

STEP THERAPY POLICY

- POLICY:** Statins Step Therapy Policy
- Altoprev[®] (lovastatin extended-release tablets – Covis)
 - Atorvaliq[®] (atorvastatin oral suspension – CMP)
 - Caduet[®] (atorvastatin/amlodipine tablets – Pfizer, generic)
 - Crestor[®] (rosuvastatin tablets – AstraZeneca, generic)
 - Ezallor Sprinkle[™] (rosuvastatin capsules – Sun)
 - Flolipid[®] (simvastatin oral suspension – Salerno/Rosemont)
 - fluvastatin capsules (generic only)
 - Lescol[®] XL (fluvastatin extended-release tablets – Novartis, generic)
 - Lipitor[®] (atorvastatin tablets – Pfizer, generic)
 - Livalo[®] (pitavastatin tablets – Lilly/Kowa, generic)
 - lovastatin tablets (generic only)
 - pravastatin tablets (generic only)
 - Roszet[®] (rosuvastatin and ezetimibe tablets – Althera)
 - Rosuvastatin and ezetimibe tablets – SCOV3 LLC
 - Vytorin[®] (ezetimibe/simvastatin tablets – Organon, generic)
 - Zocor[®] (simvastatin tablets – Organon, generic)
 - Zypitamag[®] (pitavastatin magnesium tablets – Medisure)

REVIEW DATE: 06/18/2025; selected revision 03/18/2026

OVERVIEW

Available single-entity hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (HMGs), commonly referred to as statins, include lovastatin, simvastatin, atorvastatin, pravastatin, fluvastatin, fluvastatin extended-release, pitavastatin, rosuvastatin, Altoprev, Ezallor Sprinkle, and Zypitamag; combination products are available as well.¹⁻¹⁴ All of the statins 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.¹⁵ Atorvaliq is an oral suspension that has the same indications as atorvastatin tablets.¹⁶ Ezallor Sprinkle has administration options for patients who cannot swallow an intact capsule whole.³ 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

The 2026 American College of Cardiology/American Heart Association/Multisociety Guideline on the Management of Dyslipidemia continues to recommend statins as the foundation of lipid-lowering therapy for both primary and secondary prevention of atherosclerotic cardiovascular disease (ASCVD).¹⁷ Statin therapy is recommended as first-line pharmacologic treatment when lipid-lowering therapy is indicated, with selection of moderate- or high-intensity statins based on overall cardiovascular risk, comorbidities, and tolerability. In patients with clinical ASCVD, high-intensity statin therapy is recommended unless contraindicated or not tolerated. The guideline reintroduces LDL-C treatment goals to guide therapy, emphasizing optimization of statin therapy to achieve recommended LDL-C targets prior to the addition of non-statin agents. Across risk categories, non-statin lipid-lowering therapies should be considered only when LDL-C goals are not achieved despite use of maximally tolerated statin therapy.

Table 1. High-, Moderate-, and Low-Intensity Statin Therapy.^{17*}

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL-C on average by approximately $\geq 50\%$.	Daily dose lowers LDL-C on average by approximately 30% to 50%.	Daily dose lowers LDL-C on average by $< 30\%$.
Atorvastatin (40 mg [†]) to 80 mg Rosuvastatin 20 mg (40 mg)	Atorvastatin 10 mg (20 mg) Rosuvastatin (5 mg) 10 mg Simvastatin 20 mg to 40 mg [‡] Pravastatin 40 mg (80 mg) Lovastatin 40 mg Fluvastatin extended-release 80 mg Fluvastatin 40 mg BID Pitavastatin 2 mg to 4 mg	Simvastatin 10 mg Pravastatin 10 mg to 20 mg Lovastatin 20 mg Fluvastatin 20 mg to 40 mg Livalo 1 mg

* 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 history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: atorvastatin, atorvastatin/amlodipine, ezetimibe/simvastatin, lovastatin, pravastatin, pitavastatin, rosuvastatin, simvastatin

Step 2: Altoprev, Atorvaliq, Caduet, Crestor, Ezallor Sprinkle, Flolipid, fluvastatin, fluvastatin extended-release, 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® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2023.
3. Zypitamag® tablets [prescribing information]. Princeton, NJ: Medicure; January 2024.
4. Ezallor™ Sprinkle capsules [prescribing information]. Cranbury, NJ: Sun; March 2024.
5. Zocor® tablets [prescribing information]. Jersey City, NJ: Organon; August 2023.
6. Lipitor® tablets [prescribing information]. New York, NY: Pfizer, April 2024.
7. Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; November 2023.
8. Altoprev® extended-release tablets [prescribing information]. Zug, Switzerland: Covis; April 2024.
9. Pravachol® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2022.
10. Livalo® tablets [prescribing information]. Montgomery, AL: Kowa; March 2024.
11. Vytorin® tablets [prescribing information]. Jersey City, NJ: Organon; March 2024.
12. Caduet® tablets [prescribing information]. New York, NY: Pfizer; May 2024.
13. Roszet® tablets [prescribing information]. Morristown, NJ: Althera; March 2021.
14. Rosuvastatin and ezetimibe tablets [prescribing information]. Wilmington, DE: SCO3 LLC; August 2021.
15. Flolipid® oral suspension [prescribing information]. Brooksville, FL: Salerno/Rosemont; September 2020.
16. Atorvaliq® oral suspension [prescribing information]. Farmville, NC: CMP; February 2023.
17. Blumenthal RS, Morris PB, Guadino M, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/AphA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *JACC*. 2026 March 13. [Online ahead of print].

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy Statement: The following note was added to the Policy Statement. <u>Note:</u> When compliance with the Affordable Care Act, Health Resources and Services Administration Guidelines, and Public Health Service Act section 2713 is required and the conditions for coverage listed under the Criteria are not met, approval is granted when the requested 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 drug.	06/14/2023
Selected Revision	Pitavastatin (generic): Added as a Step 1 Product. There were no other changes to the criteria.	11/08/2023
Annual Revision	Ezetimibe and atorvastatin tablets (generic product) and Lescol: Removed from Step 2 as these products are no longer available.	06/26/2024
Update	07/08/2024: No criteria changes. In the listing of the products on the first page, it was added that fluvastatin capsules are available as generic only (Lescol [brand product] was removed).	NA
Annual Revision	No criteria changes.	06/18/2025
Selected Revision	The policy name was changed to as listed. Previously, it was <i>Hydroxy-Methylglutaryl Coenzyme A Reductase Inhibitors</i> Step Therapy Policy. Fluvastatin and Fluvastatin extended-release were moved to Step 2. There were no changes to the criteria.	03/18/2026