

## STEP THERAPY POLICY

**POLICY:** Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors Step Therapy Policy

- Altoprev<sup>®</sup> (lovastatin extended-release tablets – Covis)
- Atorvaliq<sup>®</sup> (atorvastatin oral suspension – CMP)
- Caduet<sup>®</sup> (atorvastatin/amlodipine tablets – Pfizer, generic)
- Crestor<sup>®</sup> (rosuvastatin tablets – AstraZeneca, generic)
- Ezallor Sprinkle<sup>™</sup> (rosuvastatin capsules – Sun)
- Flolipid<sup>®</sup> (simvastatin oral suspension – Salerno/Rosemont)
- Fluvastatin capsules (generic only)
- Lescol<sup>®</sup> XL (fluvastatin extended-release tablets – Novartis, generic)
- Lipitor<sup>®</sup> (atorvastatin tablets – Pfizer, generic)
- Livalo<sup>®</sup> (pitavastatin tablets – Lily/Kowa, generic)
- Mevacor<sup>®</sup> (lovastatin tablets – generic only)
- Pravachol<sup>®</sup> (pravastatin tablets – Bristol-Myers Squibb, generic)
- Roszet<sup>®</sup> (rosuvastatin and ezetimibe tablets – Althera)
- Rosuvastatin and ezetimibe tablets – SCOV3 LLC
- Vytorin<sup>®</sup> (ezetimibe/simvastatin tablets – Organon, generic)
- Zocor<sup>®</sup> (simvastatin tablets – Organon, generic)
- Zypitomag<sup>®</sup> (pitavastatin magnesium tablets – Medigure)

**REVIEW DATE:** 06/26/2024

---

### OVERVIEW

Available hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (HMGs), excluding combination products, include lovastatin, simvastatin, atorvastatin, pravastatin, fluvastatin, fluvastatin extended-release, pitavastatin, rosuvastatin, Altoprev, Ezallor Sprinkle, and Zypitomag; combination products are available as well.<sup>1-14</sup> All of the HMGs are indicated as an **adjunct to diet for patients with primary hypercholesterolemia and/or mixed dyslipidemia** (to impact lipid parameters such as to reduce elevated total cholesterol [total-C] and low-density lipoprotein cholesterol [LDL-C]). Several agents have additional indications, including those related to improvement in cardiovascular (CV) outcomes. Flolipid (simvastatin oral suspension) is available and it has the same indications as simvastatin tablets.<sup>15</sup> Atorvaliq is an oral suspension that has the same indications as atorvastatin tablets.<sup>16</sup> Ezallor Sprinkle has administration options for patients who cannot swallow an intact capsule whole.<sup>3</sup> The contents can be opened and sprinkled over soft food (e.g., applesauce, pudding). Also, Ezallor Sprinkle capsules can be opened and administered by a nasogastric tube.

### Guidelines

In November 2013, the **American College of Cardiology** and the **American Heart Association** published guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular disease (ASCVD) risk in adults<sup>17</sup> with an update published in 2019.<sup>18</sup> The guideline emphasizes the appropriate intensity of statin therapy to reduce cardiovascular risk. No statin is preferred, but instead, statins with related doses are categorized as “high-intensity” (lowers low-density lipoprotein cholesterol [LDL-C] by approximately  $\geq 50\%$ ), moderate-intensity (lowers LDL-C by approximately 30% to  $< 50\%$ ), and low-intensity (lowers LDL-C by  $< 30\%$ ). Only atorvastatin and rosuvastatin are categorized as acceptable “high-intensity” statin therapies. According to the guidelines, clinical trial evidence clearly shows that ASCVD events are reduced by using the maximum-tolerated statin intensity in groups shown to benefit (e.g., those at risk). There is relatively less evidence for non-statin medications in reducing ASCVD risk. Table 1 categorizes the

06/26/2024

© 2024. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

different statin regimens as high-, moderate-, and low-intensity. Refer to the guideline for the most appropriate intensity for the individual patient.

