

## Policies Repository



**Policy Title** Niacin Extended-Release/Simvastatin (Simcor®)

**Policy Number** FS.CLIN.53

*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** **Niacin extended-release/simvastatin (Simcor®)** is indicated as an adjunct to diet to reduce total-C, LDL-C, Apo B, non-HDL-C, or TG or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson type IIa and IIb) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate. Niacin extended-release/simvastatin (Simcor®) is also indicated to reduce TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia) when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.

The use of niacin extended-release/simvastatin (Simcor®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

**Policy Description** **Niacin extended-release/simvastatin (Simcor®)** is a combination of available existing agents, niacin extended-release and simvastatin. Niacin is a B-complex vitamin that has antihyperlipidemic effects, although the precise mechanism of action is unknown. Niacin may inhibit the release of free fatty acids from adipose tissue and increase lipoprotein lipase activity. Niacin increases high-density lipoprotein (HDL) and reduces triglycerides, total cholesterol, and LDL. Simvastatin is a lipid-lowering agent classified as an HMG-CoA Reductase Inhibitor. Simvastatin inhibits 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase, the enzyme that catalyzes the conversion of HMG-CoA to mevalonate. This conversion to mevalonate is an early and rate-limiting step in the biosynthesis of cholesterol.

**Policy Guideline Inclusion** **Niacin extended-release/simvastatin (Simcor®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of a minimum 30 day trial of concurrent use of a prescription niacin product and a simvastatin-containing product
- Documentation of non-compliance with the concurrent use of a prescription niacin product and a simvastatin-containing product

**Niacin extended-release/simvastatin (Simcor®)** is denied when **any** of the following

**Policy Guideline Exclusion**

exculsion criteria are present:

- No documentation of a minimum 30 day trial of concurrent use of a prescription niacin product and a simvastatin-containing product
- No documentation of non-compliance with the concurrent use of a prescription niacin product and a simvastatin-containing product

**Policy List of Applicable Drugs**

Brand Name	Generic Name
Simcor	niacin extended-release/simvastatin

**Dosing and Administration**

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

**Policy References**

Micromedex. Simcor®. [Micromedex web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed July 28, 2009.

Simcor® [package insert]. Abbott Park, IL: Abbott Laboratories; 2008. Also available online at: [http://rxabbott.com/pdf/simcor\\_pi.pdf](http://rxabbott.com/pdf/simcor_pi.pdf). Accessed July 28, 2009.

**Policy Link to Related Policies****Printed**

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