

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Copaxone (glatiramer acetate) and Glatopa (glatiramer acetate) under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

For the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Copaxone Glatiramer acetate Glatopa

Policy/Guideline:

Prescriber Specialty:

This medication must be prescribed by or in consultation with a neurologist.

Criteria for Initial Approval:

A. Relapsing forms of multiple sclerosis

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse). Requests for Copaxone require that the patient is unable to take generic glatiramer acetate and Glatopa for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

B. Clinically isolated syndrome

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Name:	Copaxone-Glatopa		Page:	2 of 3
Effective Date: 11/1/2024			Last Review Date:	10/2024
Applies to:	□ Illinois ⊠ New Jersey ⊠ Pennsylvania Kids	□Florida ⊠Maryland □Virginia	⊠Florida Kids □Michigan □ Kentucky PRMD	

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis. Requests for Copaxone require that the patient is unable to take generic glatiramer acetate and Glatopa for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Continuation of Therapy:

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Copaxone, Glatopa, or glatiramer acetate.

Other Criteria:

Members will not use Copaxone, Glatopa, or glatiramer acetate concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limits:

- Copaxone (glatiramer acetate) prefilled syringe 20mg/mL: 30 prefilled syringes per 30 days
- Copaxone (glatiramer acetate) prefilled syringe 40mg/mL: 12 prefilled syringes per 28 days
- Glatopa (glatiramer acetate) prefilled syringe 20mg/mL: 30 prefilled syringes per 30 days
- Glatopa (glatiramer acetate) prefilled syringe 40mg/mL: 12 prefilled syringes per 28 days

References:

- 1. Copaxone [package insert]. Parsippany, NY: Teva Pharmaceuticals USA, Inc.; November 2023.
- 2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; December 2023.
- 3. Glatiramer acetate 20mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
- 4. Glatiramer acetate 40mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
- 5. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. April 14, 2024.
- 6. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 14, 2024.

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7. The Multiple Sclerosis Coalition. *The use of disease-modifying therapies in multiple sclerosis: principles and current evidence.* https://ms-coalition.org/wp-content/uploads/2019/06/MSC_DMTPaper_062019.pdf. Accessed March 01, 2024.