TEXAS Health and Human Services

Medicaid Drug Use Criteria

Hydroxy-Methylglutaryl Coenzyme A (HMG-CoA) Reductase Inhibitors (Statins)

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Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.

Medications listed in the tables and non-FDA approved indications included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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1 Dosage

1.1 Adults

HMG-CoA reductase inhibitors, or statins, are lipid-lowering agents that competitively inhibit HMG-CoA reductase, the enzyme that catalyzes cholesterol biosynthesis. Inhibiting this enzyme results in decreases in total cholesterol, low density lipoprotein cholesterol (LDL-C), triglycerides (TG) and apoprotein B (Apo B), increases in high density lipoprotein cholesterol (HDL-C), as well as increases in the number of LDL receptors on hepatic and extrahepatic tissues. Clinical and epidemiologic studies have documented that low HDL-C, high LDL-C and elevated TG augment atherosclerosis development and are risk factors for cardiovascular disease, while higher HDL-C levels and lower LDL-C concentrations are associated with reduced cardiovascular risk.[1-4, 6-17]

Statins are FDA-approved to manage hyperlipidemia (including hypercholesterolemia, mixed dyslipidemia, hypertriglyceridemia, and primary dysbetalipoproteinemia) in adults, treat homozygous familial hypercholesterolemia in adults, reduce the risk of coronary heart disease mortality and cardiovascular events in patients at high risk for coronary events, slow the progression of coronary atherosclerosis in patients with coronary artery disease by reducing total cholesterol and LDL-C levels, provide primary prevention of coronary artery disease in patients with risk factors for coronary artery disease but without symptomatic cardiovascular disease, promote secondary prevention of coronary events in patients with cardiovascular disease, and treat adolescents with heterozygous familial hypercholesterolemia unresponsive to diet therapy. [1-4, 6-17] Pitavastatin magnesium (Zypitamag®) has recently been approved for use in primary lipidemia and mixed dyslipidemia and may have fewer cytochrome P440 interactions based on its formulation [16]; rosuvastain sprinkle capsules (Ezallor Sprinkle™) have been FDA-approved to manage hypertriglyceridemia, primary dysbetalipoproteinemia, and homozygous familial hypercholesterolemia in adults. [17]

Statin combination therapies are FDA-approved to manage primary hyperlipidemia/mixed dyslipidemia and homozygous familial hypercholesterolemia (Vytorin®) when monotherapy is deemed inadequate. Caduet® is FDA-approved in those patients requiring both amlodipine and atorvastatin. [1-4, 18, 19]

Higher statin doses may be necessary in patients who respond poorly to initial prescribed amounts. Doses may be escalated incrementally every four weeks at minimum, based on patient need and tolerance, to the maximum recommended dose. However, the FDA now recommends limiting use of the highest simvastatin dose (80 mg) to only those patients who have been taking the dose for 12 months or more without evidence of myopathy, due to greater risks for muscle injury compared to lower simvastatin doses or other statins.[1-4, 14, 15]

Recommended adult statin maintenance doses as mono- and combination therapy should not exceed the maximum doses listed in Tables 1 and 2.

Table 1. HMG-CoA Reductase Inhibitor Monotherapy – Maximum Recommended Adult Dosages[1-4, 6-17]

Drug	Dosage Form / Strength	Maximum Recommended Dosage
atorvastatin (Lipitor®, generic)	10 mg, 20 mg, 40 mg, 80 mg tablets	80 mg once daily concurrent administration with nelfinavir: 40 mg once daily concurrent administration with itraconazole, clarithromycin, saquinavir plus ritonavir, darunavir plus ritonavir, or fosamprenavir alone or in combination with ritonavir, elbasvir plus grazoprevir, letermovir: 20 mg once daily
fluvastatin (generics, Lescol® XL, generics)	20 mg, 40 mg capsules; 80 mg extended-release tablets	80 mg once daily, as single dose or two divided doses concurrent administration with cyclosporine, fluconazole: do not exceed 20 mg twice daily
lovastatin (generics)	10 mg, 20 mg, 40 mg tablets	80 mg once daily with evening meal concurrent administration with amiodarone: 40 mg once daily with evening meal concurrent administration with danazol, diltiazem, or verapamil: 20 mg once daily with evening meal
lovastatin (Altoprev®)	20 mg, 40 mg, 60 mg extended-release tablets	60 mg once daily at bedtime concurrent administration with amiodarone: 40 mg once daily at bedtime concurrent administration with danazol, diltiazem, or verapamil: 20 mg once daily at bedtime
pitavastatin calcium (Livalo®)	1 mg, 2 mg, 4 mg tablets	4 mg once daily concurrent administration with rifampin: 2 mg once daily concurrent administration with erythromycin: 1 mg once daily

