MEDICAL MUTUAL®

# Drug Policy

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| **Policy:** | **HMG-CoA Reductase Inhibitor (HMG)**<br>**Preferred Step Therapy Policy** | **Annual Review Date: 04/18/2024** |
| **Impacted Drugs:** | | **Last Revised Date: 04/18/2024** |

## OVERVIEW

Available hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (HMGs), excluding combination products, include lovastatin, simvastatin, atorvastatin, pravastatin, fluvastatin, fluvastatin extended-release, rosuvastatin, Altoprev, Ezallor Sprinkle, Livalo and Zypitamag.[1-16] 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. Simvastatin is available as a combination with ezetimibe, a selective intestinal inhibitor of cholesterol and related phytosterol absorption, as Vytorin, which is available generically.[12] Rosuvastatin is combined with ezetimibe in products as well.[14,15] Atorvastatin is available as a combination with amlodipine, a dihydropyridine calcium channel blocker, as Caduet, which is also available generically.[13] Flolipid (simvastatin oral suspension) is available and it has the same indications as simvastatin tablets.[16] Atorvaliq is an oral suspension that has the same indications as atorvastatin tablets.[17] Ezallor Sprinkle has administration options for patients who cannot swallow an intact capsule whole.[4] 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.

## POLICY STATEMENT

A step therapy program has been developed to encourage use of one preferred product prior to the use of a non-preferred product. If the step therapy rule is not met for a non-preferred agent 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:** Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

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

**Non-Preferred products:** Atorvaliq, Flolipid, ezetimibe and atorvastatin (generic product)

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## CRITERIA

1. If the patient has tried a preferred product, then authorization for a non-preferred product may be given.

2. Exception can be made for patients with a documented inability to swallow tablets for Atorvaliq and FloLipid.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 365 days
**B)** *Extended Approval:* 365 days

**Step Therapy Exception Criteria**
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

**Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

**Approval Duration:** All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

## REFERENCES

1. Lovastatin tablets [prescribing information]. Goa, India: Lupin/BluePoint; September 2021.

2. Crestor® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2021.
3. Zypitamag® tablets [prescribing information]. Princeton, NJ: Medicure; September 2020.
4. Ezallor Sprinkle™ capsules [prescribing information]. Cranbury, NJ: Sun; September 2020.
5. Zocor® tablets [prescribing information]. Jersey City, NJ: Organon; May 2022.
6. Lipitor® tablets [prescribing information]. New York, NY: Pfizer, November 2020.
7. Lescol® capsules and Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; August 2017.
8. Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; September 2020.
9. Altoprev® extended-release tablets [prescribing information]. Zug, Switzerland: Covis; September 2020.
10. Pravachol® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; August 2020.
11. Livalo® tablets [prescribing information]. Montgomery, AL: Kowa; September 2020.
12. Vytorin® tablets [prescribing information]. Jersey City, NJ: Organon; June 2021.
13. Caduet® tablets [prescribing information]. New York, NY: Pfizer; January 2021.
14. Roszet® tablets [prescribing information]. Morristown, NJ: Althera; March 2021.
15. Rosuvastatin and ezetimibe tablets [prescribing information]. Wilmington, DE: SCOV3 LLC; August 2021.
16. Flolipid® oral suspension [prescribing information]. Brooksville, FL: Salerno/Rosemont; September 2020.
17. Atorvaliq® oral suspension [prescribing information]. Farmville, NC: CMP; February 2023.
18. 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.
19. 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. Available at: https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000625. Accessed on June 24, 2022.