

Statin Step Therapy Program Summary

POLICY REVIEW CYCLE

Effective Date
09-01-2024

Date of Origin

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Altoprev® (lovastatin ER) Tablet	Adjunctive therapy to diet to: <ul style="list-style-type: none"> Reduce the risk of Myocardial infarction (MI), revascularization procedures, and angina in patients without coronary heart disease (CHD), but with multiple risk factors. Slow the progression of coronary atherosclerosis in patients with CHD as part of a treatment strategy to lower Total-C and low-density lipoprotein cholesterol (LDL-C). Reduce elevated Total-C, LDL-C, Apo B, and triglyceride (TG) levels and increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. <p>Limitations of use: has not been studied in Fredrickson Types I, III, and V dyslipidemias.</p>		1
Atorvaliq® (atorvastatin) Oral suspension	To reduce the risk of: <ul style="list-style-type: none"> MI, stroke, revascularization procedures, and angina in adults with multiple risk factors for CHD but without clinically evident CHD. MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD. Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD. <p>As an adjunct to diet to reduce LDL-C in:</p> <ul style="list-style-type: none"> Adults with primary hyperlipidemia. Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). <p>As an adjunct to other LDL-C-lowering therapies to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH).</p> <p>As an adjunct to diet for the treatment of adults with:</p> <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 		16

Agent(s)	FDA Indication(s)	Notes	Ref#
Crestor® (rosuvastatin) * Tablet	<p>To reduce the risk of stroke, MI, and arterial revascularization procedures in adults without established CHD who are at increased risk of cardiovascular (CV) disease based on age, hsCRP greater than or equal to 2 mg/L, and at least one additional CV risk factor.</p> <p>As an adjunct to diet to:</p> <ul style="list-style-type: none"> Reduce LDL-C in adults with primary hyperlipidemia. Reduce LDL-C and slow the progression of atherosclerosis in adults. Reduce LDL-C in adults and pediatric patients aged 8 years and older with HeFH. <p>As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with HoFH.</p> <p>As an adjunct to diet for the treatment of adults with:</p> <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 	*generic available	2
Ezallor Sprinkle™ (rosuvastatin) Capsule	<p>As an adjunct to diet to:</p> <ul style="list-style-type: none"> Reduce LDL-C in adults with primary hyperlipidemia. Reduce LDL-C and slow the progression of atherosclerosis in adults. Reduce LDL-C in adults and pediatric patients aged 8 years and older with HeFH. <p>As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 7 years and older with HoFH.</p> <p>As an adjunct to diet for the treatment of adults with:</p> <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 		3
Flolipid™ (simvastatin) Oral suspension	<p>Adjunctive therapy to diet to:</p> <ul style="list-style-type: none"> Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal MI, stroke, and the need for revascularization procedures in patients at high risk of coronary events. Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia. Reduce total-C and LDL-C in adult patients with HoFH. 		4

Agent(s)	FDA Indication(s)	Notes	Ref#
	<ul style="list-style-type: none"> Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with HeFH after failing an adequate trial of diet therapy. <p>Limitations of Use: simvastatin has not been studied in Fredrickson Types I and V dyslipidemias.</p>		
Lescol XL® (fluvastatin ER)* Tablet	<p>To reduce the risk of undergoing coronary revascularization procedures and slow the progression of coronary atherosclerosis in adults with clinically evident CHD.</p> <p>As an adjunct to diet to:</p> <ul style="list-style-type: none"> To reduce LDL-C in adults with primary hyperlipidemia. To reduce LDL-C in adults and pediatric patients 10 years of age and older with HeFH who require 80 mg of fluvastatin daily. 	*generic available	5
Lipitor® (atorvastatin)* Tablet	<p>To reduce the risk of:</p> <ul style="list-style-type: none"> MI, stroke, revascularization procedures, and angina in adults with multiple risk factors for CHD but without clinically evident CHD. MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD. Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (CFH), and angina in adults with clinically evident CHD. <p>As an adjunct to diet to reduce LDL-C in:</p> <ul style="list-style-type: none"> Adults with primary hyperlipidemia. Adults and pediatric patients aged 10 years and older with HeFH. <p>As an adjunct to other LDL-C-lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with HoFH.</p> <p>As an adjunct to diet for the treatment of adults with:</p> <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 	*generic available	6
Livalo® (pitavastatin)* Tablet	<p>As an adjunct to diet to reduce LDL-C in:</p> <ul style="list-style-type: none"> Adults with primary hyperlipidemia. Adults and pediatric patients aged 8 years and older with HeFH. 	*generic available	7
Pravachol® (pravastatin)* Tablet	<p>To reduce the risk of MI, myocardial revascularization procedures, and cardiovascular mortality in adults with elevated LDL-C without clinically evident CHD.</p> <p>To reduce the risk of coronary death, MI, myocardial revascularization procedures, stroke or transient ischemic attack (TIA), and slow the</p>	*generic available	8