**Table 1. High-, Moderate-, and Low-Intensity Statin Therapy.**<sup>17,18\*</sup>

\* Used in the randomized controlled trials reviewed by the expert panel. Of note, individual responses to statin therapy varied in the randomized controlled trials and should be expected to vary in clinical practice. There might be a biologic basis for a less-than-average response; LDL-C – Low-density lipoprotein cholesterol; † Evidence from one randomized controlled trial only and down titration is recommended if the patient is unable to tolerate atorvastatin 80 mg; ‡ Although simvastatin 80 mg was assessed in randomized controlled trials, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis; BID – Twice daily.

**POLICY STATEMENT**

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Note: When compliance with the Affordable Care Act, Health Resources and Services Administration Guidelines, and Public Health Services Act section 2713 is required and the conditions for coverage listed under the Criteria are not met, approval is granted when the requested single-entity drug is used for the primary prevention of cardiovascular disease (CVD) in an adult aged 40 to 75 years who has one or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year CVD event risk of 10% or greater and who does NOT have a history of (or signs or symptoms of) CVD and, according to the prescriber, the alternative Step 1 Products would not be as medically appropriate for the patient as the requested single-entity drug.

**Automation:** A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

**Step 1:** atorvastatin, atorvastatin/amlodipine, ezetimibe/simvastatin, fluvastatin, fluvastatin extended-release, lovastatin, pravastatin, pitavastatin, rosuvastatin, simvastatin

**Step 2:** Altoprev, Atorvaliq, Caduet, Crestor, Ezallor Sprinkle, Flolipid, Lescol XL, Lipitor, Livalo, Pravachol, ezetimibe and rosuvastatin (brand product), Roszet, Vytorin, Zocor, Zypitamag

## CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve Atorvaliq, Flolipid, or Ezallor Sprinkle.
3. No other exceptions are recommended.

## REFERENCES

1. Lovastatin tablets [prescribing information]. Baltimore, MD/Goa, India: Lupin/BluePoint; September 2021.
2. Crestor<sup>®</sup> tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2023.
3. Zypitamag<sup>®</sup> tablets [prescribing information]. Princeton, NJ: Medicure; January 2024.
4. Ezallor<sup>™</sup> Sprinkle capsules [prescribing information]. Cranbury, NJ: Sun; March 2024.
5. Zocor<sup>®</sup> tablets [prescribing information]. Jersey City, NJ: Organon; August 2023.
6. Lipitor<sup>®</sup> tablets [prescribing information]. New York, NY: Pfizer, April 2024.
7. Lescol<sup>®</sup> XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; November 2023.
8. Altoprev<sup>®</sup> extended-release tablets [prescribing information]. Zug, Switzerland: Covis; April 2024.
9. Pravachol<sup>®</sup> tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2022.
10. Livalo<sup>®</sup> tablets [prescribing information]. Montgomery, AL: Kowa; March 2024.
11. Vytorin<sup>®</sup> tablets [prescribing information]. Jersey City, NJ: Organon; March 2024.
12. Caduet<sup>®</sup> tablets [prescribing information]. New York, NY: Pfizer; May 2024.
13. Roszet<sup>®</sup> tablets [prescribing information]. Morristown, NJ: Althera; March 2021.
14. Rosuvastatin and ezetimibe tablets [prescribing information]. Wilmington, DE: SCOV3 LLC; August 2021.
15. Flolipid<sup>®</sup> oral suspension [prescribing information]. Brooksville, FL: Salerno/Rosemont; September 2020.
16. Atorvaliq<sup>®</sup> oral suspension [prescribing information]. Farmville, NC: CMP; February 2023.
17. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guidance on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. *Circulation*. 2014;129(25 Suppl 2):S1-45.
18. Grundy SM, Stone NJ, Bailey AL, et al. ACC/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:e1082-e1143.