

Initial Prior Authorization with Logic HMG-COA Reductase Inhibitor (STATIN)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vytorin 10/80 mg Strength Only	ezetimibe / simvastatin 10/80 mg
Zocor 80 mg Strength Only	simvastatin 80 mg

Indications

FDA-approved Indications

Vytorin

Vytorin is a combination of simvastatin and ezetimibe indicated:

- As an adjunct to diet to reduce elevated 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 elevated LDL-C in adults with homozygous familial hypercholesterolemia (HoFH).

Simvastatin, when used as a component of VYTORIN, 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.

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.

Screen out Logic

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 screen out logic, 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

Authorization may be granted for the requested drug when the following criteria is 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.

Duration of Approval (DOA)

- 981-D: DOA: 36 months

Reference number(s)
981-D

References

1. Vytorin [package insert]. Jersey City, NJ: Organon LLC; March 2024.
2. Zocor [package insert]. Jersey City, NJ: Organon LLC; August 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/24/2024).