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 December 2024 Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index (Formulary) Update?

Prior to the December 2024 Formulary update, Copaxone® and Glatiramer Acetate Injection were funded under the Exceptional Access Program (EAP) for Ontario Drug Benefit (ODB) program recipients who satisfied certain clinical criteria, while Glatect® was designated on the Formulary as a Limited Use (LU) benefit.

As of the December 2024 Formulary update (effective December 30, 2024), Copaxone® and Glatiramer Acetate Injection will be 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.

3. What are the LU Criteria for Copaxone® and Glatiramer Acetate Injection?

The Reason for Use (RFU) Codes and their associated reimbursement criteria for Copaxone® and Glatiramer Acetate Injection are set out below

(as of the December 2024 Formulary update effective December 30, 2024). Please refer to the e-Formulary for the most up-to-date information.

Relapsing Remitting Multiple Sclerosis (RFU Code 691)

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

Clinically Isolated Syndrome (RFU Code 692)

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

Renewal of therapy for RRMS/CIS (RFU Code 693)

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

4. Is the Ministry requiring patients to switch from Glatect® to Copaxone® or Glatiramer Acetate Injection?

No. There will not be any requirements for patients currently using Glatect® to switch to Copaxone® or Glatiramer Acetate Injection. Patients currently using Glatect® in accordance with the LU criteria on the Formulary may continue to do so. However, prescribers and dispensers should refer to Q8 for more information on different prescribing and dispensing scenarios relating to all three products.

5. **Will the ministry consider new requests for Copaxone® or Glatiramer Acetate Injection reimbursement under the Exceptional Access Program (EAP)?**

   As of the December 2024 Formulary update (effective December 30, 2024), Copaxone® or Glatiramer Acetate Injection will be funded as LU benefits for ODB program recipients who meet the LU criteria.

6. **How should pharmacies submit claims for Copaxone® or Glatiramer Acetate Injection?**

   Pharmacies must submit claims using the drug identification number (DIN) of the product dispensed and the applicable RFU code (see Q3 above). The applicable RFU code must be documented on the prescription, which may require prescribers to issue new prescriptions.

7. **How will these changes impact patients?**

   As of the December 2024 Formulary update (effective December 30, 2024), Copaxone® and Glatiramer Acetate Injection will be designated as LU benefits on the Formulary and will be funded for ODB program recipients who meet the applicable LU criteria. Prescriptions are subject to generic substitution rules under the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) (see Q8 below).

   ODB program recipients with existing EAP approvals for Copaxone® or Glatiramer Acetate Injection may continue to receive coverage for their established therapy, in accordance with the patient's EAP approval authorization period and EAP's generic substitution policies. Once the EAP approval authorization ends, these recipients may continue to receive coverage for Copaxone® or Glatiramer Acetate Injection if they meet the applicable LU criteria on the Formulary and have prescriptions with the corresponding RFU codes.

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

As of the December 2024 Formulary update (effective December 30, 2024), ODB program recipients may receive coverage for Glatect®, Copaxone® or Glatiramer Acetate Injection upon meeting the LU criteria. Pharmacists can help ODB program recipients meeting LU criteria and wishing to "switch" between the glatiramer acetate products by consulting the prescriber and dispensing the appropriate product, in accordance with the ODBA and DIDFA. In some cases, a new prescription may be required to indicate that the recipient meets the applicable RFU code and to ensure that the desired product is dispensed.

Copaxone®/Glatiramer Acetate Injection will have comparable LU criteria as Glatect®, but with different RFU codes.

The following rules are applicable to both glatiramer-naïve and glatiramer-experienced patients:

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 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 ODBA or DIDFA, 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 patients with existing and valid EAP approvals for Copaxone® or Glatiramer Acetate Injection, pharmacies/pharmacists can continue to submit claims for Copaxone® or Glatiramer Acetate Injection, 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.
02541440	Glatiramer Acetate Injection	glatiramer acetate	20 mg/mL, 1 mL prefilled syringe	Mylan Pharmaceuticals ULC

There will not be any requirements for ODB program recipients currently using Glatect® to switch to Copaxone® or Glatiramer Acetate Injection. Patients currently using Glatect® in accordance with the LU criteria on the Formulary may continue to do so. However, prescribers and dispensers should refer to Q8 for more information on different prescribing and dispensing scenarios relating to all three products.

Additional information:

For pharmacies:

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