

## Policies Repository



**Policy Title** Ezetimibe/simvastatin (Vytorin®)

**Policy Number** FS.CLIN.81

*Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.*

*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**

**Ezetimibe/simvastatin (Vytorin®)** is indicated as adjunctive therapy to diet to reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with hyperlipidemia or mixed hyperlipidemia and to reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid lowering treatments.

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

**Policy Description**

**Ezetimibe/simvastatin (Vytorin®)** is a combination of two drugs, a cholesterol absorption inhibitor (ezetimibe) and an HMG-CoA reductase inhibitor (simvastatin). Ezetimibe reduces blood cholesterol by inhibiting

absorption of cholesterol by the small intestine, leading to a decrease in the delivery of intestinal cholesterol to the liver. This mechanism is complementary to that of the HMG-CoA reductase inhibitors.

## Policy Guideline Inclusion

**Ezetimibe/simvastatin (Vytorin®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of a trial and failure or contraindication/intolerance/allergy to **one** of the following agents:
  - Lovastatin-containing product
  - Pravastatin-containing product
  - Simvastatin-containing product
- Documentation of a trial and failure or contraindication/intolerance/allergy to rosuvastatin calcium (Crestor®)

## Policy Guideline Exclusion

**Ezetimibe/simvastatin (Vytorin®)** is denied when **any** of the following exclusion criteria are present:

- No documentation of a trial and failure or contraindication/intolerance/allergy to **one** of the following agents:
  - Lovastatin-containing product
  - Pravastatin-containing product
  - Simvastatin-containing product
- No documentation of a trial and failure or contraindication/intolerance/allergy to rosuvastatin calcium (Crestor®)

## Policy List of Applicable Drugs

Brand Name	Generic Name
Vytorin	ezetimibe/simvastatin

## 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.

Caduet® [package insert]. New York, NY: Pfizer, Inc.; 2007. Also available at: <http://www.caduet.com>. Accessed January 6, 2010.

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.

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. Lipitor. [Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed January 6, 2010.

Facts and Comparisons. Vytorin. [Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed December 22, 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.

Grundy 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.

Lipitor® [package insert]. New York, NY: Pfizer, Inc.; 2005. Also available online at: <http://www.lipitor.com>. Accessed January 6, 2010.

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?](http://www.thepinksheet.com/fdcreports/story/search/submitSearch.do?doClear=true&subsNum=&publications=pink&query=lipitor&find_button.x=13&find_button.y=6)

[doClear=true&subsNum=&publications=pink&query=lipitor&find\\_button.x=13&find\\_button.y=6](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 November 11, 2008.

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.

Vytorin® [package insert]. North Wales, PA: Merck/Schering-Plough Pharmaceuticals; 2010. Also available online at:

[http://www.vytorin.com/vytorin/shared/documents/vytorin\\_pi.pdf](http://www.vytorin.com/vytorin/shared/documents/vytorin_pi.pdf).

Accessed December 22, 2010.

---

## Policy Link to Related Policies

---

Printed

01/04/2011 10:15:42

---

The Policy Bulletins on this web site were developed to assist Independence Blue Cross and its subsidiaries ("IBC") in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an

IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins. © 2008 Independence Blue Cross. All Rights Reserved. Current Procedural Terminology © 2008 American Medical Association. All Rights Reserved.

I