**Effective Date** ..... **2/1/2024**
**Next Review Date**… ..... **2/1/2025**
**Coverage Policy Number** ..... **IP0064**

# HMG-CoA Reductase Inhibitors (Statins) and Combination Products

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## Related Coverage Resources

***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. 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.*

## Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered HMG-CoA Reductase Inhibitors (Statins) and combination products:

- **Altoprev®** (lovastatin) extended release tablet
- **Atorvaliq®** (atorvastatin) oral suspension
- **atorvastatin/ezetimibe** tablet (Liptruzet generic)
- **Crestor®** (rosuvastatin) tablet
- **Ezallor Sprinkle™** (rosuvastatin) capsule
- **FloLipid®** (simvastatin) suspension
- **Lescol® XL** (fluvastatin) extended release tablet
- **Lipitor®** (atorvastatin) tablet
- **Livalo®** (pitavastatin) tablet
- **pitavastatin tablet** (Livalo generic)
- **Pravachol®** (pravastatin) tablet
- **Roszet®** (rosuvastatin /ezetimibe) tablet
- **rosuvastatin /ezetimibe** tablet (Roszet generic)

- **Vytorin®** (simvastatin/ezetimibe) tablet
- **Zocor®** (simvastatin) tablet
- **Zypitamag®** (pitavastatin) tablet

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

**Employer Group Plans Non-Covered Products and Criteria:**

| Non-Covered Product | Criteria |
|---|---|
| **Altoprev** (lovastatin) extended release tablet | **Standard/Performance/Legacy Drug List Plans:**<br>*Step Therapy may apply.*<br><br>**Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**Altoprev** (lovastatin extended release) is medically necessary when there is documentation of failure, contraindication or intolerance to **ALL** of the following:<br>1. lovastatin<br>2. **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. pitavastatin<br>D. pravastatin<br>E. rosuvastatin<br>F. simvastatin |
| **Atorvaliq** (atorvastatin) oral suspension | **Standard/Performance/Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**Atorvaliq** is considered medically necessary when there is documentation of **ONE** of the following:<br>1. Inability to swallow capsules and tablets<br>2. **BOTH** of the following:<br>A. Failure or intolerance to atorvastatin tablet<br>B. Failure, contraindication or intolerance to **TWO** of the following:<br>i. fluvastatin/fluvastatin ER<br>ii. lovastatin<br>iii. pitavastatin<br>iv. pravastatin<br>v. rosuvastatin<br>vi. simvastatin<br><br>**Legacy Drug List Plans:**<br>*Step Therapy may apply.* |
| **atorvastatin/ezetimibe** tablet (Liptruzet generic) | **Atorvastatin/ezetimibe** (Liptruzet generic) is medically necessary when there is documentation of failure, contraindication or intolerance to **BOTH** of the following:<br>1. ezetimibe<br>2. atorvastatin or rosuvastatin |
| **Crestor** (rosuvastatin) tablet | **Crestor** (rosuvastatin) is medically necessary when there is documentation of **BOTH** of the following**:** |

| Non-Covered Product | Criteria |
|---|---|
| | 1. Trial of **rosuvastatin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. lovastatin<br>D. pitavastatin<br>E. pravastatin<br>F. simvastatin |
| **Ezallor Sprinkle** (rosuvastatin) capsule | **Standard/Performance/Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**Ezallor Sprinkle** (rosuvastatin) is medically necessary when there is documentation of **ONE** of the following:<br>1. Inability to swallow capsules and tablets<br>2. **BOTH** of the following:<br>A. Failure or intolerance to rosuvastatin tablet<br>B. Failure, contraindication or intolerance to **TWO** of the following:<br>i. atorvastatin<br>ii. fluvastatin/fluvastatin ER<br>iii. lovastatin<br>iv. pitavastatin<br>v. pravastatin<br>vi. simvastatin<br><br>**Legacy Drug List Plans:**<br>*Step Therapy may apply.* |
| **FloLipid** (simvastatin) suspension | **Standard/Performance/Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**FloLipid** (simvastatin suspension) is medically necessary when there is documentation of **ONE** of the following:<br>1. Inability to swallow capsules and tablets<br>2. **BOTH** of the following:<br>A. Failure or intolerance to simvastatin tablet<br>B. Failure, contraindication or intolerance to **TWO** of the following:<br>i. atorvastatin<br>ii. fluvastatin/fluvastatin ER<br>iii. lovastatin<br>iv. pitavastatin<br>v. pravastatin<br>vi. rosuvastatin<br><br>**Legacy Drug List Plans:**<br>*Step Therapy may apply.* |
| **Lescol XL** (fluvastatin) extended release tablet | **Lescol XL** (fluvastatin extended release) is medically necessary when there is documentation of **BOTH** of the following**:**<br>1. Trial of **fluvastatin extended release** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following: |

