



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors Drug Quantity Management Policy – Per Rx
- Altoprev[®] (lovastatin extended-release tablets – Covis)
 - Atorvaliq[®] (atorvastatin oral suspension – CMP)
 - atorvastatin and ezetimibe tablets (generic only) [obsolete 03/31/2023]
 - Crestor[®] (rosuvastatin tablets – AstraZeneca, generic)
 - Ezallor Sprinkle[™] (rosuvastatin capsules – Sun)
 - Flolipid[®] (simvastatin oral suspension – Salerno)
 - fluvastatin capsules (generic only)
 - Lescol[®] XL (fluvastatin extended-release tablets – Novartis, generic)
 - Lipitor[®] (atorvastatin tablets – Pfizer, generic)
 - Livalo[®] (pitavastatin calcium tablets – Kowa, generic)
 - lovastatin tablets (generic only)
 - pravastatin tablets (generic only)
 - Roszet[®] (rosuvastatin and ezetimibe tablets – Althera, authorized generic)
 - Vytorin[®] (simvastatin and ezetimibe tablets – Organon, generic)
 - Zocor[®] (simvastatin tablets – Organon, generic)
 - Zypitamag[®] (pitavastatin magnesium tablets – Medigure)

REVIEW DATE: 11/21/2025

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Indications

The 3-hydroxy-3-methylglutaryl coenzyme A (HMGs) reductase inhibitors, also known as statins, inhibit the enzyme catalyzing the early rate-limiting step in cholesterol biosynthesis, the conversion of HMG-CoA to mevalonate. The inhibition of this enzyme decreases cholesterol synthesis. Several nationally recognized guidelines detail the benefits of statins extensively. 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]).³⁻¹⁰ However, specific indications for each agent vary.

Dosing and Availability

The dosing and availability information for the hydroxy-methylglutaryl (HMG)-coenzyme A (CoA) Reductase Inhibitors is in Table 1.

Table 1. Dosing and Availability for the HMG CoA Reductase Inhibitors.¹⁻¹⁴

| Brand (generic/dose form) | Available Formulations | Initial Dose | Maximum Daily Dose (Dosage Range) |
|---|--|---|---|
| Atorvastatin Products | | | |
| Atorvaliq® (atorvastatin oral suspension) | 20 mg/5 mL oral suspension in 150 mL bottles | 10 to 20 mg QD | 80 mg (10 to 80 mg/day) |
| Lipitor® (atorvastatin tablets, generic) | 10 mg, 20 mg, 40 mg, and 80 mg tablets | 10 to 20 mg QD | 80 mg (10 to 80 mg/day) |
| atorvastatin and ezetimibe tablets (generic only – no longer available) | 10-10 mg, 20-10 mg, 40-10 mg, and 80-10 mg tablets | 10-10 mg or 20-10 mg QD Patient who requires a larger reduction in LDL-C (> 55%): 40-10 mg QD. | 80-10 mg (10-10 mg to 80-10 mg per day) |
| Fluvastatin Products | | | |
| fluvastatin capsules (generic only) | 20 mg and 40 mg capsules | 20 to 80 mg QD | 80 mg (20 to 80 mg/day) |
| Lescol® XL (fluvastatin extended-release tablets, generic) | 80 mg extended-release tablets | | |
| Lovastatin Products | | | |
| lovastatin tablets (generic only) | 10 mg, 20 mg, and 40 mg tablets | 20 mg QD | 80 mg (10 to 80 mg/day) |
| Altoprev® (lovastatin extended-release tablets) | 20 mg, 40 mg, and 60 mg tablets | 20, 40, or 60 mg QD | 60 mg (20 to 60 mg/day) |
| Pitavastatin Products | | | |
| Livalo® (pitavastatin calcium tablets, generic) | 1 mg, 2 mg, and 4 mg tablets | 2 mg QD | 4 mg (1 to 4 mg/day) |

