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 patients 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®, Rebi®, or interferon beta-1b (Betaseron®, Extavia®) is not recommended. Only limited data documents the use of these therapies in combination. 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. Only limited (phase 2) data have assessed the effects of combination therapy with natalizumab and glatiramer.

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.
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

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