| Pharmacy Policy Bulletin: J-0799 Glatiramer Acetate – Commercial and Healthcare Reform | |
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| **Number:** J-0799 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>**1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-0799-006 | **Original Date:** 11/08/2017 |
| **Effective Date: 10/08/2025** | **Review Date:** 09/17/2025 |

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| **Drugs Product(s):** | • Copaxone (glatiramer acetate)<br>• Glatopa (glatiramer acetate) |
| **FDA-Approved Indication(s):** | • Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. |

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| **Background:** | • The exact mechanism of action by which glatiramer acetate exerts its effects in patients with MS is not fully understood. It is thought to act by modifying immune processes that are responsible for the pathogenesis of MS.<br>• Clinically isolated syndrome is the first episode of neurological symptoms caused by inflammation and demyelination in the central nervous system. Relapsing-remitting MS (RRMS) is characterized by clearly defined attacks of new or increasing neurologic symptoms. The attacks are followed by periods of partial or complete recovery (remissions). Secondary progressive disease follows an initial relapsing remitting course, with disability gradually increasing over time.<br>• Prescribing Considerations:<br>  ○ Glatiramer has warnings and precautions for immediate post-injection reaction, chest pain, lipoatrophy, skin necrosis, immune response, hepatic injury, and administration errors.<br>  ○ Glatiramer has a black box warning for anaphylactic reactions. |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Copaxone (glatiramer acetate) or Glatopa (glatiramer acetate) may be approved when all of the following criteria are met **(A., B., and C.)**:

**A.** The member is 18 years of age or older.

**B.** The member has a diagnosis of multiple sclerosis (ICD-10: G35), classified as one (1) of the following **(1., 2., or 3.)**:

**1.** Clinically isolated syndrome

**2.** Relapsing-remitting disease

3. Active secondary progressive disease

**C.** If the request is for brand Copaxone 20 mg, the member has experienced therapeutic failure or intolerance to one (1) of the following **(1. or 2.):**
1. Glatiramer
2. Plan-preferred Glatopa

**II. Reauthorization**

When a benefit, reauthorization of Copaxone (glatiramer acetate) or Glatopa (glatiramer acetate) may be approved when the following criteria are met **(A. and B.)**:

**A.** The prescriber attests that the member has experienced a therapeutic response defined as one (1) of the following **(1., 2., or 3.):**
1. Disease stability
2. Disease improvement
3. Delayed disease progression

**B.** If the request is for brand Copaxone 20 mg, the member has experienced therapeutic failure or intolerance to one (1) of the following **(1. or 2.):**
1. Glatiramer
2. Plan-preferred Glatopa

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial and HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Copaxone [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; January 2025.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; February 2025.
3. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed June 19, 2025.