Clinical Policy: Glatiramer Acetate (Copaxone, Glatopa)

Reference Number: PA.CP.PHAR.252
Effective Date: 01/18
Last Review Date: -04/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for glatiramer acetate (Copaxone®, Glatopa®).

FDA Approved Indication(s)
Copaxone and Glatopa are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Copaxone and Glatopa are **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of a relapsing form of multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. If Copaxone 20 mg is requested, member is contraindicated or has clinically significant adverse effects to excipients in Glatopa 20 mg or the patient has been started and stabilized on treatment;
5. Member will not use other disease modifying therapies for MS concurrently;
6. Dose does not exceed 20 mg/mL per day (1 prefilled syringe/day) or 40 mg/mL three times per week (3 prefilled syringes/week).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background
Description/Mechanism of Action:
Glatiramer acetate consists of the acetate salts of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine. The mechanism(s) by which glatiramer acetate exerts its effects in patients with MS are not fully understood. However, glatiramer acetate is thought to act by modifying immune processes that are believed to be responsible for the pathogenesis of MS.

Formulations:
Copaxone is a clear, colorless to slightly yellow, sterile, nonpyrogenic solution supplied as:
- 20 mg per mL in a single-dose, prefilled syringe with a white plunger40 mg per mL in a single-dose, prefilled syringe with a blue plunger

Glatopa is a clear, colorless to slightly yellow, sterile, nonpyrogenic solution supplied as 20 mg per mL in a single-dose, prefilled syringe with a white plunger.

Appendices
Appendix A: Abbreviation Key
FDA: Food and Drug Administration
MS: multiple sclerosis

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	Approval Date
2Q 2018 annual review: no significant changes from previously approved policy; references reviewed and updated.		

References
1. Copaxone Prescribing Information. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; August 2016. Available at https://www.copaxone.com/. Accessed Accessed January 5, 2018.

2. Glatopa Prescribing Information. Princeton, NJ: Sandoz, Inc; April 2016. Available at https://www.glatopa.com/. Accessed 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. July 2016. Accessed Accessed January 5, 2018.