PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 10/21/2011
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ARCHIVE DATE:

MEDICATIONS WHICH CONTAIN SIMVASTATIN 80 MG:
ZOCOR (simvastatin) 80 mg
Simvastatin 80 mg
VYTORIN (ezetimibe-simvastatin) 10-80 mg
Ezetimibe-simvastatin 10-80 mg

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

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.

MEDICATIONS WHICH CONTAIN SIMVASTATIN 80 MG

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy:** A medication with 80 mg of simvastatin is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older
  2. Medication with 80 mg of simvastatin is prescribed according to FDA recommendations
  3. Evidence provided by either the individual or prescriber of treatment with a medication with 80 mg of simvastatin for 12 months previously without evidence of muscle toxicity
  4. Individual has been adherent with the medication throughout the 12 months
  5. There are no significant interacting drugs

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** A medication with 80 mg of simvastatin is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement
  2. Individual has been adherent with the medication throughout the 12 months
  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     a. Contraindications as listed in FDA-approved package label
     b. Significant adverse effect such as:
        i. Myopathy
        ii. Rhabdomyolysis
        iii. Hepatotoxicity
  4. There are no significant interacting drugs

  Renewal duration: 12 months

MEDICATIONS WHICH CONTAIN SIMVASTATIN 80 MG

Description:

In 2011, the Food and Drug Administration (FDA) issued a recommendation that use of medications which contain 80 mg of simvastatin—the highest approved dose—be sharply curtailed because of the risk of muscle injury.

FDA said this dose should only be used by individuals who have been taking it for 12 months or longer without ill effect. Another goal of the recommendation was to inform providers to not start individuals on 80 mg of simvastatin. These recommendations were prompted by a comprehensive review of clinical trial data and from the agency's Adverse Event Reporting System that tracks the safety of drugs once they are on the market.

All statins carry some risk of myopathy, characterized by unexplained muscle weakness or pain. Myopathy can be debilitating and the rare form of myopathy, known as rhabdomyolysis, can lead to kidney failure and death.

The risk is greater for individuals who take the 80 mg doses of simvastatin, especially in the first year of treatment. The muscle damage is often caused by interactions with other medications and 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. Vytorin is now available as a generic product.

The maximum amount of simvastatin found in Vytorin is 80 mg. FDA has revised the drug labels for simvastatin (brand and generic) and Vytorin (brand and generic) to include the new restrictions for the 80 mg dose. The labels of simvastatin (brand and generic) and Vytorin (brand and generic) have all been changed to include dosing recommendations when these drugs are used with medicines that can increase the level of simvastatin, thus increasing the risk of myopathy.

For individuals taking 40 mg of simvastatin and who are not meeting their LDL cholesterol goal, FDA is advising providers to choose a different statin rather than raise the simvastatin dose to 80 mg.

Like all statins, simvastatin is used to lower low-density lipoprotein (LDL) cholesterol. The 80 mg dose of simvastatin has been shown to lower LDL cholesterol by an additional 6% over the 40 mg dose.

It is important that individuals should not stop their statin medication without consulting their provider. The benefits of the treatment far outweigh the risks, as the occurrence of rhabdomyolysis is considered extremely rare.

Resources:

Zocor (simvastatin) product information, revised by manufacturer Merck Sharp & Dohme Corp. 04-2020, at DailyMed http://dailymed.nlm.nih.gov accessed September 11, 2020

Simvastatin product information, revised by manufacturer Dr. Reddy's Laboratories Limited 02-2016, at DailyMed http://dailymed.nlm.nih.gov accessed September 11, 2020

MEDICATIONS WHICH CONTAIN SIMVASTATIN 80 MG

Vytorin (simvastatin/ezetimibe) product information, revised by manufacturer PD-Rx Pharmaceuticals, Inc., at DailyMed http://dailymed.nlm.nih.gov accessed September 11, 2020

Simvastatin/ezetimibe product information, revised by manufacturer Dr.Reddys Laboratories Inc. 11-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 11, 2020