



MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS
LAST CRITERIA REVISION DATE: 10-17-2011
NEXT REVIEW DATE: 3rd QTR 2012

ORIGINAL EFFECTIVE DATE: 10-21-2011
LAST REVIEW DATE: 10-1-2011
ARCHIVE DATE:

Medications which contain simvastatin 80mg

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the members specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety. The Guideline is not a guarantee of coverage.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available. The guideline in effect on the date of service will determine coverage.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257884.htm>

As referenced in the above link to the Food and Drug Administration website is the FDA's recommendation that the use of medications which containing 80 mg of simvastatin—the highest approved dose of the popular cholesterol-lowering statin—be sharply curtailed because of the risk of muscle injury.

FDA says this dose should only be used by patients who have been taking it for 12 months or longer without ill effect.



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“Our overall goal is to get doctors to not start patients on 80 mg of simvastatin,” says Eric Colman, M.D., deputy director of FDA’s Division of Metabolism and Endocrinology Products.

And if health care professionals find that patients now taking 40 mg of simvastatin aren’t meeting their LDL cholesterol goal, FDA is advising them to choose a different statin rather than raising the simvastatin dose to 80 mg, says Amy Egan, M.D., deputy director for safety in the FDA division.

All statins, despite their proven benefit in lowering the risk of heart attacks and strokes, carry some risk of an injury called myopathy, characterized by unexplained muscle weakness or pain.

But the risk is greater for patients who take the 80 mg doses of simvastatin, especially in the first year of treatment. Colman says the muscle damage is often caused by interactions with other medications. And some people are genetically predisposed towards simvastatin-related myopathy, he says.

Last year, an estimated 2.1 million people were prescribed a medication containing 80 mg of simvastatin, says Egan. “It is the most potent statin available in generic form and is relatively inexpensive,” she notes.

The statin 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.

FDA has revised the drug labels for simvastatin and Vytorin to include the new restrictions for the 80 mg dose, says Egan. The labels of simvastatin, Vytorin and Simcor have all been changed to include dosing recommendations when these drugs are used with medicines that can increase the level of simvastatin in the body, thus increasing the risk of myopathy.

Like all statins, simvastatin is used to lower the amount of low-density lipoprotein (LDL) cholesterol—known as “bad cholesterol”—in the blood. And the 80 mg dose of simvastatin has been shown to lower LDL cholesterol by an additional 6% over the 40 mg dose.

But myopathy can be debilitating. Moreover, a rare form of myopathy, called rhabdomyolysis, can lead to kidney failure and death.

Colman says one thing FDA does not want patients to do is stop taking their statins without consulting their doctor. “The benefits of the treatment far outweigh the risks,” he says, calling occurrences of rhabdomyolysis “extremely rare.”



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Precertification:

Precertification* for medications which contain simvastatin 80mg is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit, who do not have previous claim history (BCBSAZ) for medications which contain simvastatin 80mg on the first effective date of this policy. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/Q1List.pdf>:

"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions" This list may also be requested by calling (602) 864-4273 or (800)

232-2345, ext. 4273.

Please refer to this list for maximum dosage and other drug limitations.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Criteria:

- ❖ **Under the member's BCBSAZ retail and mail order prescription benefit**, simvastatin 80mg is considered **medically necessary** for individuals 18 years of age and older* when prescribed according to the FDA recommendations which limit the treatment for continued therapy to individuals who are stable on 80mg dosing. Evidence of treatment with 80mg of simvastatin for 12 months previously may be provided by either the individual or individual's provider when the individual is a new to BCBSAZ.



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Criteria: (cont.)

- ❖ for the following indication of treatment of new individuals with medications that contain 80mgs of simvastatin is considered ***experimental or investigational*** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.
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Resources:

FDA notice of limit of use for 80mg simvastatin 9-9-2011

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm257884.htm>



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