Glatect (glatiramer acetate) Frequently Asked Questions

1. What is the funding status of Glatect (glatiramer acetate)?

Effective **September 27, 2018**, Glatect will be added to the Ontario Drug Benefit (ODB) Formulary as a Limited Use (LU) benefit for the monotherapy treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS) and for the monotherapy treatment of patients who have experienced a single demyelinating event/ Clinically Isolated Syndrome (CIS).

2. What are the Limited Use Criteria for Glatect?

Reason For Use (RFU) Code and Clinical Criteria

RRMS (Code 535)

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 Glatect is used as monotherapy

Authorization period: 1 year

CIS (Code 536)

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 Glatect is used as monotherapy.

Authorization period: 1 year

RRMS (Code 537)

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.

Authorization period: 1 year

3. What is difference between Glatect and Copaxone?

Glatect and Copaxone are both glatiramer acetate products. Glatiramer acetate is an immunomodulatory medicine that is administered subcutaneously. Glatect and Copaxone are manufactured and marketed by different companies.

4. Are patients with existing Exceptional Access Program (EAP) approval for Copaxone required to switch to Glatect?

No. Patients who have an existing Exceptional Access Program (EAP) approval for Copaxone or who become ODB recipients after starting Copaxone can continue to receive Copaxone for the duration of the EAP approval period. The ministry will also consider EAP renewal requests for Copaxone for patients with existing EAP approvals.

Claims for Glatect will be reimbursed under the ODB program when prescribed in accordance with the LU criteria and accompanied by a valid, fully completed prescription with the appropriate LU documentation (RFU code).

5. Will the ministry consider new requests for Copaxone reimbursement under the Exceptional Access Program, for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS) or a single demyelinating event /Clinically Isolated Syndrome(CIS)?

The ministry will no longer accept requests to start Copaxone therapy under the EAP for the treatment of RRMS or CIS.

The ministry will no longer consider requests for the reimbursement of Copaxone under the EAP for the treatment of RRMS or CIS in patients who are treatment naïve to Copaxone.

6. Will the ministry consider requests for Copaxone reimbursement under the Exceptional Access Program for patients who do not respond to Glatect, or are intolerant to Glatect?

The ministry will not consider requests for Copaxone reimbursement for patients who do not respond to Glatect, or are intolerant to Glatect under any program. The physician may wish to consider other therapeutic options.

7. Is Glatect currently funded for indications other than RRMS?

Effective the date of September 2018 Formulary update Glatect will be listed on the ODB Formulary as a Limited Use (LU) benefit for the treatment of RRMS or CIS. At this time, there is no reimbursement for Glatect for any other indications either as an LU benefit or through the Exceptional Access Program.

8. How should pharmacies submit claims for Glatect?

Pharmacies should be submitting claims using the drug identification number (DIN) of the product and the appropriate reason for use code.

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