

**Regence BlueCross BlueShield of Oregon · Regence BlueShield  
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho  
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**Medication Policy Manual**

**Policy No:** dru138

**Topic:** Crestor<sup>®</sup>, rosuvastatin

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**Revised Date:** April 7, 2009

**Next Review Date:** March 2010

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Rosuvastatin (Crestor<sup>®</sup>) is an oral medication used to treat high cholesterol.

## Policy/Criteria

- I.** Most contracts require prior authorization approval of rosuvastatin prior to coverage. Rosuvastatin may be considered medically necessary for treatment of dyslipidemias when either criterion A or B below is met:

**A.** Greater than a 40% reduction in LDL-C is needed.

**OR**

- B.** At least one of the following statin products has been ineffective at achieving the LDL-C target after at least two months of treatment or was not tolerated:

1. simvastatin (Zocor<sup>®</sup>)

**OR**

2. pravastatin (Pravachol<sup>®</sup>)

**OR**

3. lovastatin (Mevacor<sup>®</sup>)

## II. Administration and Authorization Period

**A.** Regence considers rosuvastatin to be a self-administered medication.

**B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

## Position Statement

- At equipotent dosing, there are no differences in efficacy (measured by LDL-C lowering) between the high potency statin products. <sup>[5-12, 44-48]</sup>
- Additionally, there is no evidence that demonstrates significant differences in safety profiles or discontinuation rates among the available high potency statin products. <sup>[5-12]</sup>
- At initial starting doses, several statin products may achieve up to 41% LDL-C reduction (see Appendices 1 and 2).
- Among the statin products, rosuvastatin (Crestor<sup>®</sup>) and simvastatin provide the highest LDL-C lowering at the lowest cost when greater than 41% LDL-C lowering is needed. Relative to other high potency statin products, atorvastatin (Lipitor<sup>®</sup>) and simvastatin/ezetimibe (Vytorin<sup>®</sup>) do not provide the best value in LDL-C reduction (see Appendix 1).

- For patients who need moderate LDL-C lowering (i.e., 40% or less), generic simvastatin, pravastatin and lovastatin provide the best values (see Appendix 1).

### *Overall Efficacy*

- Several outcomes trials have demonstrated that statins reduce the risks of cardiovascular and cerebrovascular events. <sup>[13-18, 29-39, 42-43, 49-55]</sup>
  - \* Rosuvastatin reduced rates of heart attack, stroke, death and the need for revascularization in patients with elevated C-reactive protein levels (a marker of inflammation) but normal LDL-C levels (less than 130 mg/dL). <sup>[54]</sup>
  - \* A reduction of LDL-C by 50% and C-reactive protein by 37% was also noted. This study suggested that statin therapy may benefit patients with otherwise normal LDL-C but with elevated indicators of inflammation. Further study is needed to confirm the usefulness of this approach. <sup>[54]</sup>
- Reductions in cardiovascular and cerebrovascular risk is not unique to any specific statin and have been demonstrated with many of the available statins in a variety of patient populations, such as in patients with coronary heart disease, high cholesterol levels, normal cholesterol levels, hypertension, diabetes and previous stroke. <sup>[13-18, 29-39, 42-43, 49-55]</sup>
- Several primary or secondary prevention trials with simvastatin, pravastatin, lovastatin, and atorvastatin consistently demonstrate that reductions in cardiovascular events correlate with LDL-C reduction. <sup>[13-19, 29-39, 42-43, 49-55]</sup>
- The 2004 update to the NCEP ATP III Guidelines recommends aggressive LDL-C lowering in individuals depending on their risk for heart attack or stroke. <sup>[40-41]</sup>
- Comparative clinical trials have demonstrated that more individuals may achieve NCEP ATP III LDL-C goals with high potency statins (rosuvastatin, atorvastatin, and ezetimibe/simvastatin). <sup>[1-4]</sup>
- The combination of simvastatin and ezetimibe provides potent LDL-C lowering, without significant increases in adverse events relative to other individual statins. <sup>[7,27, 44, 46]</sup>
- Other statins, including simvastatin, pravastatin, and lovastatin have moderate LDL-lowering capacity of up to 41% LDL-C reduction. <sup>[9-11]</sup>

