

## STEP THERAPY CRITERIA

<b>DRUG CLASS</b>	<b>HMG-COA REDUCTASE INHIBITOR (STATIN)</b>
<b>BRAND NAME (generic)</b>	<b>VYTORIN 10/80 MG STRENGTH ONLY (ezetimibe/simvastatin 10/80mg)</b>
	<b>ZOCOR 80 MG STRENGTH ONLY (simvastatin 80mg)</b>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Initial Step Therapy; Post Step Therapy Prior Authorization</b>	

### POLICY

#### FDA-APPROVED INDICATIONS

##### **Vytorin**

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is indicated as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate.

##### Primary Hyperlipidemia

Vytorin is indicated for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and non-high-density lipoprotein cholesterol (non-HDL-C), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia.

##### Homozygous Familial Hypercholesterolemia (HoFH)

Vytorin is indicated for the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

##### Limitations of Use

No incremental benefit of Vytorin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. Vytorin has not been studied in Fredrickson type I, III, IV, and V dyslipidemias.

##### **Zocor**

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is indicated as an adjunct to diet when the response to a diet restricted in saturated fat and

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cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with coronary heart disease (CHD) or at high risk of CHD, Zocor can be started simultaneously with diet.

#### Reductions in Risk of CHD Mortality and Cardiovascular Events

In patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, Zocor is indicated to:

- Reduce the risk of total mortality by reducing CHD deaths.
- Reduce the risk of non-fatal myocardial infarction and stroke.
- Reduce the need for coronary and non-coronary revascularization procedures.

#### Hyperlipidemia

Zocor is indicated to:

- Reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb).
- Reduce elevated TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia).
- Reduce elevated TG and VLDL-C in patients with primary dysbetalipoproteinemia (Fredrickson type III hyperlipidemia).
- Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

#### Adolescent Patients with Heterozygous Familial Hypercholesterolemia (HeFH)

Zocor is indicated as an adjunct to diet to reduce total-C, LDL-C, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with HeFH, if after an adequate trial of diet therapy the following findings are present:

1. LDL cholesterol remains  $\geq 190$  mg/dL; or
2. LDL cholesterol remains  $\geq 160$  mg/dL and
  - There is a positive family history of premature cardiovascular disease (CVD) or
  - Two or more other CVD risk factors are present in the adolescent patient.

The minimum goal of treatment in pediatric and adolescent patients is to achieve a mean LDL-C  $< 130$  mg/dL. The optimal age at which to initiate lipid-lowering therapy to decrease the risk of symptomatic adulthood CAD has not been determined.

#### Limitations of Use

Zocor has not been studied in conditions where the major abnormality is elevation of chylomicrons (i.e., hyperlipidemia Fredrickson types I and V).

#### **INITIAL STEP THERAPY**

If the patient has filled a prescription for at least a 290 day supply of 10/80 mg strength of ezetimibe/simvastatin (Vytorin) or at least a 290 day supply of 80 mg strength of simvastatin (Zocor) within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

#### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has been prescribed the 10/80 mg strength of ezetimibe/simvastatin (Vytorin) OR the 80 mg strength of simvastatin (Zocor) chronically for 12 months or more.

#### **REFERENCES**

1. Vytorin [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; October 2016.
2. Zocor [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2015.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed November 2017.
4. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed November 2017.