

Policies Repository



Policy Title Rosuvastatin calcium (Crestor®)

Policy Number FS.CLIN.69

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Rosuvastatin (Crestor®)** is indicated for the treatment of primary hyperlipidemia and mixed dyslipidemia as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C.

The use of rosuvastatin (Crestor®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Rosuvastatin calcium (Crestor®)**, a HMG-CoA reductase inhibitor, inhibits the rate-limiting enzyme in de novo cholesterol synthesis. HMG-CoA reductase inhibitors are frequently used to reduce the levels of plasma total cholesterol and low-density lipoprotein (LDL) cholesterol in individuals with hypercholesterolemia. It is believed that HMG-CoA reductase inhibitors lower cholesterol levels by reducing the production of mevalonic acid, which results in the following:

- A reduction in hepatic cholesterol synthesis
- A compensatory increase in the expression of high-affinity LDL receptors on hepatocyte membranes
- Stimulation of LDL catabolism

Policy Guideline Inclusion **Rosuvastatin calcium (Crestor®)** is approved when the following inclusion criterion is met:

- Documentation of a trial and failure or contraindication/intolerance/allergy to **one** of the following agents:
 - a lovastatin-containing product
 - a pravastatin-containing product
 - a simvastatin-containing product

Policy Guideline Exclusion

Rosuvastatin calcium (Crestor®) is denied when the following exclusion criterion is present:

- No documentation of a trial and failure or contraindication/intolerance/allergy to **one** of the following agents:
 - a lovastatin-containing product
 - a pravastatin-containing product
 - a simvastatin-containing product

Policy List of Applicable Drugs

Brand Name	Generic Name
Crestor	rosuvastatin

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Ballantyne CM, Blazing MA, King TR, Brady WE, Palmisano J. Efficacy and safety of ezetimibe co-administered with simvastatin compared with atorvastatin in adults with hypercholesterolemia. *Am J Cardiol.* 2004; 93(12):1487-1494.

Branchi A, Fiorenza AM, Torri A, et al. Effect of atorvastatin 10 mg and simvastatin 20 mg on serum triglycerides levels in patients with hypercholesterolemia. *Curr Ther Res Clin Exp.* 2001; 62(5):408-415.

Cannon CP, Braunwald MD, McCabe CH, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndrome [published correction appears in *N Engl J Med.* 2006; 354(7):778]. *N Engl J Med.* 2004; 350(15):1495-1504.

Chan WB, Ko GT, Yeung VT, et al. A comparative study of atorvastatin and simvastatin as monotherapy for mixed hyperlipidaemia in Type 2 diabetic patients. *Diabetes Res Clin Pract.* 2004; 66(1):97-99.

Crestor® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2010. Also available at: <http://www1.astrazeneca-us.com/pi/crestor.pdf>. Accessed August 23, 2010.

Davidson M, Ma P, Stein EA, et al. Comparison of effects on low-density lipoprotein cholesterol and high-density lipoprotein cholesterol with rosuvastatin versus atorvastatin in patients with type IIa or IIb hypercholesterolemia. *Am J Cardiol.* 2002; 89(3):268-275.

Facts and Comparisons. Crestor. [Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed August 23, 2010.

Gartlehner G, Hansen R, Kahwati L, et al. Drug class review on HMG-CoA reductase inhibitors (statins). Oregon Health and Science University (OHSU). Final Report Update 1, July 2005.

Grace KA, Swiecki J, Hyatt R, et al. Implementation of a therapeutic-interchange clinic for HMG-Co A reductase inhibitors. *Am J Health Syst Pharm.* 2002; 59(11):1077-1082.

Grundty SM, Cleeman JI, Merz CN, et al. Implication of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines [published correction appears in *Circulation.* 2004; 110(6):763]. *Circulation.* 2004; 110(2):227-239.

Hippisley-Cox J, Cater R, Pringle M, Coupland C. Cross sectional survey of effectiveness of lipid lowering drugs in reducing serum cholesterol concentration in patients in 17 general practices. *BMJ*. 2003;326(7391):689.

Jones PH, Davidson MH, Stein EA, et al.STELLAR Study Group. Comparison of the efficacy and safety of rosuvastatin versus atorvastatin, simvastatin, and pravastatin across doses (STELLAR Trial). *Am J Cardiol*. 2003;92(2):152-160.

Jones P, Kafonek S, Laurora I, Hunninghake D. Comparative dose efficacy study of atorvastatin versus simvastatin, pravastatin, lovastatin, and fluvastatin in patients with hypercholesterolemia (the CURVES Study) [published correction appears in *Am J Cardiol*. 1998;82(1):128]. *Am J Cardiol*. 1998;81(5):582-587.

Kadikoylu G, Yukselen V, Yavasoglu I, Bolaman Z. Hemostatic effects of atorvastatin versus simvastatin. *Ann Pharmacother*. 2003;37(4):478-484.

LaRosa JC, Grundy SM, Waters DD, et al.Intensive lipid lowering with atorvastatin in patients with stable coronary disease. *N Engl J Med*. 2005;352(14):1425-1435.

Marz W, Wollschlager H, Klein G, Neiss A, Wehling M. Safety of low-density lipoprotein cholesterol reduction with atorvastatin versus simvastatin in a coronary heart disease population (the TARGET TANGIBLE trial). *Am J Cardiol*. 1999;84(1):7-13.

McManus B. FDC Reports. Lipitor adds claims for high-dose use from TNT, IDEAL- but label is mixed. 2007;69:11. [The Pink Sheet Web site]. 03/12/07. Available at: http://www.thepinksheet.com/fdcreports/story/search/submitSearch.do?doClear=true&subsNum=&publications=pink&query=lipitor&find_button.x=13&find_button.y=6 [via subscription only]. Accessed August 23, 2010.

Pearson TA, Denke MA, McBride PE, et al.A community-based, randomized trial of ezetimibe added to statin therapy to attain NCEP ATP III goals for LDL cholesterol in hypercholesterolemic patients: The Ezetimibe Add-on to Statin for Effectiveness (EASE) Trial.*Mayo Clin Proc*. 2005;80(5):587-595.

Pedersen TR, Faergeman O, Kastelein JJ, et al.High-dose atorvastatin vs usual-dose simvastatin for secondary prevention after myocardial infarction: the IDEAL study: a randomized controlled trial [published correction appears in *JAMA*. 2005;294(24):3092]. *JAMA*. 2005;294(19):2437-2445.

Taylor AJ, Grace K, Swiecki J, et al. Lipid-lowering efficacy, safety, and costs of a large-scale therapeutic statin formulary conversion program. *Pharmacotherapy*. 2001;21(9):1130-1139.

Policy Link to Related Policies

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