### *Safety*

- All marketed statins have safety records that are consistent for the statin class. <sup>[6-11, 20-24]</sup>
- Rhabdomyolysis is a rare side-effect of all statins (0.1%). <sup>[6-11, 23-24]</sup>

- \* Myopathy (muscle weakness) and rhabdomyolysis are commonly linked to additional factors that may increase statin serum levels, such as impaired hepatic and renal function, hypothyroidism, or concomitant use of certain medications, such as fibrates or azole antifungals.
- \* Based on clinical trial safety data and world-wide post-marketing adverse reports, the incidence of myopathy and rhabdomyolysis among available statins is similar.
- Dipstick positive proteinuria (greater than 2+) has been reported in a small number of patients with all statins; however, the clinical relevance of this has not been established. [6,25]
- Hepatotoxicity occurs rarely (less than 1% ) with statins. [6-11]
- \* Statins are contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases. [5-12]
- \* At equipotent doses, there are no differences in rates of clinically relevant elevations in LFTs among statins.
- \* Prescribing information indicates initial and routine liver function tests (LFTs) are necessary with all statins.
- Risks for certain drug-drug interactions are inherent with all statins (see Appendix 3).
- Dosage adjustment is not needed for any statin in mild to moderate renal dysfunction. Dosage adjustment may be needed in severe renal dysfunction (Creatinine Clearance [ClCr] < 30 ml/min). [5-12] (See appendix 4.)

### *Half Tablet Program*

- Simvastatin, pravastatin, lovastatin and rosuvastatin are eligible medications under the RegenceRx Half-Tablet Program.
- \* As part of this program, when higher strength tablets of these statins can be split and used for the prescribed dose, the member pays only one copayment for a two month supply of medication.
- \* More information about the RegenceRx Half-Tablet Program can be found at [www.RegenceRx.com](http://www.RegenceRx.com).

## Appendix 1: Statin Comparison Chart

% LDL- C Lowering (5-12)	Formulary	Statin Name and Strengths	Cost Per Month*
Less than 35%	√	<b>simvastatin</b> (Zocor) 5 mg, 10mg	\$5 - \$7
	√	<b>lovastatin</b> (Mevacor) 10 mg, 20 mg, 40 mg	\$8- \$18
	√	<b>pravastatin</b> (Pravachol) 10 mg, 20 mg, 40 mg	\$8 - \$10
35% - 40%	√	<b>simvastatin</b> (Zocor) 20 mg, 40 mg	\$7
		Lipitor 10 mg	\$81
		Lescol XL <sup>®</sup> 80mg	\$95
41% - 52%	√	<b>simvastatin</b> (Zocor) 40 mg, 80 mg	\$6-\$7
		Vytorin 10 mg/10 mg, 10 mg/20 mg	\$95 - \$97
	√	Crestor 5 mg, 10 mg	\$99 - \$100
		Lipitor 20 mg, 40 mg	\$104 - \$107
Greater than 52%	√	Crestor 20 mg, 40 mg	\$93 - \$96
		Vytorin 10 mg/40 mg, 10 mg/80 mg	\$95 - \$97
		Lipitor 80 mg	\$101

\* Approximate cost estimates based on a 30-day supply as of 12/2008. Actual prices may vary depending on the pharmacy and the amount or strength of the medication dispensed.

