MEDICAL MUTUAL®

Drug Policy

Policy:	**201307**	**Initial Effective Date: 01/25/2013**
Code(s):	**HCPCS J1595**	**Annual Review Date: 03/21/2024**
SUBJECT:	**Glatiramer Acetate (Copaxone®, Glatopa™)**	**Last Revised Date: 03/21/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Copaxone, Glatopa and generic glatiramer acetate are indicated for the treatment of relapsing forms of **multiple sclerosis** (MS) to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults.

POLICY STATEMENT

This policy involves the use of glatiramer. Prior authorization is recommended for pharmacy and medical benefit coverage of glatiramer Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with glatiramer as well as the monitoring required for AEs and long-term efficacy, initial approval requires glatiramer be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of glatiramer is recommended in those who meet the following criteria:

The patient does NOT have a Non-Relapsing Form of Multiple Sclerosis (MS) [e.g., primary progressive MS]. The efficacy of Copaxone and Glatopa have not been established in patients with MS with non-relapsing forms of MS. AND;

The Patient Will NOT be Using Concurrently with Other Disease-Modifying Agents Used for Multiple Sclerosis. Note: Examples of disease-modifying agents used for multiple sclerosis include Avonex® (interferon beta 1a injection [intramuscular]), Betaseron®/Extavia® (interferon beta-1b injection), Rebif® (interferon beta-1a injection [subcutaneous]), Briumvi® (ublituximab), Copaxone®/Glatopa® (glatiramer acetate injection),

Plegridy® (peginterferon beta-1a injection), Aubagio® (teriflunomide tablets), Gilenya® (fingolimod tablets), Mavenclad® (cladribine tablets), Mayzent® (siponimod tablets), Tecfidera® (dimethyl fumarate delayed-release capsules), Bafiertam® (monomethyl fumarate delayed-release capsules), Vumerity® (diroximel fumarate delayed-release capsules), Zeposia® (ozanimod capsules), Ocrevus® (ocrelizumab injection for intravenous use), Tascensco ODT® (fingolimod), Tysabri® (natalizumab injection for intravenous infusion), Lemtrada® (alemtuzumab injection for intravenous use), and Kesimpta® (ofatumumab injection for subcutaneous use), Ponvory™ (ponesimod tablets). These agents are not indicated for use in combination. Additional data are required to determine if use of disease-modifying multiple sclerosis agents in combination is safe and provides added efficacy. AND;

1. **Relapsing Forms of Multiple Sclerosis (MS) in Patients Who Are Not Currently Receiving Glatiramer Acetate Injection (Copaxone, Glatopa).** Approve for patients who meet the following criteria (a, b, c, d and e):
   - **a)** Patient is 18 years of age or older; AND
   - **b)** The patient has a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
   - **c)** The agent is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; AND
   - **d)** If brand Copaxone or Glatopa is prescribed, the patient must meet the following criteria (a and b):
     a. The patient has previously failed or is intolerant to generic glatiramer acetate 20mg/mL or 40mg/mL; AND
     b. Brand Copaxone/Glatopa is being requested due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, has or would result in a significant allergy or serious adverse reaction [Documentation Required].

2. **Relapsing Forms of Multiple Sclerosis (MS) in Patients Who Are Currently Receiving Glatiramer Acetate Injection (Copaxone, Glatopa) or Who Have Received Glatiramer Acetate Injection (Copaxone, Glatopa) in the Past.** Approve if the patient meets the following criteria (a, b, c, d, e, and f):
   - **a)** Patient is 18 years of age or older; AND
   - **b)** The patient has a relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; AND
   - **c)** The agent is prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS; and
   - **d)** The patient has had beneficial response to the requested medication.
   - **e)** The patient has no contraindications to the requested medication.
   - **f)** If brand Copaxone or Glatopa is prescribed, the patient has previously failed or is intolerant to generic glatiramer acetate 20mg/mL or 40mg/mL; AND Brand Copaxone/Glatopa is being requested due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, has or would result in a significant allergy or serious adverse reaction [Documentation Required].

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Dosing in Multiple sclerosis (MS) (relapsing): *Dosing must meet the following: (medical benefit only)*

20 mg once daily or 40 mg 3 times per week administered at least 48 hours apart

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Duration of Therapy in MS is indefinite.

Labs/Diagnostics. None.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Copaxone® injection for subcutaneous use [prescribing information]. Overland Park, KS and North Wales, PA: Teva Neuroscience and Teva Pharmaceuticals; January 2014.
2. Centers for Medicare & Medicaid Services: Interferon beta. No national or local coverage determination found in the coverage database. January 25, 2013.
3. Coyle, P. K. (2008). Early treatment of multiple sclerosis to prevent neurologic damage. *Neurology, 71*(24 Suppl 3), S3-S7.
4. Fox, R. J., Bethoux, F., Goldman, M. D., & Cohen, J.A. (2006). Multiple sclerosis: advances in understanding, diagnosing, and treating the underlying disease. *Cleve Clin J Med, 73*(1), 91-102.
5. Frohman, E. M., Goodin, D. S., Calabresi, P. A., Corboy, J. R., Coyle, P. K., Filippi, M., Stuart, W. H. (2003). The utility of MRI in suspected MS: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology, 61*(5), 602-611.
6. Glatopa™ [prescribing information]. Princeton, NJ: Sandoz; March 2014.
7. Goodin, D. S., Frohman, E. M., Garmany, G. P. Jr, Halper, J., Likosky, W. H., Lublin, F. D., … Van den Noort, S. (2002). Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology, 58*(2), 169-178.
8. Hawker, K. (2011). Progressive multiple sclerosis: characteristics and management. *Neurol Clin, 29*(2), 423-434.
9. Kita, M. (2011). FDA-approved preventative therapies for MS: first-line agents. *Neurol Clin, 29*(2), 401-409.
10. Lublin FD, Cofield SS, Cutter GR, et al, for the CombiRx Investigators. Randomized study combining interferon and glatiramer acetate in multiple sclerosis. Ann Neurol. 2013;73:327-340.
11. Glatiramer acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 17 September 2018. Accessed on 14 January 2020.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Code J1595

Edits and Denials:

Prior approval: Prior approval is required for glatiramer **(HCPCS Code J1595)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J1595** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

Appeals: Appeals submitted to Medical Review will be approved by a nurse reviewer if documentation meets criteria outlined within the Corporate Medical Policy.

Appeals submitted to Medical Review will be forwarded to the Chief Medical Officer or specialty matched physician reviewer if documentation does not meet criteria outlined within the Corporate Medical Policy.

HCPCS Code(s):	
J1595	Injection, glatiramer acetate, 20 mg