



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 [discontinued])
 - 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: 12/09/2024

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Page 1 of 10 - Cigna National Formulary Coverage - Policy:Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors Drug Quantity Management Policy – Per Rx

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) <u>Note:</u> 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 2 mg tablets	30 tablets	90 tablets

(pitavastatin calcium tablets, generic)	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	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
Flolipid® (simvastatin oral suspension)	20 mg/5 mL oral suspension 40 mg/5 mL oral suspension (150 mL glass bottles)	150 mL	450 mL

Hydroxy-Methylglutaryl-Coenzyme A Reductase Inhibitors Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(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.

Altoprev 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; December 2022.
2. Atorvastatin and ezetimibe tablets [prescribing information]. Morristown, NJ: Althera; January 2021.
3. Fluvastatin capsules [prescribing information]. Parsippany, NJ: Teva; August 2020.
4. Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; November 2023.
5. Lovastatin tablets [prescribing information]. Parsippany, NJ: Teva; August 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; January 2024.
10. Crestor® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2024.
11. Ezallor Sprinkle™ capsules [prescribing information]. Cranbury, NJ: Sun; August 2023.
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

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