## Appendix 2: Starting and Maximum Daily Doses for Formulary/Preferred Statins <sup>[5-12]</sup>

	<b>lovastatin</b> (Mevacor)	<b>simvastatin</b> (Zocor)	<b>pravastatin</b> (Pravachol)	<b>Crestor</b>	<b>Vytorin</b>
<b>Initial Dose</b>	20 mg	10 mg – 40 mg	10 mg – 40 mg	5 mg – 10 mg	10 mg/ 20 mg
<b>Maximum Dose</b>	80 mg	80 mg	80 mg	40 mg	10 mg/ 80 mg

### Appendix 3: Drug Interactions with Statin Products <sup>[5-12, 26]</sup>

Concomitant drug	Crestor	Lipitor	Lescol	lovastatin (Mevacor)	pravastatin (Pravachol)	simvastatin (Zocor)	Vytorin
amiodarone - may ↑ statin level	--	--	--	X	--	X	X
antacids - may ↓ statin level	X	X	--	--	--	--	--
azoles (i.e., itraconazole, ketoconazole, fluconazole, etc.) - may ↑ statin level	--	X	X	X	--	X	X
bile acid sequestrants – (i.e., colestipol, cholestyramine) - may ↓ statin plasma level	--	X*	X*	X*	X*	--	--
cimetidine, ranitidine, omeprazole - may ↑ statin level	--	--	X	--	--	--	--
cyclosporine - may ↑ statin level	X	--	--	--	--	--	--
diclofenac - may ↑ diclofenac levels	--	--	X	--	--	--	--
digoxin - may ↑ digoxin levels	--	X	X	--	--	X	X
fibrate derivatives (i.e., gemfibrozil) - may ↑ statin level	X	X	X	X	X	X	X
glyburide - may ↑ statin conc; may ↑ glyburide level	--	--	X	--	--	--	--
grapefruit juice (> 1 quart/day) - may ↑ statin level	--	X	--	X	--	X	X
isradipine - may ↓ statin level	--	--	--	X	--	--	--
macrolides (i.e., erythromycin, clarithromycin) - may ↑ statin level	--	X	--	X	--	X	X
nefazodone - may ↑ statin level	--	X	--	X	--	X	X
niacin - may ↑ statin level	X	X	X	X	X	X	X
oral contraceptives - may ↑ estrogen and progestin level	X	X	--	--	--	--	--
phenytoin - may ↑ statin level; may ↑ phenytoin level	--	--	X	--	--	--	--
protease inhibitors (ritonavir, saquinavir) - may ↓ statin plasma level	--	--	--	--	X	--	--
protease inhibitors (nelfinavir, ritonavir) - may ↑ statin plasma level	--	X	--	X	--	X	X
rifampin - may ↓ statin plasma level	--	--	X	--	--	X	X
verapamil - may ↓ statin plasma level	--	X	--	X	--	X	X
warfarin - may ↑ INR	X	--	X	X	--	X	X

\*Dosing with a statin should occur at least 1 hour before or at least 4 hours after administration of a bile acid sequestrant.

Appendix 4: Dosage Adjustments in Patients with Renal Dysfunction <sup>[5-12]</sup>							
	Crestor	Lipitor	Lescol	lovastatin (Mevacor)	pravastatin (Pravachol)	simvastatin (Zocor)	Vytorin
<b>Renal Dysfunction</b>	For CrCl* <30, ml/min start at 5 mg/d & do not exceed 10 mg/d	No adjustment	No adjustment (not studied in severe renal impairment)	For CrCl <30, ml/min use doses > 20 mg cautiously	Closely monitor (lack of good data in renal dysfunction)	Adjustment not needed, in mild-moderate, but caution in severe renal dysfunction (CrCl < 30 ml/min)	Adjustment not needed, in mild-moderate, but caution in severe renal dysfunction (CrCl < 30 ml/min)
<b>% excreted in urine</b>	28%	<2%	~5%	~10%	~20%	13%	13%

\*CrCl = Creatinine Clearance

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Cross References	
Lipitor <sup>®</sup> , atorvastatin, dru119	
Vytorin <sup>®</sup> , ezetimibe/simvastatin, dru139	

Codes	Number	Description
N/A		