simvastatin (Zocor®) 80 mg

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO106

Description

Simvastatin (Zocor) is an orally administered 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor used to reduce LDL-C and prevent cardiovascular events.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Simvastatin (Zocor)	80 mg tablets	Prevention of cardiovascular events/cardiovascular disease and reduce the risk of atherosclerotic cardiovascular disease, homozygous familial hypercholesterolemia	30 tablets/30 days

Initial Evaluation

I. **Simvastatin 80 mg (Zocor)** may be considered medically necessary when the following criteria below are met:
   A. Member has been established and stabilized on the 80 mg dose for a duration of 12 or more months without evidence of muscle toxicity (e.g. myopathy, rhabdomyolysis) within the past 12 months.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent; **AND**
II. Member has exhibited improvement or stability of disease symptoms; **AND**
III. Member has not experienced symptoms of muscle toxicity (e.g. myopathy, rhabdomyolysis).

Supporting Evidence

I. In 2011, the FDA issued a dose limitation on simvastatin 80 mg stating that it should not be started in new patients and should only be used in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). Furthermore, 2018 AHA/ACC guidelines note simvastatin 80 mg/day is not recommended due to increased risk of myopathy.

If patient is unable to achieve LDL-C goal with simvastatin 40 mg/day, switch to a high-intensity statin.

II. The SEARCH trial was a seven-year, randomized, double-blind study that compared the efficacy and safety of simvastatin 80 mg versus simvastatin 20 mg, with or without vitamin B12 and folate in survivors of myocardial infarction.

- Incidence of major vascular events between the simvastatin 80 mg group and simvastatin 20 mg group was 24.5% vs 25.7%, respectively (95% CI 0.88, 1.01, p=0.10).
- 0.9% of patients in the simvastatin 80 mg group experienced myopathy versus 0.02% in the simvastatin 20 mg group. Risk for myopathy and rhabdomyolysis was highest in the first 12 months of therapy.

References

1. Zocor [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc. 1991.
2. Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH) Collaborative Group. Intensive lowering of LDL cholesterol with 80 mg versus 20 mg simvastatin daily in 12,064 survivors of myocardial infarction: a double-blind randomised trial. *Lanciet*. 2010;376(9753):1658-1669.
3. U.S. Food & Drug Administration. (2011). FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury. Retrieved from https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-new-restrictions-contraindications-and-dose-limitations-zocor.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625[PubMed 30586774]

Policy Implementation/Update:

Action and Summary of Changes	Date
Updates to wording of initial criteria in efforts to clarify policy intent	**05/2021**
Criteria transitioned to policy with supporting evidence section added.	10/2019
New criteria	01/2017