with previous LU/RFU codes of 691, 692 and 693 prior to the August 2025 Formulary update are still valid and RFU code 279 may be temporarily used in claims for payment to supply Copaxone® or Glatiramer Acetate Injection, for the remaining duration of the original LU authorization period or the effective date of the August 2026 Formulary update, whichever is earlier.

7. **Is there any action required for ODB program recipients on Glatect®?**

   No action would be required for recipients on Glatect® as there are no changes to the LU/RFU codes of Glatect®.

8. **When will LU/RFU codes 691, 692, 693 be deactivated/discontinued?**

   LU/RFU codes 691, 692, and 693 will be deactivated effective the August 2025 Formulary update.

9. **What if an ODB program recipient presents a prescription for Copaxone® or Glatiramer Acetate with an old RFU code (691, 692, 693)?**

If the prescription cannot be clarified to the applicable updated RFU/LU code, the temporary transition code RFU 279 may be submitted to allow for continuity of care and for the claim to be processed in HNS. The transition code will be activated for a period of 12 months as of the August 2025 Formulary update. It is expected that by the August 2026 Formulary update, all recipients have a prescription for the correct LU code.

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