Clinical Policy: Glatiramer (Copaxone, Glatopa)

Reference Number: ERX.SPA.119
Effective Date: 10.01.16
Last Review Date: 05.18 Revision Log

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 Envolve Pharmacy Solutions™ 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 Copaxone 20 mg is requested, member has contraindications or clinically significant adverse effects to the excipients in Glatopa 20 mg;
5. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
6. Dose does not exceed 20 mg/day (1 prefilled syringe/day) or 40 mg three times per week (3 prefilled syringes/week).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 C*);
4. If request is for a dose increase, new dose does not exceed 20 mg/day (1 prefilled syringe/day) or 40 mg three times per week (3 prefilled syringes/week).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glatiramer acetate (Glatopa)	20 mg SC QD	20 mg/day

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: General Information

- Disease-modifying therapies for MS are: daclizumab (Zinbryta®), glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (Ocrevus™).

V. Dosage and Administration

Drug Name	Dosing regimen	Maximum Dose
Glatiramer acetate (Copaxone)	20 mg SC QD or 40 mg SC TIW	20 mg/day or 40 mg TIW
Glatiramer acetate (Glatopa)	20 mg SC QD	20 mg/day

VI. Product Availability

Drug Name	Availability
Glatiramer acetate (Copaxone)	Single-dose, prefilled syringe: 20 mg/mL, 40 mg/mL
Glatiramer acetate (Glatopa)	Single-dose, prefilled syringe: 20 mg/mL

VII. References

1. Copaxone Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2016. Available at https://www.copaxone.com/. Accessed January 5, 2018.
2. Glatopa Prescribing Information. Princeton, NJ: Sandoz, Inc; April 2016. Available at https://www.glatopa.com/. Accessed January 5, 2018.
3. 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.
4. 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. March 2017. Accessed January 5, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from USS.SPMN.36 Multiple Sclerosis (MS) Treatments and converted to new template. Added Glatopa to policy. Added max dosing, clarified monotherapy restriction,	08.16	09.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
modified approval duration to 6 months for initial and 12 months for re-auth.		
Converted to new template. Added age requirement as safety and efficacy have not been established in pediatric populations. Removed MRI requirement as it is a non-specific diagnostic test (plus, specialist involvement in care is required). Added PPMS as a diagnosis not covered.	06.17	08.17
2Q 2018 annual review: No significant changes. References reviewed and updated.	01.05.18	05.18

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.