Clinical Policy Title:	glatiramer acetate
Policy Number:	RxA.146
Drug(s) Applied:	Copaxone®, Glatopa®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug name	Indication	Dosing Regimen	Maximum Dose
gatiramer acetate (Copaxone®, Glatopa®)	Relapsing MS	20 mg SC once daily or 40 mg SC three times per week	20 mg/day or 40 mg three times per week.

Dosage forms

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

Clinical Policy

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

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. Trial and failure of at least two (2) preferred agents: Aubagio, Avonex, Betaseron, Copaxone, Glatopa, Kesimpta, Ocrevus, Plegridy, or Zeposia.
5. 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;
6. Glatiramer is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix D*);

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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Sclerosis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
glatiramer acetate (Glatopa®)	20 mg SC once daily	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: 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 include:

- Infusion therapies
  - natalizumab (Tysabri®)
  - mitoxantrone
  - ocrelizumab (Ocrevus™)

  - alemtuzumab (Lemtrada®)
- Injectable therapies
  - glatiramer (Copaxone®, Glatopa®)
  - interferon beta-1a (Avonex®, Rebif®)
  - interferon beta-1b (Betaseron®, Extavia®)
  - peginterferon beta-1a (Plegridy®)
- Oral therapies
  - dimethyl fumarate (Tecfidera®)
  - monomethyl fumarate (Bafiertam™)
  - diroximel fumarate (Vumerity®)
  - teriflunomide (Aubagio®)
  - fingolimod (Gilenya™)
  - siponimod (Mayzent®)
  - ozanimod (Zeposia®)
  - cladribine (Mavenclad®)
  - dalfampridine (Ampyra®)

References

1. Copaxone Prescribing Information. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; July 2020. Available at https://www.copaxone.com/. Accessed May 27, 2021.
2. Glatopa Prescribing Information. Princeton, NJ: Sandoz, Inc; July 2020. Available at https://www.glatopa.com/. Accessed May 27, 2021.
3. Glatiramer Acetate 20 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; September 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f38b5606-d2d7-44ec-912f- 46882aa2fa7b. Accessed May 27, 2021.
4. Glatiramer Acetate 40 mg/mL Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; September 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=456a34c7-8511-4000-99a7- ad8f8de6d35e. Accessed May 27, 2021.
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. September 2019. Accessed May 27, 2021.
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. Accessed May 27, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020

Updated references Updated criteria II.A.1. to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria."	05/08/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Added Commercial & Medicaid approval duration in Initial and Continued approval criteria. 3. Continued therapy approval criteria II.A.1 was rephrased to "Member is currently receiving medication.." 4. References were reviewed and updated.	01/31/2021	03/09/2021
Policy was reviewed: 1. Clinical policy title was updated. 2. Removed 'updated' and 'Appendix D' from review/revision history 5/20/20. 3. Continued therapy approval criteria II.A.4 was added indicating ," Trial and failure of at…….or Zeposia." 4. References were reviewed and updated.	5/27/21	6/10/21