Effective Date: 10/01/2013
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C10270-A

Copaxone/Glatopa (glatiramer acetate)

PRODUCTS AFFECTED

Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), glatiramer acetate

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Multiple Sclerosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. RELAPSING FORMS OF MULTIPLE SCLEROSIS:
1. Documentation of a definitive diagnosis of a relapsing form of multiple sclerosis as defined by the McDonald criteria (see Appendix), including: Relapsing-remitting multiple sclerosis [RRMS], secondary-progressive multiple sclerosis [SPMS] with relapses, and progressive-relapsing multiple sclerosis [PRMS] or First clinical episode with MRI features consistent with multiple sclerosis
AND
2. Member is not currently being treated with a disease-modifying agent (DMA) other than the

requested agent
AND

3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to glatiramer include: Known hypersensitivity to glatiramer acetate or mannitol]
AND
4. IF REQUEST IS FOR A NON-FORMULARY PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. RELAPSING FORM OF MULTIPLE SCLEROSIS:

1. (a) Documentation of a stable number or decrease in acute attacks (relapses) within the last 6months
OR
(b) Documentation of lack of progression or sustained disability
OR
(c) Recent (within last 6 months) MRI shows lack of development of new asymptomatic lesions
AND
2. Documentation member has been adherent to therapy at least 85% of the time as verified by Prescriber and member's medication fill history
AND
3. Member has not experienced any intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a neurologist or a MS specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age or older

QUANTITY:

40mg/ml solution: maximum 40mg SC three times per week
20mg/ml solution: 20mg SC once daily
Glatiramer 20 mg/mL and 40 mg/mL solutions for injection are NOT interchangeable

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Subcutaneous

DRUG CLASS:
Multiple Sclerosis Agents

FDA-APPROVED USES:
Glatiramer is 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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Summary of 2017 McDonald Criteria for the Diagnosis of MS

CLINICAL PRESENTATION	ADDITIONAL CRITERIA TO MAKE MS DIAGNOSIS
…in a person who has experienced a typical attack/CIS at onset	
• 2 or more attacks and clinical evidence of 2 or more lesions; OR • 2 or more attacks and clinical evidence of 1 lesion with clear historical evidence of prior attack involving lesion in different location	None. DIS and DIT have been met.
• 2 or more attacks and clinical evidence of 1 lesion	DIS shown by <u>one</u> of these criteria: - additional clinical attack implicating different CNS site - 1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord
• 1 attack and clinical evidence of 2 or more lesions	DIT shown by <u>one</u> of these criteria: - Additional clinical attack - Simultaneous presence of both enhancing and non-enhancing MS-typical MRI lesions, or new T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan) - CSF oligoclonal bands
• 1 attack and clinical evidence of 1 lesion	DIS shown by <u>one</u> of these criteria: - Additional attack implicating different CNS site - 1 or more MS-typical T2 lesions in 2 or more areas of CNS: periventricular, cortical, juxtacortical, infratentorial or spinal cord **AND** DIT shown by <u>one</u> of these criteria: - Additional clinical attack - 2 or more T2 spinal cord lesions - CSF oligoclonal bands
…in a person who has steady progression of disease since onset	
1 year of disease progression (retrospective or prospective)	DIS shown by <u>one</u> of these criteria: - 1 or more MS-typical T2 lesions (periventricular, cortical, juxtacortical, infratentorial) - 2 or more T2 spinal cord lesions - CSF oligoclonal bands

DIT = Dissemination in time
DIS = Dissemination in space
CNS = central nervous system
T2 lesion = hyperintense lesion on T2-weighted MRI
CSF = cerebrospinal fluid

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Copaxone and Glatopa are administered by subcutaneous (SC) injection and are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). The approved doses of Copaxone are 20 mg SC once daily (QD) and 40 mg SC three times per week. The approved dose of Glatopa is20 mg QD. The Glatopa 20 mg per mL dose is not interchangeable with the glatiramer acetate 40 mg per mL dose. Various trials have established the effectiveness in patients with MS (e.g., decrease in the annualized relapse rate). MS is a chronic demyelinating, disabling disease of the central nervous system (CNS) characterized by recurrent and progressive neurologic dysfunction. MS lesions occur in many different parts of the CNS and the symptoms and clinical course of the disease are highly variable

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of glatiramer acetate products are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. The following are also contraindicated for the use of glatiramer acetate: Hypersensitivity to glatiramer acetate, mannitol, or any ingredient in the formulation, impaired renal function, Under 18 years of age or elderly over 65 years of age or chronic progressive multiple sclerosis.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Copaxone SOSY 20MG/ML
Copaxone SOSY 40MG/ML
Glatiramer Acetate SOSY 20MG/ML
Glatiramer Acetate SOSY 40MG/ML
Glatopa SOSY 20MG/ML
Glatopa SOSY 40MG/ML

REFERENCES

1. Copaxone (glatiramer acetate) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals; January 2022.
2. Glatopa (glatiramer acetate) [prescribing information]. Princeton, NJ: Sandoz Inc; July 2020.
3. Thompson, A., Banwell, B., et al. (2018). Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. The Lancet Neurology, 17(2), pp.162-173
4. McDonald WI, Compston A, Edan G, et al. Recommended diagnostic criteria for multiple sclerosis: guidelines from the International Panel on the diagnosis of multiple sclerosis. Ann Neurol 2001; 50:121.
5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: disease-modifying therapies

for adults with multiple sclerosis: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. https://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/WNL/A/WNL_2018_04 19_RAEGRANT_NEUROLOGY2017835181R1_SDC3.pdf. Published April 2018. Accessed March 20, 2019.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Prescriber Requirements Coding/Billing Information Available Dosage Forms	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file