Clinical Policy: Glatiramer Acetate (Copaxone, Glatopa)
Reference Number: CP.PHAR.252
Effective Date: 08.01.16
Last Review Date: 05.19
Line of Business: Commercial, HIM, Medicaid

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

Description
Glatiramer acetate (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. If request is for brand Copaxone, member has experienced clinically significant adverse effects to generic glatiramer (including Glatopa) or has contraindication(s) to its excipients;
      5. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (see Appendix D);
      6. Dose does not exceed 20 mg per day (1 prefilled syringe per day) or 40 mg three times per week (3 prefilled syringes per week).

   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.
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;  
   3. Glatiramer is not prescribed concurrently with other disease modifying therapies for  
      MS (see Appendix D);  
   4. If request is for a dose increase, new dose does not exceed 20 mg per day (1 prefilled  
      syringe per day) or 40 mg three times per week (3 prefilled syringes per week).  
   Approval duration: 12 months  

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 the off-label use policy for the relevant line of business if diagnosis is NOT  
      specifically listed under section III (Diagnoses/Indications for which coverage is  
      NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance  
      marketplace, and CP.PMN.53 for Medicaid.  

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 policies –  
   CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and  
   CP.PMN.53 for Medicaid 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  
This table provides a listing of preferred alternative therapy recommended in the approval  
criteria. The drugs listed here may not be a formulary agent for all relevant lines of business  
and may require prior authorization.  

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>glatiramer acetate (Glatopa)</td>
<td>20 mg SC QD</td>
<td>20 mg/day</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only  
and generic (Brand name®) when the drug is available by both brand and generic.  

Appendix C: Contraindications/Boxed Warnings  
- Contraindication(s): known hypersensitivity to glatiramer acetate or mannitol  
- Boxed warning(s): none reported
Appendix D: General Information

- Disease-modifying therapies for MS are: glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebi®), 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>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapsing MS</td>
<td>20 mg SC QD or 40 mg SC TIW</td>
<td>20 mg/day or 40 mg TIW</td>
</tr>
</tbody>
</table>

VI. Product Availability

Single-dose, prefilled syringe: 20 mg/mL, 40 mg/mL

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>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1595</td>
<td>Injection, glatiramer acetate, 20 mg</td>
</tr>
</tbody>
</table>

**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy split from CP.PHAR.18 MS Treatments. Criteria: added max dosing, clarified monotherapy restriction, removed re-authorization requirement for documented adherence, added contraindications and reasons to discontinue, modified efficacy criteria from “No increase in neurologic dysfunction/disability as a result of relapses or progressive disease, including a change in diagnostic status from RRMS to SPMS” to “Responding positively to therapy”. Changed renewal approval duration to 12 months.</td>
<td>06.16</td>
<td>08.16</td>
</tr>
<tr>
<td>Added age requirement. Removed MRI requirement. Removed contraindication from initial and re-auth criteria.</td>
<td>07.17</td>
<td>08.17</td>
</tr>
<tr>
<td>2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for Centene Medicaid and HIM lines of business; HIM: MRI requirement removed; age added; modified requirement for “failure” of Glatopa 20 to “contraindications or adverse effects to excipients” as it is the same active ingredient as Copaxone 20; references reviewed and updated.</td>
<td>01.05.18</td>
<td>05.18</td>
</tr>
<tr>
<td>2Q 2019 annual review: no significant changes; modified re-direction to indicate that generic glatiramer is preferred before all strengths of Copaxone per SDC; added Commercial line of business since re-directions are now the same; updated Sections V and VI to reflect that Copaxone, Glatopa, and generic glatiramer are all available in the same dosage forms with the same dosing regimens; references reviewed and updated.</td>
<td>02.12.19</td>
<td>05.19</td>
</tr>
</tbody>
</table>

**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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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