MODEL APPEAL LETTER – COPAXONE 40MG DRAFT

Today’s Date

PLAN NAME

PLAN ADDRESS

PLAN ADDRESS

Re: PATIENT’S NAME, INSURANCE ID#, CLAIM # (if applicable)

Dear ________:

This is to support an appeal of your denial of Copaxone (glatiramer acetate) 40 mg for my patient (name), who was diagnosed with relapsing remitting multiple sclerosis in (month/year)___.

Copaxone 40 mg is the preferred therapy for this patient because:

If first line therapy:

I believe it offers the greatest likelihood for benefit as first line therapy for this patient (provide reason(s) here)

If patient could not tolerate or benefit from interferon therapy:

he/she experienced intolerable side effects on interferon therapy (describe).

If the patient has been on Copaxone 20 mg:

Although he/she has previously benefited from daily subcutaneous injections of the lower, 20 mg dose of Copaxone, I recommend switching her/him to higher dosage with less frequent injections (because she/he has a documented history or injection site reactions/other difficulties with self-injection; a history or poor adherence, etc.)

Copaxone received FDA approval for marketing in 1996 for the treatment of patients with relapsing-remitting forms of multiple sclerosis. Glatiramer acetate is not interferon therapy. The agency’s approval was based on review of data from a phase III multicenter, double-blind placebo-controlled trial by the
Copolymer 1 Multiple Sclerosis Study Group.\textsuperscript{1} A reduction in relapse rate and neurologic improvement were demonstrated again in a later study of Copaxone concluded in 1998.\textsuperscript{2}

In January, 2014, the FDA approved a new 40 mg/mL dose of this medication, injected three times per week, which is double the standard 20 mg/mL dose that is injected daily. The approval was based on benefits and safety demonstrated in a one-year phase III trial comparing the higher, less-frequent dose of the medication with placebo.\textsuperscript{3}

Finally, I include for your information the National Multiple Sclerosis Society’s Disease Management Consensus Statement. Note the statement “all of these FDA-approved agents should be included in formularies and covered by third party payers so that physicians and patients can determine the most appropriate agent on an individual basis”.

I have reviewed my original recommendation for Copaxone and continue to believe it offers the greatest likelihood of benefit in this case. I may be reached at (XXX-XXXX) should you require additional information on this patient. Otherwise, I look forward to your response as soon as possible.

Sincerely,


Abstract #1: Copaxone (glatiramer acetate) 40 mg.


Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: results of a phase III multicenter, double-blind placebo-controlled trial.


Abstract

We studied copolymer 1 (Copaxone) in a multicenter (11-university) phase III trial of patients with relapsing-remitting multiple sclerosis (MS). Two hundred fifty-one patients were randomized to receive copolymer 1 (n = 125) or placebo (n = 126) at a dosage of 20 mg by daily subcutaneous injection for 2 years. The primary end point was a difference in the MS relapse rate. The final 2-year relapse rate was 1.19 +/- 0.13 for patients receiving copolymer 1 and 1.68 +/- 0.13 for those receiving placebo, a 29% reduction in favor of copolymer 1 (p = 0.007) (annualized rates = 0.59 for copolymer 1 and 0.84 for placebo). Trends in the proportion of relapse-free patients and median time to first relapse favored copolymer 1. Disability was measured by the Expanded Disability Status Scale (EDSS), using a two-neurologist (examining and treating) protocol. When the proportion of patients who improved, were unchanged, or worsened by > or = 1 EDSS step from baseline to conclusion (2 years) was evaluated, significantly more patients receiving copolymer 1 were found to have improved and more receiving placebo worsened (p = 0.037). Patient withdrawals were 19 (15.2%) from the copolymer 1 group and 17 (13.5%) from the placebo group at approximately the same intervals. The treatment was well tolerated. The most common adverse experience was an injection-site reaction. Rarely, a transient self-limited systemic reaction followed the injection in 15.2% of those receiving copolymer 1 and 3.2% of those receiving placebo.
Abstract #2: Copaxone (glatiramer acetate) 40 mg.
Neurology. 1998 Mar;50(3):701-8

Extended use of glatiramer acetate (Copaxone) is well tolerated and maintains its clinical effect on multiple sclerosis relapse rate and degree of disability.


Abstract

When 251 relapsing-remitting patients with multiple sclerosis were randomized to receive daily subcutaneous injections of glatiramer acetate, previously called copolymer 1 (Copaxone; n = 125) or placebo (n = 126) for 24 months, there were no laboratory abnormalities associated with glatiramer acetate treatment and it was well tolerated with few side effects. Patients receiving glatiramer acetate had significantly fewer relapses and were more likely to be neurologically improved, whereas those receiving placebo were more likely to worsen. This study was extended for 1 to 11 months (mean of 5.2 months for the glatiramer acetate group and 5.9 months for the placebo group). The blinding and study conditions used during the core 24-month study were unchanged throughout the extension. The results of this extension study confirm the excellent tolerance and safety profile of glatiramer acetate for injection. The clinical benefit of glatiramer acetate for both the relapse rate and for neurologic disability was sustained at the end of the extension trial.
Abstract #3: Copaxone (glatiramer acetate) 40 mg.


Three times weekly glatiramer acetate in relapsing-remitting multiple sclerosis


Abstract

OBJECTIVE:

To assess the efficacy and safety of glatiramer acetate (GA) 40mg administered 3× weekly (tiw) compared with placebo in patients with relapsing-remitting multiple sclerosis (RRMS).

METHODS:

This randomized, double-blind study was conducted in 142 sites in 17 countries. Patients with RRMS with at least 1 documented relapse in the 12 months before screening, or at least 2 documented relapses in the 24 months before screening, and an Expanded Disability Status Scale score ≤ 5.5, were randomized 2:1 to receive either subcutaneous (sc) GA 40mg tiw (1ml) or placebo for 12 months.

RESULTS:

Of 1,524 patients screened, 1,404 were randomized to receive GA 40mg sc tiw (n = 943) or placebo (n = 461). Ninety-three percent and 91% of patients in the placebo and GA groups, respectively, completed the 12-month study. GA 40mg tiw was associated with a 34.0% reduction in risk of confirmed relapses compared with placebo (mean annualized relapse rate = 0.331 vs 0.505; p < 0.0001). Patients who received GA 40mg tiw experienced highly significant reduction (p < 0.0001) in the cumulative number of gadolinium-enhancing T1 (44.8%) and new or newly enlarging T2 lesions (34.7%) at months 6 and 12. GA 40mg tiw was safe and well tolerated. The most common adverse events in the GA group were injection site reactions (35.5% with GA vs 5.0% with placebo).

INTERPRETATION:

GA 40mg sc tiw is a safe and effective regimen for the treatment of RRMS, providing the convenience of fewer sc injections per week.