Clinical Policy: Glatiramer Acetate (Copaxone, Glatopa)

Reference Number: CP.PHAR.252
Effective Date: 09.01.16
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

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 one of the following (a, b, or c):
   a. Clinically isolated syndrome;
   b. Relapsing-remitting MS;
   c. Secondary progressive 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. Documentation of baseline number of relapses per year and expanded disability status scale (EDSS) score;
7. 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:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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 meets one of the following (a or b):
   a. If member has received < 1 year of total treatment: Member is responding positively to therapy;
   b. If member has received ≥ 1 year of total treatment: Member meets one of the following (i, ii, iii, or iv):
      i. Member has not had an increase in the number of relapses per year compared to baseline;
      ii. Member has not had ≥ 2 new MRI-detected lesions;
      iii. Member has not had an increase in EDSS score from baseline;
      iv. Medical justification supports that 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:
Medicaid/HIM – first re-authorization: 6 months; **second and subsequent re-authorizations:** 12 months
Commercial – 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 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
EDSS: expanded disability status scale
FDA: Food and Drug Administration
MS: multiple sclerosis

Appendix B: Therapeutic Alternatives
Not applicable

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®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), diroximel fumarate (Vumerity™), monomethyl fumarate (Bafiertam™), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), ocrelizumab (Ocrevus™) , cladribine (Mavenclad®), siponimod (Mayzent®), and ozanimod (Zeposia®).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Relapsing MS	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW

VI. Product Availability

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

VII. References

1. Copaxone Prescribing Information. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; July 2019. Available at https://www.copaxone.com/. Accessed January 27, 2020.
2. Glatopa Prescribing Information. Princeton, NJ: Sandoz, Inc; July 2019. Available at https://www.glatopa.com/. Accessed January 27, 2020.
3. Glatiramer Acetate 20 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; August 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f38b5606-d2d7-44ec-912f-46882aa2fa7b. Accessed January 27, 2020.
4. Glatiramer Acetate 40 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; August 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=456a34c7-8511-4000-99a7-ad8f8de6d35e. Accessed January 27, 2020.
5. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58(2): 169-178.

6. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. Updated June 2019. Accessed January 27, 2020.
7. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018; 90(17): 777-788. Full guideline available at: https://www.aan.com/Guidelines/home/GetGuidelineContent/904.

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.

HCPCS Codes	Description
J1595	Injection, glatiramer acetate, 20 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.	06.16	08.16
Added age requirement. Removed MRI requirement. Removed contraindication from initial and re-auth criteria.	07.17	08.17
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.	01.05.18	05.18
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.	02.12.19	05.19
RT4: added coverage for CIS and SPMS per Copaxone's updated FDA labeling; references reviewed and updated.	08.02.19	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2020 annual review: modified Commercial approval durations to "6 months or to the member's renewal date, whichever is longer", consistent with standard approach for injectable agents; references reviewed and updated.	01.27.20	05.20
Added requirements for documentation of baseline relapses/EDSS and objective measures of positive response upon re-authorization; modified Medicaid/HIM continued approval duration to 6 months for the first re-authorization and 12 months for second/subsequent re-authorizations; references reviewed and updated.	05.27.20	08.20

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.