STEP THERAPY POLICY

POLICY: Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors 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 – Lily/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 – Medicure)

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Available single-entity hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (HMGs) 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 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 lipoproprotein 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

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[17] with an update published in 2019.[18] 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 ≥ 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 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.[17,18*]

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL-C on average by approximately ≥ 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	Simvastatin 10 mg Pravastatin 10 mg to 20 mg Lovastatin 20 mg Fluvastatin 20 mg to 40 mg Livalo 1 mg

	Pitavastatin 2 mg to 4 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.

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

***Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors Step Therapy Policy* product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

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.

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: SCOV3 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. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Policy Statement:** The following note was added to the Policy Statement. Note: 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