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# North Dakota Medicaid Pharmacy Program Quarterly News

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Spring 2011

Welcome to the Spring 2011 edition of the “North Dakota Medicaid Pharmacy Program Quarterly News,” a pharmacy newsletter presented by the North Dakota Department of Human Services and published by Health Information Designs, Inc. This newsletter is published as part of a continuing effort to keep the Medicaid provider community informed of important changes in the North Dakota Medicaid Pharmacy Program.

The North Dakota Department of Human Services has contracted with Health Information Designs, Inc. (HID) to review and process prior authorizations (PAs) for medications. For a current list of medications requiring a PA, as well as the necessary forms and criteria, visit [www.hidndmedicaid.com](http://www.hidndmedicaid.com), or call HID at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup. This allows you to determine if a specific NDC is covered (effective date), reimbursement amount, MAC pricing, copay information, and any limitations (prior authorization or quantity limits).

The Spring 2011 newsletter provides information regarding new restrictions for simvastatin. Also included is an overview of authorized generics and the guidelines for use of the products.

The North Dakota Medicaid Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, or to make comments, please contact Health Information Designs, Inc. at (334) 502-3262, call toll free at 1-800-225-6998, or e-mail us at [info@hidinc.com](mailto:info@hidinc.com).



### Helpful Numbers

PA Help Desk                      866-773-0695  
To fax PAs                            866-254-0761  
To report adverse reactions      800-FDA-1088

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Visit HID's North Dakota Department of Human Services Prior Authorization Webpage, [www.hidndmedicaid.com](http://www.hidndmedicaid.com).

## Simvastatin

The U.S. Food and Drug Administration recently announced safety label changes for the cholesterol-lowering medication simvastatin. The highest approved dose of simvastatin (80mg) has been associated with an elevated risk of muscle injury or myopathy, particularly during the first 12 months of use. The FDA recommends that simvastatin 80mg be used only in patients who have been taking this dose for 12 months or more and have not experienced any muscle toxicity. The 80mg dose should not be prescribed to new patients. The FDA also recommends that patients currently taking 40mg of simvastatin that are not meeting their LDL cholesterol goal be switched to a different statin rather than raising the simvastatin dose to 80mg.

Last year, an estimated 2.1 million people were prescribed a medication containing 80mg of simvastatin. All statins, despite their proven benefit in lowering the risk of heart attacks and strokes, carry some risk of myopathy, characterized by unexplained muscle weakness or pain. The risk is greater for those patients taking 80mg doses of simvastatin, especially in the first year of treatment. The muscle damage is often caused by interactions with other medications although some people are genetically predisposed towards simvastatin-related myopathy.

Simvastatin is sold under the brand name Zocor and as a single-ingredient generic drug. It is also sold in combination with ezetimibe as Vytorin, and niacin as Simcor. The FDA has revised the drug labels for simvastatin and Vytorin to include the new 80mg dosing restrictions. The agency also revised the labels for simvastatin, Vytorin, and Simcor to include new dosing recommendations when these drugs are used in combination with certain medications that increase the level of simvastatin in the body, thus increasing the risk of myopathy.

FDA recommends that healthcare professionals:

- Maintain patients on simvastatin 80mg only if they have been taking this dose for 12 or more months without evidence of muscle toxicity.
- Not start new patients on simvastatin 80mg.
- Place patients who do not meet their LDL cholesterol (LDL-C) goal on simvastatin 40mg on alternative LDL-C lowering treatment(s) that provides greater LDL-C lowering.
- Follow the recommendations in the simvastatin-containing medicine labels regarding drugs that may increase the risk for muscle injury when used with simvastatin.
- Switch patients who need to be initiated on a drug that interacts with simvastatin to an alternative statin with less potential for the drug-drug interaction.
- Report adverse events involving simvastatin-containing medications to the FDA MedWatch program.

Atorvastatin	Fluvastatin	Pitavastatin	Lovastatin	Pravastatin	Rosuvastatin	Vytorin*	Simvastatin	%↓ LDL-C
-	40mg	1mg	20mg	20mg	-	-	10mg	30%
10mg	80mg	2mg	40 or 80mg	40mg	-	-	20mg	38%
20mg	-	4mg	80mg	80mg	5mg	10/10mg	40mg	41%
40mg	-	-	-	-	10mg	10/20mg	80mg	47%
80mg	-	-	-	-	20mg	10/40mg	-	55%
-	-	-	-	-	40mg	10/80mg	-	63%

\*No incremental benefit of Vytorin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.

### References:

FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury. Available at [www.fda.gov](http://www.fda.gov). Accessed June 27, 2011.

## Authorized Generics

An authorized generic is a pharmaceutical product that was originally marketed and sold by a brand company, but is relabeled and marketed under a generic product name. An authorized generic may be marketed by the brand company or through a subsidiary, or the brand company may license the product to another company for marketing in return for royalties. Brand companies may launch an authorized generic for several reasons:

1. Settle patent litigation with a generic company by partnering with it.
2. Participation in generic market once generic competition starts.
3. Maintain manufacturing capacity for the drug substance.

In 1984, Congress enacted Hatch-Waxman with the intent to open up the market for products that were previously patent protected. Hatch-Waxman allowed generic manufacturers to file an Abbreviated New Drug Application (ANDA). The ANDA requires the generic company to demonstrate that its product is bioequivalent to a referenced NDA's brand name product. Because the proof of bioequivalence for a drug is much easier to establish than the requirements for a New Drug Application (NDA), the ANDA is a far less expensive process than filing a NDA.

The Medicare Act of 2003 amended Hatch-Waxman in an effort to reduce the barriers to more generics entering the marketplace. The first generic company that files an ANDA obtains a period of 180 days during which it can exclude any other prospective generic product from entering the market, thus establishing a greater market share after exclusivity ends. The position of the FDA is that authorized generics *do not* have to abide by the 180-day market exclusivity to the first generic because the FDA lacks the authority to regulate changes in approved products that do not potentially affect the safety or the effectiveness of the product. Since authorized generics are manufactured under the original, approved NDA submitted for the brand-name drug, the FDA considers authorized generics to be identical to the brand.

### Authorized Generics and North Dakota Medicaid

Because authorized generics are considered 'identical' to the brand by the FDA, North Dakota Medicaid requires that prescriptions written for a brand product, available as an authorized generic, be filled with the authorized generic. The FDA listing of authorized generics is available at [www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.pdf](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.pdf).

#### References:

FDA Listing of Authorized Generics. Available at [www.fda.gov](http://www.fda.gov). Accessed June 28, 2011.  
Authorized Generics: Antitrust Issues and the Hatch-Waxman Act. Available at [www.fenwick.com](http://www.fenwick.com). Accessed June 28, 2011.



Health Information Designs, Inc. (HID) is the most experienced and qualified provider of drug utilization review and pharmacy support services in the country. We specialize in helping our clients promote clinically appropriate and cost-effective prescribing, dispensing, and utilization of prescription drugs.

For 33 years, HID has worked to improve the quality and cost effectiveness of health care through clinically rational use of prescription medication. Our clients include public and private healthcare plans throughout the U.S. with a combined total of over 14 million covered lives.

Health Information Designs, Inc. was founded in 1976 and is incorporated as a C Corporation in the State of Delaware. HID's initial mission was to market drug utilization review (DUR) services nationally and since its founding, has provided DUR services for clients in approximately two-thirds of the United States. HID is headquartered in Auburn, Alabama, with regional offices in Arkansas, Maryland, and Mississippi.

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