Quality Tip: Simvastatin Dosing

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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.

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. New label instructions include:

Contraindicated with:

• Itraconazole • Ketoconazole • Posaconazole (New) • Erythromycin • Clarithromycin	• Telithromycin • HIV protease inhibitors • Nefazodone • Gemfibrozil • Cyclosporine • Danazol

Do not exceed 10mg Simvastatin with:

- Amiodarone
- Verapamil
- Diltiazem

(Note: These drugs are contraindicated with Simcor as Simcor is only available with 20 mg or 40 mg of Simvastatin.)

Do not exceed 20mg Simvastatin with:

- Amlodipine (New)
- Ranolazine (New)

Providers with patients meeting criteria will receive a listing of patients who are taking Simvastatin 80mg, who are taking Simvastatin with a contraindicated medication, or a medication with a restricted dose. These lists are for your use as you have ongoing clinical visits with your patients to make medication adjustments as needed for their safe care.