

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Glatiramer acetate (Copaxone, Glatopa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Comments
Glatopa (glatiramer acetate) 20mg/mL Glatiramer 20mg/mL	Preferred
Brand Copaxone 20mg/mL Brand and generic Copaxone (glatiramer acetate) 40mg/mL Glatopa (glatiramer acetate) 40mg/ml	Non Preferred

APPROVAL CRITERIA

Requests for Glatopa (glatiramer acetate) 20mg/mL or glatiramer 20mg/mL may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS); **OR**
- II. Individual has experienced a first clinical episode and has MRI features consistent with multiple sclerosis (DrugPoints B IIa).

Requests for Brand Copaxone 20mg/mL may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsing multiple sclerosis(RMS); **OR**
- II. Individual has experienced a first clinical episode and has MRI features consistent with multiple sclerosis(DrugPoints B IIa);

AND

- III. The individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic agent (Glatopa 20mg or glatiramer 20mg);

AND

1. Generics have inadequate response;
- OR**
2. Generics caused adverse outcome;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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OR

- IV. The individual has a genuine allergic reaction to an inactive ingredient in generic agents(s). Allergic reaction(s) must be clearly documented in the patient's medical record.

Requests for Brand or generic Copaxone (glatiramer acetate) 40 mg/mL, or Glatopa (glatiramer acetate) 40mg/mL may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsing multiple sclerosis (RMS); **OR**
- II. Individual has experienced a first clinical episode and has MRI features consistent with multiple sclerosis (DrugPoints B IIa);

AND

- III. Individual requires assistance by a caregiver to administer injections; **AND**
- IV. Caregiver is unable to administer a 20 mg/mL injection on a daily basis.

Copaxone (glatiramer acetate) or Glatopa (glatiramer acetate) may **not** be approved for the following:

- I. Individual is using to treat primary progressive multiple sclerosis (PPMS); **OR**
- II. Individual is using to treat secondary progressive multiple sclerosis (SPMS); **OR**
- III. Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy or Betaseron).

Note: GI upset or irritation is not generally considered an allergy or failed treatment. Patients should be referred to their physician or pharmacist for advice on dose adjustment, and/or other options to reduce GI upset/irritation. Common documented side effects attributed to the drug (i.e. headache, nausea, blurred vision, fatigue, muscle aches) are not considered an allergy and would be expected to occur at the same level in both the generic and brand agent.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 28, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Olek MJ, Gonzalez-Scarano F, Dashe JF. Clinical presentation, course and prognosis of multiple sclerosis in adults. Last updated June 28, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 29, 2018.
6. 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: 777-788. Available from <https://www.aan.com/Guidelines/home/GuidelineDetail/898>. Accessed: June 28, 2018.

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