



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)
- Crestor[®] (rosuvastatin tablets – AstraZeneca, generic)
- Ezallor Sprinkle[™] (rosuvastatin capsules – Sun)
- Flolipid[®] (simvastatin oral suspension – Salerno)
- Lescol[®] (fluvastatin capsules – Novartis, generic)
- Lescol[®] XL (fluvastatin extended-release tablets – Novartis, generic)
- Lipitor[®] (atorvastatin tablets – Pfizer, generic)
- Livalo[®] (pitavastatin calcium tablets – Kowa, generic)
- lovastatin tablets (generic only)
- Pravachol[®] (pravastatin tablets – Bristol-Myers Squibb, generic)
- Roszet[®] (rosuvastatin and ezetimibe tablets – Althera, generic)
- Vytorin[®] (simvastatin and ezetimibe tablets – Organon/Merck, generic)
- Zocor[®] (simvastatin tablets – Organon/Merck, generic)
- Zypitamag[®] (pitavastatin magnesium tablets – Medicure)

REVIEW DATE: 11/27/2023

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Indications

HMG-CoA reductase inhibitors (HMGs, statins) have an important role in the management of various lipid disorders and in reducing cardiovascular (CV) events.¹⁻¹⁶ The impact is attributed to a large part in reducing low-density lipoprotein cholesterol (LDL-C), which has been identified as a major risk factor for heart disease. HMGs also impact other lipid parameters which are beneficially modified (e.g., total-cholesterol, triglycerides [TGs]). This class of medications has been very well-studied with favorable long-term outcome data for many HMGs. Related guidelines consider HMGs first-line agents; HMGs may be given with or without other medications (e.g., ezetimibe) and some HMG products are combined with other agents. Although specific indications differ, HMGs have proven to be beneficial in reducing CV morbidity and mortality in many outcome trials in various populations. Some agents are also FDA-approved for use in children with genetic that have inherited genetic disorders that cause extremely elevated LDL-C levels (e.g., heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia). Atorvastatin and rosuvastatin and categorized as high-potency statins and lead to LDL-C reductions of 60% and 63%, respectively, at the maximum doses. Simvastatin, lovastatin, fluvastatin, pravastatin and pitavastatin led to LDL-C reductions of 47%, 41% to 42%, 35% to 36%, 37%, and 44%, respectively, at maximum doses. Lowering of LDL-C by 1% leads to an approximate 1% reduction in the risk of atherosclerotic cardiovascular disease (ASCVD). HMGs represent a cornerstone in the management of hyperlipidemias.

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			
Lescol® (fluvastatin capsules, generic) <u>Note:</u> Brand Lescol no longer available.	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			
Pravachol® (pravastatin tablets, generic) <u>Note:</u> Brand Pravachol no longer available.	10 mg, 20 mg, 40 mg, and 80 mg tablets	40 mg QD	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, generic)	5-10 mg, 10-10 mg, 20-10 mg, and 40-10 mg tablets	<ul style="list-style-type: none"> • 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 mg/10 mg to 40 mg/10 mg per 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			
Folipid® (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, 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 (Lescol, generic) 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			
Lescol® (fluvastatin capsules, generic) <u>Note:</u> Brand Lescol no longer available.	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 40 mg tablets	60 tablets	180 tablets
Altoprev® (lovastatin extended-release tablets)	20 mg tablets 40 mg tablets 60 mg tablets	30 tablets	90 tablets
Pitavastatin Products			
Livalo® (pitavastatin calcium tablets, generic)	1 mg tablets	30 tablets	90 tablets
	2 mg tablets 4 mg tablets		
Zypitamag® (pitavastatin magnesium tablets)	2 mg tablets 4 mg tablets	30 tablets	90 tablets
Pravastatin Products			
Pravachol® (pravastatin tablets, generic) Note: Brand Pravachol no longer available.	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, 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 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 exceptions 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 exception 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 exception 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Atorvastatin 80 mg tablets (Lipitor, generic)

No exceptions recommended.

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

No exceptions recommended.

Fluvastatin Products

Fluvastatin 20 mg capsules (Lescol [brand no longer available], 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 exception 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 (Lescol [brand no longer available], generic)

No exceptions recommended.

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

No exceptions 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 exception 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Lovastatin 40 mg tablets

No exceptions recommended.

Altoprev 20 mg, 40 mg, and 60 mg tablets

No exceptions recommended.

Pitavastatin Products

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

No exceptions recommended.

Zypitamag 2 mg and 4 mg tablets

No exceptions recommended.

Pravastatin Products

Pravastatin 10 mg tablets (Pravachol [brand no longer available], 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 20 mg tablets (Pravachol [brand no longer available], 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 40 mg tablets (Pravachol [brand no longer available], 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Pravastatin 80 mg tablets (Pravachol [brand no longer available], generic)

No exceptions 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 exception 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 exception 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 exception 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 exceptions recommended.

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

No exceptions 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 exception 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 exception 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 exception 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 exception allows for a quantity sufficient for a dose of up to 80 mg per day.

Simvastatin 80 mg tablets (Zocor, generic)

No exceptions recommended.

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

No exceptions recommended.

Flolipid 20 mg/5 mL oral suspension

No exceptions 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. Lescol® capsules [prescribing information]. East Hanover, NJ: Novartis; August 2017.
4. Lescol® XL extended-release tablets [prescribing information]. East Hanover, NJ: Novartis; September 2020.
5. Lovastatin tablets [prescribing information]. Parsippany, NJ: Teva; August 2020.
6. Altoprev® extended-release tablets [prescribing information]. Zug, Switzerland: Covis; September 2020.
7. Livalo® tablets [prescribing information]. Montgomery, AL: Kowa; November 2022.
8. Zypitamag® tablets [prescribing information]. Princeton, NJ: Medicure; September 2020.
9. Pravachol® tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2022.
10. Crestor® tablets [prescribing information]. Wilmington, DE: AstraZeneca; July 2023.
11. Ezallor Sprinkle™ capsules [prescribing information]. Cranbury, NJ: Sun; August 2023.
12. Roszet® tablets [prescribing information]. Morristown, NJ: Althera; March 2021.
13. Zocor® tablets [prescribing information]. Jersey City, NJ: Organon; August 2023.
14. Flolipid oral suspension [prescribing information]. Brookville, FL: Salerno; September 2020.
15. Atorvaliq® oral suspension [prescribing information]. Farmville, NC; CMP; February 2023.
16. Vytorin® tablets [prescribing information]. Jersey City, NJ: Organon; June 2022.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>The approval duration was changed from 3 years to 1 year.</p> <p>Zypitamag 1 mg tablets: The Zypitamag 1 mg tablets were removed from the policy (obsolete).</p> <p>Policy was updated to include the existing quantity limits when the product is obtained via home delivery.</p>	11/16/2022
Selected Revision	<p>Atorvastatin and ezetimibe tablets, generic: New quantity limits added to the policy. No exceptions apply.</p>	02/01/2023
Selected Revision	<p>Atorvaliq: New quantity limits added to the policy. No exceptions apply.</p>	03/29/2023
Annual Revision	<p>Policy was updated to include the existing quantity limits for simvastatin and ezetimibe tablets (Vytorin, generic). No exceptions apply.</p> <p>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 exceptions apply.</p>	11/27/2023

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