

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 covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Copaxone is 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.
2. Glatopa and glatiramer acetate are indicated for the treatment of patients with relapsing forms of multiple sclerosis.

B. Compendial Use

Relapsing-remitting multiple sclerosis, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis

All other indications are considered experimental/investigational and are not covered benefits.

II. 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 the treatment of clinically isolated syndrome of multiple sclerosis.

III. 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.

IV. OTHER CRITERIA

Members will not use Copaxone, Glatopa, or glatiramer acetate concomitantly with other medications used for the treatment of multiple sclerosis, excluding Ampyra.

Reference number(s)
1841-A

V. REFERENCES

1. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2019.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; October 2018.
3. Glatiramer acetate [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2018.
4. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. May 01, 2019.
5. 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 May 01, 2019.
6. The Multiple Sclerosis Coalition. *The use of disease-modifying therapies in multiple sclerosis: principles and current evidence*. http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed May 01, 2019.