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

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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

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

A. Treatment of MS for individuals with relapsing-remitting MS (RRMS), including those who have experienced a first clinical episode and have MRI features consistent with MS.

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

A. Treatment of MS for individuals with relapsing-remitting MS (RRMS), including those who have experienced a first clinical episode and have MRI features consistent with MS; **AND**

B. 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**

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

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2. Generics caused adverse outcome;

OR

C. 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.

III. 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:

A. Treatment of MS for individuals with relapsing-remitting MS (RRMS), including those who have experienced a first clinical episode and have MRI features consistent with MS; **AND**

B. Individual requires assistance by a caregiver to administer injections; **AND**

C. Caregiver is unable to administer a 20 mg/mL injection on a daily basis.

Copaxone (glatiramer acetate) or Glatopa (glatiramer acetate) for the treatment of MS **may not be approved** for individuals with **any** of the following:

I. Primary progressive MS (PPMS); OR
II. Secondary progressive MS (SPMS); OR
III. In combination with **any** IFN-B agent or in combination with natalizumab for all conditions.

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.

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

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.