

## 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: 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]. Kansas City, MO: Teva Neuroscience, Inc.; January 2014.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; January 2016.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. April 25, 2016.
4. 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 25, 2016.
5. National Multiple Sclerosis Society. *Disease Management Consensus Statement*. New York, NY: National Multiple Sclerosis Society; 2008. Available at: [http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/ExpOp\\_Consensus.pdf](http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/ExpOp_Consensus.pdf). Accessed April 26, 2016.
6. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58:169-178.