Agent(s)	FDA Indication(s)	Notes	Ref#
	<p>progression of coronary atherosclerosis in adults with clinically evident CHD.</p> <p>As an adjunct to diet:</p> <ul style="list-style-type: none"> To reduce LDL-C in adults with primary hyperlipidemia. To reduce LDL-C in pediatric patients ages 8 years and older with HeFH. For the treatment of adults with: <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 		
Roszet® (ezetimibe-rosuvastatin) Tablet	<p>As an adjunct to diet in adults with primary non-familial hyperlipidemia to reduce LDL-C.</p> <p>Alone or as an adjunct to other LDL-C lowering therapies in adults with HoFH to reduce LDL-C.</p>		12
Vytorin® (ezetimibe-simvastatin)* Tablet	<p>As an adjunct to diet to reduce elevated LDL-C:</p> <ul style="list-style-type: none"> In adults with primary hyperlipidemia. In adults and pediatric patients aged 10 years and older with HeFH. <p>As an adjunct to other LDL-C-lowering therapies to reduce elevated LDL-C in adults with HoFH.</p>	*generic available	10
Zocor® (simvastatin)* Tablet	<p>To reduce the risk of total mortality by reducing risk of CHD death, non-fatal MI and stroke, and the need for coronary and non-coronary revascularization procedures in adults with established CHD, CVD, peripheral vascular disease, and/or diabetes, who are at high risk of CHD events.</p> <p>As an adjunct to diet to reduce LDL-C:</p> <ul style="list-style-type: none"> In adults with primary hyperlipidemia. In adults and pediatric patients aged 10 years and older with HeFH. <p>As an adjunct to other LDL-C-lowering therapies to reduce LDL-C in adults with HoFH.</p> <p>As an adjunct to diet for the treatment of adults with:</p> <ul style="list-style-type: none"> Primary dysbetalipoproteinemia. Hypertriglyceridemia. 	*generic available	9
Zypitamag® (pitavastatin) Tablet	<p>As an adjunct to diet to reduce LDL-C in adults with primary hyperlipidemia.</p>		11

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

CLINICAL RATIONALE

<p>Statins</p>	<p>Among lipid-lowering drugs, statins are the cornerstone of low-density lipoprotein cholesterol (LDL-C) lowering therapy, in addition to healthy lifestyle interventions. Statins are recommended as first-line treatment to prevent atherosclerotic cardiovascular disease events (ASCVD). Both high intensity and medium intensity statin therapy reduce primary and secondary ASCVD events.(14)</p> <p>The most recent 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the management of Blood Cholesterol states that clinical atherosclerotic cardiovascular disease (ASCVD) includes the following, all of atherosclerotic origin:(14)</p> <ul style="list-style-type: none"> • Acute coronary syndrome (ACS) • History of myocardial infarction (MI) • Stable or unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack (TIA) • Peripheral artery disease (PAD) including aortic aneurysm
<p>Safety</p>	<p>Altoprev is contraindicated in the following conditions:(1)</p> <ul style="list-style-type: none"> • Concomitant administration of strong CYP3A inhibitors • Concomitant administration of erythromycin • Active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels • Pregnancy • Lactation <p>Atorvaliq, Crestor, Ezallor Sprinkle, Lescol XL, Lipitor, Pravachol, Roszet, are contraindicated in patients with:(2,3,5,6,8,12,16)</p> <ul style="list-style-type: none"> • Acute liver failure or decompensated cirrhosis • Hypersensitivity to any excipients in the product <p>Flolipid is contraindicated in the following conditions:(4)</p> <ul style="list-style-type: none"> • Concomitant administration of strong CYP3A4 inhibitors • Concomitant administration of gemfibrozil, cyclosporine, or danazol • Hypersensitivity to any component of this medication • Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels • Women who are pregnant or may become pregnant. • Nursing mothers. <p>Livalo and Zypitamag are contraindicated in the following conditions:(7,11)</p> <ul style="list-style-type: none"> • Concomitant use of cyclosporine • Acute liver failure or decompensated cirrhosis • Hypersensitivity to any excipients in the product <p>Vytorin and Zocor are contraindicated in the following conditions:(9,10)</p> <ul style="list-style-type: none"> • Concomitant use of strong CYP3A4 inhibitors • Concomitant use of cyclosporine, danazol, or gemfibrozil • Acute liver failure or decompensated cirrhosis

