STEP THERAPY CRITERIA

DRUG CLASS	**HMG-COA REDUCTASE INHIBITOR (STATIN)**
BRAND NAME (generic)	**VYTORIN 10/80 MG STRENGTH ONLY (ezetimibe / simvastatin 10/80mg)** **ZOCOR 80 MG STRENGTH ONLY (simvastatin 80mg)**

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization

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

Zocor is indicated:

- To reduce the risk of total mortality by reducing risk of coronary heart disease death, non-fatal myocardial infarction and stroke, and the need for coronary and non-coronary revascularization procedures in adults with established coronary heart disease, cerebrovascular disease, peripheral vascular disease, and/or diabetes, who are at high risk of coronary heart disease events.
- As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C):
    - In adults with primary hyperlipidemia
    - In adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).

- As an adjunct to other LDL-C lowering therapies to reduce LDL-C in adults with homozygous familial hypercholesterolemia (HoFH)
- As an adjunct to diet for treatment of adults with:
    - Primary dysbetalipoproteinemia.
    - Hypertriglyceridemia.

INITIAL STEP THERAPY*

**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 290 day supply of the 10/80 mg strength of ezetimibe/simvastatin (Vytorin) or at least a 290 day supply of the 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 taking 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]. Jersey City, NJ: Organon LLC; June 2021.
2. Zocor [package insert]. Jersey City, NJ: Organon LLC; May 2022.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022; Accessed November 2, 2022.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed November 2, 2022.

