

Clinical Policy: Glatiramer Acetate (Copaxone, Glatopa)

Reference Number: HIM.PA.SP68

Effective Date: 03.01.21

Last Review Date: 05.23

Line of Business: HIM

[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 \geq 18 years;
4. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);
5. Documentation of both baseline number of relapses per year and expanded disability status scale (EDSS) score;
6. Dose does not exceed one of the following (a or b):
 - a. 20 mg per day (1 prefilled 20 mg syringe per day);
 - b. 40 mg three times per week (3 prefilled 40 mg syringes per week).

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Multiple Sclerosis (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 one of the following (a or b):
 - a. 20 mg per day (1 prefilled 20 mg syringe per day);
 - b. 40 mg three times per week (3 prefilled 40 mg syringes per week).

Approval duration:

If member has received < 1 year of total treatment – up to a total of 12 months of treatment

If member has received ≥ 1 year of total treatment – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

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 – HIM.PA.154 for health insurance marketplace 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[®], Tascenso ODT[™]), teriflunomide (Aubagio[®]), alemtuzumab (Lemtrada[®]), mitoxantrone (Novantrone[®]), natalizumab (Tysabri[®]), ocrelizumab (Ocrevus[®]), cladribine (Mavenclad[®]), siponimod (Mayzent[®]), ozanimod (Zeposia[®]), ponesimod (Ponvory[™]), ublituximab-xiiv (Briumvi[™]), and ofatumumab (Kesimpta[®]).

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 syringes: 20 mg/mL, 40 mg/mL

VII. References

1. Copaxone Prescribing Information. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; January 2023. Available at <https://www.copaxone.com/>. Accessed January 30, 2023.
2. Glatopa Prescribing Information. Princeton, NJ: Sandoz, Inc; April 2022. Available at <https://www.glatopa.com/>. Accessed January 30, 2023.
3. Glatiramer Acetate 20 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f38b5606-d2d7-44ec-912f-46882aa2fa7b>. Accessed January 30, 2023.
4. Glatiramer Acetate 40 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=456a34c7-8511-4000-99a7-ad8f8de6d35e>. Accessed January 30, 2023.
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. 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>. Reaffirmed on September 18, 2021.

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 created (split from CP.PHAR.252) per December SDC and prior clinical guidance, removed generic redirection.	12.15.20	02.21
2Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	02.08.21	05.21
2Q 2022 annual review: no significant changes; references reviewed and updated.	02.07.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.12.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2023 annual review: no significant changes; to be inclusive of members continuing therapy from a different benefit, revised continued approval duration to reference the duration of total treatment received rather than the number of re-authorizations; references reviewed and updated.	01.30.23	05.23

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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