| | | | |
|---|--|---|--|
| Zypitamag® (pitavastatin magnesium tablets) | 2 mg and 4 mg tablets | 2 mg QD | 4 mg (2 to 4 mg/day) |
| Pravastatin Products | | | |
| pravastatin tablets (generic only) | 10 mg, 20 mg, 40 mg, and 80 mg tablets | 40 mg QD (adults and adolescents) 20 mg QD (patients 8 to 13 years old) | 80 mg (10 to 80 mg/day) |
| Rosuvastatin Products | | | |
| Crestor® (rosuvastatin tablets, generic) | 5 mg, 10 mg, 20 mg, and 40 mg tablets | 10 or 20 mg QD | 40 mg (5 to 40 mg) |
| Ezallor Sprinkle™ (rosuvastatin capsules) | 5 mg, 10 mg, 20 mg, and 40 mg capsules | 5 to 20 mg QD | 40 mg (5 to 40 mg) |
| Roszet® (rosuvastatin and ezetimibe tablets, authorized generic) | 5-10 mg, 10-10 mg, 20- 10 mg, and 40-10 mg tablets | <ul style="list-style-type: none"> • One tablet QD • Depends on indication, LDL-C level, and risk of CV events. • For patients switching from co-administration of a statin and ezetimibe: dose is based on an equivalent dose of rosuvastatin and 10 mg of ezetimibe. | 40-10 mg (5-10 mg to 40-10 mg/day) |

Table 1 (continued). Dosing and Availability for the HMG CoA Reductase Inhibitors.¹⁻¹⁴

| Brand (generic/dose form) | Available Formulations | Initial Dose | Maximum Daily Dose (Dosage Range) |
|--|--|-------------------------|--|
| Simvastatin Products | | | |
| Flolipid® (simvastatin oral suspension) | 20 mg/5 mL and 40 mg/5 mL oral suspension (150 mL glass bottles) | 10 mg to 20 mg QD | 80 mg (5 to 80 mg/day) 80 mg has restricted dosing. |
| Vytorin® (simvastatin and ezetimibe tablets, generic) | 10-10 mg tablets 10-20 mg tablets 10-40 mg tablets 10-80 mg tablets | 10-10 mg to 10-20 mg QD | 10-80 mg (10-10 mg to 10-80 mg/day) 10-80 mg has restricted dosing |
| Zocor® (simvastatin tablets, generic) | 5 mg (generic only), 10 mg, 20 mg, 40 mg, and 80 mg tablets | 10 mg to 20 mg QD | 80 mg (5 to 80 mg/day) 80 mg has restricted dosing. |

HMG – Hydroxy-methylglutaryl; CoA – Coenzyme A; QD – Once daily; LDL-C – Low-density lipoprotein cholesterol; CV – Cardiovascular.

Additional Dosing Information

Fluvastatin (generic only) and Fluvastatin extended-release (Lescol XL, generic)

For patients taking cyclosporine or fluconazole, Lescol therapy should not exceed a daily dose of 20 mg twice daily.³

Simvastatin Products

Due to the increased risk of myopathy, including rhabdomyolysis, particularly during the first year of treatment, use of the 80-mg dose of simvastatin should be restricted to patients who have been taking simvastatin 80 mg chronically (e.g., for 12 months or more) without evidence of muscle toxicity.^{13,14,16}

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of HMG-CoA Reductase Inhibitors. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

| Product | Dosage Form | Retail Maximum Quantity per Rx | Home Delivery Maximum Quantity Per Rx |
|--|--|--------------------------------|---------------------------------------|
| Atorvastatin Products | | | |
| Atorvaliq® (atorvastatin oral suspension) | 20 mg/5 mL oral suspension in 150 mL bottles | 600 mL (4 bottles) | 1,800 mL (12 bottles) |
| Lipitor® (atorvastatin tablets, generic) | 10 mg tablets 20 mg tablets 40 mg tablets 80 mg tablets | 30 tablets | 90 tablets |
| atorvastatin and ezetimibe tablets (generic only) Note: Generic atorvastatin and ezetimibe is no longer available. | 10-10 mg tablets 20-10 mg tablets 40-10 mg tablets 80-10 mg tablets | 30 tablets | 90 tablets |