| Non-Covered Product | Criteria |
|---|---|
| | A. atorvastatin<br>B. lovastatin<br>C. pitavastatin<br>D. pravastatin<br>E. rosuvastatin<br>F. simvastatin |
| **Lipitor** (atorvastatin) tablet | **Lipitor** (atorvastatin) is medically necessary when there is documentation of **BOTH** of the following**:**<br>1. Trial of **atorvastatin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. fluvastatin/fluvastatin ER<br>B. lovastatin<br>C. pitavastatin<br>D. pravastatin<br>E. rosuvastatin<br>F. simvastatin |
| **Livalo** (pitavastatin) tablet | **Livalo** (pitavastatin calcium) is medically necessary when there is documentation of **BOTH** of the following:<br>1. Trial of **pitavastatin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. lovastatin<br>D. pravastatin<br>E. rosuvastatin<br>F. simvastatin |
| **Pravachol** (pravastatin) tablet | **Pravachol** (pravastatin) is medically necessary when there is documentation of **BOTH** of the following**:**<br>1. Trial of **pravastatin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. lovastatin<br>D. pitavastatin<br>E. rosuvastatin<br>F. simvastatin |
| **Roszet** (rosuvastatin /ezetimibe) tablet | **Standard/Performance/Legacy Drug List Plans:**<br>**Roszet** (rosuvastatin/ezetimibe) is medically necessary when there is documentation of failure, contraindication or intolerance to **EITHER** of the following**:**<br>1. ezetimibe<br>2. atorvastatin or rosuvastatin<br><br>**Value/Advantage/Cigna Total Savings Drug List Plans:** |

| Non-Covered Product | Criteria |
|---|---|
| | **Roszet** (rosuvastatin/ezetimibe) is medically necessary when there is documentation of failure, contraindication or intolerance to **BOTH** of the following**:**<br>1. ezetimibe<br>2. atorvastatin or rosuvastatin |
| **rosuvastatin /ezetimibe** tablet (Roszet generic) | **Rosuvastatin/ezetimibe** (Roszet generic) is medically necessary when there is documentation of failure, contraindication or intolerance to **BOTH** of the following:<br>1. ezetimibe<br>2. atorvastatin or rosuvastatin |
| **Vytorin** (simvastatin/ezetimibe) tablet | **Standard/Performance/Legacy Drug List Plans:**<br>*Step Therapy may apply.*<br><br>**Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**Vytorin** (simvastatin/ezetimibe) is medically necessary when there is documentation of **BOTH** of the following**:**<br>1. Trial of **simvastatin/ezetimibe** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. lovastatin<br>D. pitavastatin<br>E. pravastatin<br>F. rosuvastatin |
| **Zocor** (simvastatin) tablet | **Zocor** (simvastatin) is medically necessary when there is documentation of **BOTH** of the following**:**<br>1. Trial of **simvastatin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.<br>2. Failure, contraindication or intolerance to **TWO** of the following:<br>A. atorvastatin<br>B. fluvastatin/fluvastatin ER<br>C. lovastatin<br>D. pitavastatin<br>E. pravastatin<br>F. rosuvastatin |
| **Zypitamag** (pitavastatin) tablet | **Standard/Performance/Value/Advantage/Cigna Total Savings Drug List Plans:**<br>**Zypitamag** (pitavastatin magnesium) is medically necessary when there is documentation of failure, contraindication or intolerance to **THREE** of the following:<br>1. atorvastatin<br>2. fluvastatin/fluvastatin ER<br>3. lovastatin<br>4. pitavastatin<br>5. pravastatin<br>6. rosuvastatin<br>7. simvastatin<br><br>**Legacy Drug List Plans:**<br>*Step Therapy may apply.* |

**Individual and Family Plans Non-Covered Products and Criteria:**

| Non-Covered Product | Criteria |
|---|---|
| Pitavastatin tablets | Documented failure, contraindication, or intolerance to **THREE** of the following:<br><br>1. atorvastatin<br>2. fluvastatin/fluvastatin ER<br>3. lovastatin<br>4. pravastatin<br>5. rosuvastatin<br>6. simvastatin |

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Continuation of HMG-CoA Reductase Inhibitors (Statins) and combination products is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

## References


1. Crestor® tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2018.
2. Zocor® tablets [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2020.
3. Lipitor® tablets [prescribing information]. New York, NY: Pfizer, Inc.; April 2019.
4. Lescol® capsules and Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; August 2017.
5. Altoprev® extended-release tablets [prescribing information]. Florham Park, NJ: Shionogi; February 2018.
6. Pravachol® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2016.
7. Livalo® tablets [prescribing information]. Montgomery, AL: Kowa Pharmaceuticals; October 2019.
8. Vytorin® tablets [prescribing information]. North Wales, PA: Merck; October 2019.
9. Flolipid® oral suspension [prescribing information]. Brooksville, FL: Salerno; July 2017.
10. Zypitamag® tablets [prescribing information]. Somerset, NJ: Medicure; February 2020.
11. Ezallor™ capsules [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals; December 2018.
12. Atorvaliq® oral suspension [prescribing information]. Farmville, NC: CMP Pharma Inc.; February 2023.