

SPECIALTY GUIDELINE MANAGEMENT

COPAXONE (glatiramer acetate) GLATOPA (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.

FDA-Approved Indication: Copaxone and Glatopa are indicated for the treatment of patients with relapsing forms of multiple sclerosis.

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 24 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis.

B. First clinical episode of multiple sclerosis

Authorization of 24 months may be granted to members for the treatment of a first clinical episode of multiple sclerosis.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2016.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; April 2016.
3. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. April 19, 2018.
4. 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 19, 2018.

| Reference number(s) |
|---------------------|
| 1841-A |

5. 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 April 19, 2018.