Drug Quantity Limits (continued)

| Product | Dosage Form | Retail Maximum Quantity per Rx | Home Delivery Maximum Quantity Per Rx |
|---|---|--------------------------------|---------------------------------------|
| Fluvastatin Products | | | |
| fluvastatin capsules (generic only) | 20 mg capsules | 30 capsules | 90 capsules |
| | 40 mg capsules | 60 capsules | 180 capsules |
| Lescol® XL (fluvastatin extended-release tablets, generic) | 80-mg extended-release tablets | 30 tablets | 90 tablets |
| Lovastatin Products | | | |
| lovastatin tablets (generic only) | 10 mg tablets | 30 tablets | 90 tablets |
| | 20 mg tablets | 60 tablets | 180 tablets |
| | 40 mg tablets | | |
| Altoprev® (lovastatin extended-release tablets) | 20 mg tablets 40 mg tablets 60 mg tablets | 30 tablets | 90 tablets |
| Pitavastatin Products | | | |
| Livalo® | 1 mg tablets | 30 tablets | 90 tablets |

| | | | |
|---|--|------------|------------|
| (pitavastatin calcium tablets, generic) | 2 mg tablets 4 mg tablets | | |
| Zypitamag® (pitavastatin magnesium tablets) | 2 mg tablets 4 mg tablets | 30 tablets | 90 tablets |
| Pravastatin Products | | | |
| pravastatin tablets (generic only) | 10 mg tablets 20 mg tablets 40 mg tablets 80 mg tablets | 30 tablets | 90 tablets |
| Rosuvastatin Products | | | |
| Crestor® (rosuvastatin tablets, generic) | 5 mg tablets 10 mg tablets 20 mg tablets 40 mg tablets | 30 tablets | 90 tablets |
| Ezallor Sprinkle™ (rosuvastatin capsules) | 5 mg capsules 10 mg capsules 20 mg capsules 40 mg capsules | 30 tablets | 90 tablets |
| Roszet® (rosuvastatin and ezetimibe tablets, authorized generic) | 5-10 mg tablets 10-10 mg tablets 20-10 mg tablets 40-10 mg tablets | 30 tablets | 90 tablets |
| Simvastatin Products | | | |
| Zocor® (simvastatin tablets, authorized generic) | 5 mg tablets (generic only) 10 mg tablets 20 mg tablets 40 mg tablets 80 mg tablets (generic only) | 30 tablets | 90 tablets |
| Vytorin (ezetimibe and simvastatin tablets, generic) | 10-10 mg tablets 10-20 mg tablets 10-40 mg tablets 10-80 mg tablets | 30 tablets | 90 tablets |
| Folipid® (simvastatin oral suspension) | 20 mg/5 mL oral suspension 40 mg/5 mL oral suspension (150 mL glass bottles) | 150 mL | 450 mL |

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Atorvastatin Products

Atorvaliq 20 mg/5 mL oral suspension

No overrides recommended.

Atorvastatin 10 mg tablets (Lipitor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets

AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 240 capsules per dispensing at retail or 720 capsules per dispensing at home delivery..

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Atorvastatin 20 mg tablets (Lipitor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Atorvastatin 40 mg tablets (Lipitor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Atorvastatin 80 mg tablets (Lipitor, generic)

No overrides recommended.

Atorvastatin/ezetimibe 10-10 mg, 20-10 mg, 40-10 mg, and 80-10 mg tablets

No overrides recommended.

Fluvastatin Products

Fluvastatin 20 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

2. If the patient is taking cyclosporine or fluconazole and requires a dose of 20 mg twice daily, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Fluvastatin 40 mg capsules

No overrides recommended.

Fluvastatin 80 extended-release tablets (Lescol XL, generic)

No overrides recommended.

Lovastatin Products

Lovastatin 10 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 240 tablets per dispensing at retail or 720 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Lovastatin 20 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Lovastatin 40 mg tablets

No overrides recommended.

Atoprev 20 mg, 40 mg, and 60 mg tablets

No overrides recommended.

Pitavastatin Products

Pitavastatin 1 mg, 2 mg, and 4 mg tablets (Livalo, generic)

No overrides recommended.

Zypitamag 2 mg and 4 mg tablets

No overrides recommended.

Pravastatin Products

Pravastatin 10 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 240 capsules per dispensing at retail or 720 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 20 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the

requested quantity, not to exceed 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 40 mg tablets

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 80 mg tablets

No overrides recommended.

