Clinical Policy: Glatiramer Acetate (Copaxone, Glatopa)
Reference Number: CP.CPA.329
Effective Date: 06.01.18
Last Review Date: 05.18
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Glatiramer (Copaxone®, Glatopa®) is a polypeptide.

FDA Approved Indication(s)
Copaxone and Glatopa are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Copaxone and Glatopa are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Multiple Sclerosis (must meet all):
      1. Diagnosis of relapsing-remitting MS;
      2. Prescribed by or in consultation with a neurologist;
      3. Age ≥ 18 years;
      4. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (see Appendix C);
      5. Dose does not exceed 20 mg/mL per day (1 prefilled syringe/day) or 40 mg/mL three times per week (3 prefilled syringes/week).

   Approval duration: 6 months or to the member’s renewal date, whichever is longer

   B. Other diagnoses/indications
      1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Multiple Sclerosis (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      2. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (see Appendix C);
3. If request is for a dose increase, new dose does not exceed 20 mg/mL per day (1 prefilled syringe/day) or 40 mg/mL three times per week (3 prefilled syringes/week).

**Approval duration: 6 months or to the member’s renewal date, whichever is longer**

**B. Other diagnoses/indications** (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

   **Approval duration: Duration of request or 6 months (whichever is less); or**
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

   **A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 or evidence of coverage documents;

   **B.** Primary progressive MS.

**IV. Appendices/General Information**

   **Appendix A: Abbreviation/Acronym Key**
   FDA: Food and Drug Administration
   MS: multiple sclerosis

   **Appendix B: Therapeutic Alternatives**
   Not applicable

   **Appendix C: General Information**
   Disease-modifying therapies for MS are: daclizumab (Zinbryta®), glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebit®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (GilenyaTM), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocrelizumab (OcrevusTM).

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glatiramer acetate (Copaxone)</td>
<td>20 mg SC QD or 40 mg SC TIW</td>
<td>20 mg/day or 40 mg TIW</td>
</tr>
<tr>
<td>Glatiramer acetate (Glatopa)</td>
<td>20 mg SC QD</td>
<td>20 mg/day</td>
</tr>
</tbody>
</table>

**VI. Product Availability**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glatiramer acetate (Copaxone)</td>
<td>Single-dose, prefilled syringe: 20 mg/mL, 40 mg/mL</td>
</tr>
<tr>
<td>Glatiramer acetate (Glatopa)</td>
<td>Single-dose, prefilled syringe: 20 mg/mL</td>
</tr>
</tbody>
</table>

**VII. References**

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPSC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1595</td>
<td>Injection, glatiramer acetate, 20 mg</td>
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Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>01.05.18</td>
<td>05.18</td>
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Policy created: no significant changes from previously approved corporate policy; policy split from CP.CPA.206 Multiple Sclerosis; added age; removed COC statement for reauth; added requirement for no concurrent use with other MS therapies; references reviewed and updated.

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage
decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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