

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)
- 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)
- lovastatin tablets (generic only)
- Pravachol[®] (pravastatin tablets – Bristol-Myers Squibb, generic)
- Roszet[®] (rosuvastatin and ezetimibe tablets – Althera, generic)
- Zocor[®] (simvastatin tablets – Organon/Merck, generic)
- Zypitamag[®] (pitavastatin magnesium tablets – Medicure)

REVIEW DATE: 11/16/2022; selected revision 02/01/2023

OVERVIEW

Indications

Atorvastatin Products

Atorvastatin (Lipitor, generic) is indicated as an adjunct therapy to diet:¹

- To reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) levels in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson types IIa and IIb).
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.
- For the treatment of patients with elevated serum TG levels (Fredrickson type IV).
- To reduce elevated TG in adults with primary dysbetalipoproteinemia (Fredrickson type III).
- As an adjunct to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with HeFH if after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥ 190 mg/dL or LDL-C remains ≥ 160 mg/dL and there is a positive family history of premature cardiovascular (CV) disease or ≥ 2 other CV disease risk factors are present in the pediatric patient.
- For prevention of CV disease in adults without clinically evident coronary heart disease (CHD), but with multiple risk factors for CHD such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, to reduce the risk to myocardial infarction (MI), stroke, revascularization procedures and angina.
- In patients with type 2 diabetes and without clinically evident CHD, but with multiple risk factors for CHD such as retinopathy, albuminuria, smoking or hypertension to reduce the risk of MI and the risk of stroke.

- In patients with clinically evident CHD it is indicated to reduce the risk of non-fatal MI, fatal and non-fatal stroke, risk of revascularization procedures, risk of hospitalization for congestive heart failure (CHF), and the risk of angina.

Atorvastatin and ezetimibe (generic only) is indicated:²

- As an adjunct to diet to reduce elevated Total-C, LDL-C, Apo B, non-HDL-C, and TG levels and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed dyslipidemia.
- As an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable, to reduce elevated Total-C and LDL-C in patients with HoFH.

Fluvastatin Products

Fluvastatin (Lescol [brand no longer available], generic) and fluvastatin extended-release (Lescol XL, generic) are indicated as an adjunct to diet:^{3,4}

- To reduce elevated total-C, LDL-C, TG, and apo B, and to increase HDL-C in adults with primary hypercholesterolemia and mixed dyslipidemia.
- To reduce the risk of undergoing coronary revascularization procedures in patients with clinically evident CHD.
- To slow the progression of atherosclerosis in patients with CHD.
- To reduce elevated total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 16 years of age, with heterozygous familial hypercholesterolemia (HeFH) after failing an adequate trial of diet therapy.

Lovastatin Products

Lovastatin (generic only) is indicated as an adjunct to diet:⁵

- In patients at risk for atherosclerotic vascular disease due to hypercholesterolemia.
- For the reduction of elevated lower total-C and LDL-C in patients with primary hypercholesterolemia (Types IIa and IIb), when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacological measures has been inadequate.
- For use in the primary prevention of CHD: in patients without symptomatic CV disease who have average to moderately elevated total-C and LDL-C and below average HDL-C, to reduce the risk of MI, unstable angina, and coronary revascularization procedures.
- To slow the progression of coronary atherosclerosis in patients with CHD as part of a treatment strategy to lower total-C and LDL-C to target levels.
- For use in adolescent boys and girls who are at least one year post-menarche and who are 10 to 17 years of age as an adjunct to diet to reduce total-C, LDL-C, and Apo B levels in those with HeFH after an adequate trial of diet therapy and the following findings are present: 1) LDL-C remains > 189 mg/dL or 2) LDL-C remains > 160 mg/dL and there is a positive family history of premature CV disease or there are two or more other CV disease risk factors present.

Atoprev is indicated:⁶

- To reduce the risk of MI, unstable angina, and coronary revascularization procedures in patients without symptomatic CHD, but who are at high risk.
- To slow the progression of coronary atherosclerosis in patients with CHD as part of a treatment strategy to lower total-C and LDL-C target levels. (Note: indication based on data with immediate-release lovastatin).
- As an adjunct to diet for the reduction of elevated total-C, LDL-C, Apo B, and TGs, and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and mixed dyslipidemia (Fredrickson types IIa and IIb).

Pitavastatin Products

Livalo is indicated as an adjunct to diet:⁷

- To reduce elevated Total-C, LDL-C, Apo B, and TG, and to increase HDL-C in adults with primary hyperlipidemia or mixed dyslipidemia.
- To reduce elevated Total-C, LDL-C, and Apo B in pediatric patients ≥ 8 years of age with HeFH to reduce total-C, LDL-C, and ApoB.

Zypitamag is indicated:⁸

- As an adjunct to diet in adults with primary hyperlipidemia and mixed dyslipidemia to reduce elevated Total-C, LDL-C, Apo B, and TG, and to increase HDL-C.

Pravastatin Products

Pravastatin (Pravachol [brand no longer available], generic) is indicated as an adjunct to diet:⁹

- To reduce elevated total-C, LDL-C, Apo B, and TG levels, and to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia.
- To reduce elevated serum TG levels in patients with hypertriglyceridemia.
- For the treatment of patients with primary dysbetalipoproteinemia who are not responding to diet.
- To reduce the risk of MI, revascularization, and CV mortality in hypercholesterolemic patients without clinically evident CHD.
- To reduce the risk of total mortality by reducing coronary death, MI, revascularization, stroke/transient ischemic attack (TIA), and the progression of coronary atherosclerosis in patients with clinically evident CHD.
- For the treatment of HeFH in children and adolescents aged ≥ 8 years if after an adequate trial of diet therapy.