Rosuvastatin Products

Rosuvastatin 5 mg tablets (Crestor, generic) and Ezallor Sprinkle 5 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 240 tablets/capsules per dispensing at retail or 720 tablets/capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 40 mg per day.

Rosuvastatin 10 mg tablets (Crestor, generic) and Ezallor Sprinkle 10 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 120 tablets/capsules per dispensing at retail or 360 tablets/capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 40 mg per day.

Rosuvastatin 20 mg tablets (Crestor, generic) and Ezallor Sprinkle 20 mg capsules

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 60 tablets/capsules per dispensing at retail or 180 tablets/capsules per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 40 mg per day.

Rosuvastatin 40 mg tablets (Crestor, generic) and Ezallor Sprinkle 40 mg capsules

No overrides recommended.

Rosuvastatin/ezetimibe 5-10 mg, 10-10 mg, 20-10 mg, and 40-10 mg tablets (Roszet, generic)

No overrides recommended.

Simvastatin Products

Simvastatin 5 mg tablets (Zocor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 480 tablets per dispensing at retail or 1,440 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Simvastatin 10 mg tablets (Zocor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 240 tablets per dispensing at retail or 720 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Simvastatin 20 mg tablets (Zocor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

2. If the patient has been taking 80 mg per day in three divided doses (e.g., 20 mg in the morning, 20 mg mid-day, and 40 mg in the evening), for 12 months or more without evidence of muscle toxicity, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.

Simvastatin 40 mg tablets (Zocor, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

Note: This override allows for a quantity sufficient for a dose of up to 80 mg per day.

Simvastatin 80 mg tablets (Zocor, generic)

No overrides recommended.

Ezetimibe and Simvastatin 10-10 mg, 10-20 mg, 10-40 mg, 10-40 mg tablets (Vytorin, generic)

No overrides recommended.

Flolipid 20 mg/5 mL oral suspension

No overrides recommended.

Flolipid 40 mg/5 mL oral suspension

1. If the patient has been taking 80 mg per day for 12 months or more without evidence of muscle toxicity, approve the requested quantity not to exceed 300 mL (2 bottles) per dispensing at retail or 900 mL (6 bottles) per dispensing at home delivery.

REFERENCES

1. Lipitor® tablets [prescribing information]. New York, NY: Pfizer; April 2024.
2. Atorvastatin and ezetimibe tablets [prescribing information]. Morristown, NJ: Althera; January 2021.
3. Fluvastatin capsules [prescribing information]. Parsippany, NJ: Teva; September 2020.
4. Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; November 2023.
5. Lovastatin tablets [prescribing information]. Parsippany, NJ: Teva; September 2020.
6. Altoprev® extended-release tablets [prescribing information]. Zug, Switzerland: Covis; March 2024.
7. Livalo® tablets [prescribing information]. Montgomery, AL: Kowa; September 2024
8. Zypitamag® tablets [prescribing information]. Princeton, NJ: Medicure; January 2024.
9. Pravastatin tablets [prescribing information]. Durham, NC: Accord; March 2025.
10. Crestor® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2024.
11. Ezallor Sprinkle™ capsules [prescribing information]. Cranbury, NJ: Sun; February 2025.
12. Roszet® tablets [prescribing information]. Wilmington, DE: Althera; August 2024.
13. Zocor® tablets [prescribing information]. Jersey City, NJ: Organon; August 2023.
14. Flolipid oral suspension [prescribing information]. Brookville, FL: Salerno; February 2023.
15. Atorvaliq® oral suspension [prescribing information]. Farmville, NC; CMP; April 2024.
16. Vytorin® tablets [prescribing information]. Jersey City, NJ: Organon; March 2024.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|---|-------------|
| Annual Revision | Policy was updated to include the existing quantity limits for simvastatin and ezetimibe tablets (Vytorin, generic). No overrides apply. Pitavastatin 1 mg, 2 mg, and 4 mg tablets (Livalo, generic): Generic to Livalo added to the policy. The same quantity limits apply to the generic as are already in place for the brand product. No overrides apply. | 11/27/2023 |
| Annual Revision | Brand Pravachol and brand Lescol removed from the policy (obsolete). | 12/09/2024 |
| Annual Revision | No criteria changes | 11/21/2025 |

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