Drug	Dosage Form / Strength	Maximum Recommended Dosage
pitavastatin magnesium (Zypitamag™)	1 mg, 2 mg, 4 mg tablets	4 mg once daily concurrent administration with rifampin: 2 mg once daily concurrent administration with erythromycin: 1 mg once daily
pravastatin (Pravachol®, generics)	10 mg, 20 mg 40 mg, 80 mg tablets	80 mg once daily concurrent administration with immunosuppressives (e.g., cyclosporine): 20 mg once daily concurrent administration with clarithromycin: 40 mg once daily
rosuvastatin (Crestor®, generics)	5 mg, 10 mg, 20 mg, 40 mg tablets	40 mg once daily concurrent administration with gemfibrozil, lopinavir/ritonavir, or atazanavir/ritonavir: 10 mg once daily concurrent administration with cyclosporine: 5 mg once daily
rosuvastatin (Ezallor Sprinkle™)	10 mg, 20 mg, 40 mg sprinkle capsules	40 mg once daily concurrent administration with gemfibrozil, lopinavir/ritonavir, or atazanavir/ritonavir: 10 mg once daily concurrent administration with cyclosporine: 5 mg once daily
simvastatin (Zocor®, FloLipid®, tablet generics)	5 mg, 10 mg, 20 mg, 40 mg, 80 mg tablets; 20 mg/5 mL, 40 mg/5 mL suspension	40 mg once daily in evening for most patients* concurrent administration with amiodarone, amlodipine, or ranolazine: 20 mg once daily in evening concurrent administration with verapamil, diltiazem, or dronedarone: 10 mg once daily in evening concurrent lomitapide: simvastatin dose should be reduced by 50%; simvastatin dose should not exceed 20 mg/day for most patients prescribed lomitapide concurrently (40 mg/day in patients on 80 mg/day dose for at least 1 year) *80 mg dose restricted to those patients chronically maintained on 80 mg without evidence of myopathy

Table 2. HMG-CoA Reductase Inhibitor Combination Therapy – Maximum Recommended Adult Dosages[1-4, 18, 19]

Drug	Dosage Form / Strength	Maximum Recommended Dosage
amlodipine/atorvastatin (Caduet®, generics)	2.5 mg/10 mg, 2.5 mg/20 mg, 2.5 mg/40 mg, 5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 5 mg/80 mg, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg tablets	10 mg/80 mg once daily concurrent administration with nelfinavir: 10 mg/40 mg once daily concurrent administration with itraconazole, clarithromycin, saquinavir plus ritonavir, darunavir plus ritonavir, or fosamprenavir alone or in combination with ritonavir, elbasvir plus grazoprevir, letermovir: 10 mg/20 mg once daily
ezetimibe/simvastatin (Vytorin®)	10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg tablets	10 mg/40 mg once daily in evening for most patients* concurrent administration with amiodarone, amlodipine, or ranolazine: 10 mg /20 mg once daily in evening concurrent administration with verapamil, diltiazem, or dronedarone: 10 mg/10 mg once daily in evening *10 mg/80 mg dose restricted to those patients chronically maintained on 80 mg without evidence of myopathy

1.2 Pediatrics

HMG-CoA reductase inhibitors are FDA-approved for use as a dietary adjunct to reduce total cholesterol, LDL-C, TG, and Apo B in adolescent boys, and girls who are at least one-year post-menarche, (for pravastatin, children and adolescents 8-18 years of age regardless of menarchal status) with elevated LDL-C due to heterozygous familial hypercholesterolemia. Pitavastatin calcium (Livalo®) has recently been FDA-approved for use in children/adolescents over 8 years of age as an adjunct to diet to manage heterozygous familial hypercholesterolemia by lowering total cholesterol, LDL-C, and apo B. Rosuvastatin has expanded FDA approval for use in children as young as 8 years of age with heterozygous familial hypercholesterolemia and has gained FDA approval for homozygous familial hypercholesterolemia in pediatric patients 7-17 years of age. Simvastatin oral suspension (FloLipid®) has been approved for use in conjunction with diet to improve total cholesterol, LDL-C, and ApoB in pediatric patients 10-17 years of age (girls at least one year post-menarchal) with heterozygous familial hypercholesterolemia. Safety and efficacy of pitavastatin magnesium (Zypitamag®) or rosuvastatin sprinkle capsules (Ezallor Sprinkle™) in pediatric patients have not been established. Safety and effectiveness of HMG-CoA reductase inhibitors in pre-menarchal girls or children younger than 10 years of age (for pravastatin and