Rosuvastatin Products

Rosuvastatin (Crestor, generic) is indicated:¹⁰

- As an adjunct to diet to reduce elevated Total-C, LDL-C, Apo B, non-HDL-C, and TG levels and to increase HDL-C in adults with primary hyperlipidemia or mixed dyslipidemia.
- As an adjunct to diet to treat adults with hypertriglyceridemia.
- As an adjunct to diet for the treatment of adults with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia).
- As an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable, to reduce LDL-C, Total-C, and Apo B in adults with HoFH.
- As adjunctive therapy to slow the progression of atherosclerosis in adults as a part of a treatment strategy to lower Total-C and LDL-C to target levels.
- For the primary prevention of CV disease in patients without clinically evident CHD, but with an increased risk of CV disease based on age (≥ 50 years of age in men and ≥ 60 years of age in women), high-sensitivity C-reactive protein (hsCRP) ≥ 2 mg/L, and the presence of at least one additional CV disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature CHD to reduce the risk of stroke, reduce the risk of MI, and reduce the risk of arterial revascularization procedures.
- As an adjunct to diet to reduce Total-C, LDL-C, and Apo B levels in children and adolescents 8 to 17 years of age with HeFH if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature CV disease or two or more other CV disease risk factors.
- To reduce LDL-C, Total-C, non-HDL-C and Apo B in children and adolescents 7 to 17 years of age with HoFH, either alone or with other lipid-lowering treatments (e.g., LDL apheresis).

Ezallor Sprinkle is indicated:¹¹

- To reduce LDL-C, Total-C, and Apo B in adults with HoFH, either alone or with other lipid-lowering treatments (e.g., LDL apheresis).
- As an adjunct to diet to treat adults with hypertriglyceridemia.
- As an adjunct to diet for the treatment of adults with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia).

Rosuvastatin/ezetimibe (Roszet, authorized generic) is indicated:¹²

- As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce LDL-C.
- Alone or as an adjunct to other LDL-C lowering therapies in patients with HoFH to reduce LDL-C.

Simvastatin Products

Simvastatin (Zocor, generic) and Flolipid are indicated as follows:^{13,14}

- In patients at high risk of coronary events due to existing CHD, diabetes, peripheral vessel disease, history of stroke and other cerebrovascular disease, it is indicated to:
 - Reduce the risk of total mortality by reducing CHD deaths;
 - Reduce the risk of non-fatal MI and stroke;
 - Reduce the need for coronary and non-coronary revascularization procedures.
- In hyperlipidemia to:
 - Reduce elevated total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson types IIb);
 - Reduce elevated TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia);
 - Reduce elevated TG and very low-density lipoprotein cholesterol (VLDL-C) in patients with primary dysbetalipoproteinemia (Fredrickson type III hyperlipidemia);
 - Reduce total-C and LDL-C in patients with HoFH as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.
- In adolescent boys and girls who are at least 1 year post-menarche and aged 10 to 17 years as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in those with HeFH after an adequate trial of diet therapy and the following findings are present: 1) LDL-C remains ≥ 190 mg/dL or 2) LDL-C remains ≥ 160 mg/dL and there is a positive family of premature CV disease or there are \geq two other CV disease risk factors present.

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 Dose (Dosage Range)
Atorvastatin Products			
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)	10-10 mg, 20-10mg, 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)	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	10 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)
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.
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

Flolipid and Simvastatin (Zocor, generic)

The recommended daily dose for patients with HoFH is 40 mg per day in the evening.^{13,14} 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.

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.

Automation: None.

Drug Quantity Limits

Product	Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity Per Rx
Atorvastatin Products			
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)	10-10 mg tablets 20-10 mg tablets 40-10 mg tablets 80-10 mg tablets	30 tablets	90 tablets
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
Altoprev® (lovastatin extended-release tablets)	20 mg tablets 40 mg tablets 60 mg tablets	30 tablets	90 tablets
Pitavastatin			
Livalo® (pitavastatin calcium tablets)	1 mg tablets 2 mg tablets 4 mg tablets	30 tablets	90 tablets
Zypitamag® (pitavastatin magnesium tablets)	2 mg tablets 4 mg tablets	30 tablets	90 tablets

Drug Quantity Limits (continued)

Product	Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity Per Rx
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
Flolipid® (simivastatin oral suspension)	20 mg/5 mL oral suspension 40 mg/5 mL oral suspension (150 mL glass bottles)	150 mL	450 mL

CRITERIA

Atorvastatin Products

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 (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 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 (Lescol [brand no longer available], generic)

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

Livalo 1 mg, 2 mg, and 4 mg tablets

No overrides recommended.

Zypitamag 2 mg and 4 mg tablets

No overrides 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 override 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 override 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 override 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 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.

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; November 2020.
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; September 2020.
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; September 2020.
11. Ezallor Sprinkle™ capsules [prescribing information]. Cranbury, NJ: Sun; September 2020.
12. Roszet® tablets [prescribing information]. Morristown, NJ: Althera; March 2021.
13. Zocor® tablets [prescribing information]. Jersey City, NJ: Organon; May 2022.
14. Flolipid oral suspension [prescribing information]. Brookville, FL: Salerno; September 2020.

HoFH – Homozygous familial hypercholesterolemia.