

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

###### **A. 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.

##### **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 disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

##### **V. REFERENCES**

1. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2019.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; January 2020.
3. Glatiramer acetate [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2020.

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4. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. April 7, 2020.
5. 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 7, 2020.
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](http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color). Accessed May 01, 2019.