VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

COPAXONE® (Glatiramer acetate)

Effective Date: 7/28/05
Date Developed: 7/28/05 by C. Wilhelmy MD
Last Approval Date: 7/26/16, 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

Copaxone is a Biological. Glatiramer is a mixture of random polymers of four amino acids; L-alanine, L-glutamic acid, L-lysine and L-tyrosine. The resulting mixture is antigenically similar to myelin basic protein, which is an important component of the myelin sheath of nerves. Glatiramer is thought to suppress T-lymphocytes specific for a myelin antigen, it is also proposed that glatiramer interferes with the antigen-presenting function of certain immune cells opposing pathogenic T-cell function.

Pre-Authorization Criteria:
Copaxone is used for the treatment of relapsing remitting type multiple sclerosis. Studies indicate that it reduces the frequency of attacks and the severity of disability and appears to be most effective for patient with minimal disability.

FDA-approved Indications: treatment of relapsing forms of multiple sclerosis
Note: Should be prescribed by, or after consultation with, a neurologist or an MS specialist

EXCLUSIONS

Coverage of glatiramer acetate is *not* recommended in the following circumstances:

1. Concurrent use of glatiramer acetate with interferon beta-1a (Avonex®, Rebif®) or interferon beta-1b (Betaseron®, Extavia®) is not recommended. Only limited data documents the use of these therapies in combination.[9-10,14] Additional studies are needed to determine if combination therapy is effective and safe. Trials with combination therapy among these immunomodulators are currently underway.

2. Patient is receiving natalizumab (Tysabri®). Natalizumab is indicated as monotherapy for MS patients with relapsing forms of the disease.[11] Only limited (phase 2) data have assessed the effects of combination therapy with natalizumab and glariramer.[17]

3. Patient is concurrently receiving fingolimod. Use of glatiramer acetate with fingolimod has not been studied or established.

4. Coverage is not recommended for circumstances *not* listed in the *Recommended Authorization Criteria*. Criteria will be updated as new published data are available.

VENTURA COUNTY
HEALTH CARE PLAN

DOSING: ADULTS - Multiple sclerosis (relapsing-remitting): SubQ: 20 mg daily

DOSING: ELDERLY - Refer to adult dosing.

DOSAGE FORMS - Injection, solution [preservative free]: 20 mg/mL (1 mL) [prefilled syringe; contains mannitol; packaged with alcohol pads]

ADMINISTRATION - For SubQ administration in the arms, abdomen, hips or thighs. Bring to room temperature prior to use.

CONTRAINDICATIONS - Previous hypersensitivity to any component of the copolymer formulation, glatiramer acetate, or mannitol

PREGNANCY RISK FACTOR - B

PREGNANCY IMPLICATIONS - There are no adequate and well-controlled studies in pregnant women. Use in pregnancy only if clearly necessary.

LACTATION - Excretion in breast milk unknown/use caution

PATIENT EDUCATION - It is essential to provide the patient with proper handling and reconstitution instruction, since they will most likely have to self-administer the drug for an extended period. Patients using prefilled glass syringe should use only the autoject® 2 for glass syringe device (not the original Copaxone® autoject).

REFERENCE

1. Copaxone® [package insert]. Kansas City, MO: Teva Neuroscience, Inc.; February 2009. Select Drug Information from Lexi-Comp Online <http://www.lexi.com/web/partpage.jsp?id=100002>™ Copyright (1978 to present) Lexi-Comp, Inc.

Revision History:

Date Approved by P&T Committee: 7/28/05
Date Reviewed/Updated: 6/11/08 by W. Rosario, M.D
Date Approved by P&T Committee: 7/28/08
Date Reviewed/Updated: 10/04/11 by A. Reeves MD
Date Reviewed/No Updates: 4/2/12; 1/16/13 by A. Reeves
Date Approved by P&T Committee: 10/25/11; 4/24/12; 1/29/13
Date Reviewed/No Updates: 1/28/14 by C. Sanders MD

VENTURA COUNTY
HEALTH CARE PLAN

Date Approved by P&T Committee: 1/28/14
Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 01.27.15
Date Reviewed/Updated: 2/17/15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/Updated: 7/26/16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 7/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI