

FORMULARY UPDATE - SIMVASTATIN

DATE: June 30, 2011

Dear Phoenix Health Plan (PHP) Providers:

Effective August 1, 2011, Simvastatin 80mg will be considered non-formulary for PHP members; current users will be grandfathered.

FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (Simvastatin) to reduce the risk of muscle injury.

[06-08-2011] The U.S. Food and Drug Administration (FDA) is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication, Simvastatin (80 mg) because of increased risk of muscle damage. Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug. In addition to these new limitations, FDA is requiring changes to the Simvastatin label to add new contraindications (should not be used with certain medications) and dose limitations for using Simvastatin with certain medicines.

Patients taking Simvastatin 80 mg daily have an increased risk of myopathy compared to patients taking lower doses of this drug or other drugs in the same class. This risk appears to be higher during the first year of treatment, is often the result of interactions with certain medicines, and is frequently associated with a genetic predisposition toward Simvastatin-related myopathy. Patients with myopathy generally have muscle pain, tenderness or weakness, and an elevation of a muscle enzyme in the blood (creatinine kinase, or CK). The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure which can be fatal. Rhabdomyolysis is rare; hospitalized rhabdomyolysis occurs in 4.9 people out of every 100,000 people exposed to Simvastatin for one full year (the average incidence for hospitalized rhabdomyolysis for Atorvastatin, Pravastatin, or Simvastatin is 4.4 people out of every 100,000 people).¹

FDA recommends that healthcare professionals should:

- Maintain patients on Simvastatin 80 mg only if they have been taking this dose for 12 or more months without evidence of muscle toxicity.
- Not start new patients on Simvastatin 80 mg.
- Place patients who do not meet their LDL cholesterol (LDL-C) goal on Simvastatin 40 mg on alternative LDL-C lowering treatment(s) that provides greater LDL-C lowering.
- Follow the recommendations in the Simvastatin-containing medicines labels regarding drugs that may increase the risk for muscle injury when used with Simvastatin.
- Switch patients who need to be initiated on a drug that interacts with Simvastatin to an alternative statin with less potential for the drug-drug interaction.
- Report adverse events involving Simvastatin-containing medicines to the FDA MedWatch program.

For additional information, please contact a PHP Pharmacy Representative at 602-824-3700.

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