

Reference number(s)
1841-A

## SPECIALTY GUIDELINE MANAGEMENT

### COPAXONE (glatiramer acetate) GLATOPA (glatiramer acetate) glatiramer acetate

#### POLICY

##### I. INDICATIONS

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

Indicated 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.

##### II. PRESCRIBER SPECIALTIES

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

##### III. 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).

###### B. Clinically isolated syndrome

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

##### IV. 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.

##### V. OTHER

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).

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## VI. 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](http://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](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed April 14, 2024.
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/MS\\_CDMTPaper\\_062019.pdf](https://ms-coalition.org/wp-content/uploads/2019/06/MS_CDMTPaper_062019.pdf). Accessed March 01, 2024.