	<ul style="list-style-type: none"> Hypersensitivity to any excipients in the product
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REFERENCES

Number	Reference
1	Altoprev prescribing information. Covis Pharma. September 2020.
2	Crestor prescribing information. AstraZeneca. July 2023.
3	Ezallor Sprinkle prescribing information. Sun Pharmaceutical Industries, Inc. August 2023.
4	Flolipid prescribing information. Salerno Pharmaceuticals LP. September 2020.
5	Lescol XL prescribing information. Sandoz Inc. November 2023.
6	Lipitor prescribing information. Pfizer Inc. December 2022.
7	Livalo prescribing information. Kowa Pharmaceuticals America, Inc. January 2024.
8	Pravachol prescribing information. Bristol-Myers Squibb Company. May 2022.
9	Zocor prescribing information. Organon LLC. August 2023.
10	Vytorin prescribing information. Organon LLC. February 2024.
11	Zypitamag prescribing information. Medicure. January 2024.
12	Roszet prescribing information. Althera Pharmaceuticals LLC. March 2021.
13	Reference no longer used.
14	Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APHA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. <i>Circulation</i> . 2019;139(25). doi:10.1161/cir.0000000000000625
15	Reference no longer used.
16	Atorvaliq prescribing information. CMP Pharma, Inc. February 2023.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Altoprev	lovastatin tab er	20 MG ; 40 MG ; 60 MG	M ; N ; O	N		
Atorvaliq	atorvastatin calcium susp	20 MG/5ML	M ; N ; O	N		
Ezallor sprinkle	rosuvastatin calcium sprinkle cap	10 MG ; 20 MG ; 40 MG ; 5 MG	M ; N ; O	N		
Flolipid	simvastatin susp	20 MG/5ML ; 40 MG/5ML	M ; N ; O	N		
Roszet	ezetimibe-rosuvastatin calcium tab	10-10 MG ; 10-20 MG ; 10-40 MG ; 10-5 MG	M ; N ; O	M ; N		
Zypitamag	pitavastatin magnesium tab	2 MG ; 4 MG	M ; N ; O	N		

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Altoprev	lovastatin tab er	20 MG ; 40 MG ; 60 MG	Commercial ; HIM ; ResultsRx
Atorvaliq	atorvastatin calcium susp	20 MG/5ML	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Ezallor sprinkle	rosuvastatin calcium sprinkle cap	10 MG ; 20 MG ; 40 MG ; 5 MG	Commercial ; HIM ; ResultsRx
Flolipid	simvastatin susp	20 MG/5ML ; 40 MG/5ML	Commercial ; HIM ; ResultsRx
Roszet	ezetimibe-rosuvastatin calcium tab	10-10 MG ; 10-20 MG ; 10-40 MG ; 10-5 MG	Commercial ; HIM ; ResultsRx
Zypitamag	pitavastatin magnesium tab	2 MG ; 4 MG	Commercial ; HIM ; ResultsRx

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
Step Therapy		
	TARGET AGENT(S)	PREREQUISITE AGENT(S)
	Altoprev (lovastatin ER) Atorvaliq (atorvastatin oral suspension) Ezallor Sprinkle (rosuvastatin) Flolipid (simvastatin oral suspension) Roszet, Ezetimibe/Rosuvastatin Zypitamag (pitavastatin)	Any generic statin or statin combination
	*generic available	
	Target Agent(s) will be approved when ONE of the following is met: 1. The patient has a medication history of use in the past 90 days, intolerance or hypersensitivity to ONE prerequisite agent OR 2. The patient has an FDA labeled contraindication to ALL prerequisite agents	
	Length of approval: 12 months	