rosuvastatin in heterozygous familial hypercholesterolemia, younger than 8 years of age regardless of menarchal status; for rosuvastatin in homozygous familial hypercholesterolemia, younger than 7 years of age) have not been well established.[1-4, 6-17]

Ezetemibe/simivastatin (Vytorin®) combination therapy has been effectively used to manage children and adolescents with heterozygous familial hypercholesterolemia.[1-4, 18] The amlodipine/atorvastatin (Caduet®) combination has not been FDA-approved the pediatric population as safety and efficacy have not been established with this combination therapy.[1-4, 19]

Maximum recommended doses for HMG-CoA reductase inhibitors as both monotherapy and combination therapy in pediatric patients are summarized in Tables 3 and 4.

Table 3. Maximum Recommended HMG-CoA Reductase Inhibitor Pediatric Dosages: Monotherapy[1-4, 6-17]

Treatment Indication	Drug Name	Maximum Recommended Dosage
Heterozygous familial hypercholesterolemia	atorvastatin	10- less than 18 years of age: 20 mg once daily
Heterozygous familial hypercholesterolemia	fluvastatin	10- less than 18 years of age: 80 mg daily, as single evening dose or two divided doses
Heterozygous familial hypercholesterolemia	lovastatin (immediate-release only)	10- less than 18 years of age: 40 mg once daily with evening meal
Heterozygous familial hypercholesterolemia	pitavastatin	Greater than 8 years to less than 18 years of age: 4 mg once daily
Heterozygous familial hypercholesterolemia	pravastatin	8-13 years of age: 20 mg once daily 14- less than 18 years of age: 40 mg once daily

Treatment Indication	Drug Name	Maximum Recommended Dosage
Heterozygous familial hypercholesterolemia	rosuvastatin	8-9 years of age: 10 mg once daily 10- less than 18 years of age: 20 mg once daily
Homozygous familial hypercholesterolemia	rosuvastatin	7- less than 18 years of age: 20 mg once daily
Heterozygous familial hypercholesterolemia	simvastatin	10- less than 18 years of age: 40 mg once daily in evening

Table 4. Maximum Recommended HMG-CoA Reductase Inhibitor Pediatric Dosages: Combination Therapy[1-4, 1]

Treatment Indication	Drug Name	Maximum Recommended Dosage
Heterozygous familial hypercholesterolemia	ezetimibe/ simvastatin	10- less than 18 years of age (girls postmenarchal): 10 mg/40 mg once daily

2 Duration of Therapy[1-4, 6-41]

There is no basis for limiting therapy duration for HMG-CoA reductase inhibitors as control of cholesterol and other coronary heart disease risk factors is a life-long process.

3 Duplicative Therapy

The use of two or more HMG-CoA reductase inhibitors in combination is not justified. Additional therapeutic benefit is not realized when HMG-CoA reductase inhibitors are used concomitantly and may result in increased adverse reactions such as myopathy and rhabdomyolysis. Patients receiving multiple HMG-CoA reductase inhibitors concurrently will be reviewed.

4 Drug-Drug Interactions

Patient profiles will be assessed to identify those drug regimens which may result in clinically significant drug-drug interactions. Drug-drug interactions considered most significant for HMG-CoA reductase inhibitors are summarized in Table 4. Only those drug-drug interactions classified as clinical significance level 1 or those considered life-threatening which have not yet been classified will be reviewed:

Table 4. Significant Drug-Drug Interactions for HMG-CoA Reductase Inhibitors[1-4, 6-19]

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
HMGs	cyclosporine	co-administration may lead to increased HMG concentrations and potential for enhanced pharmacologic/ adverse effects (e.g., MYO, RHAB) due to inhibition of HMG metabolism (CYP3A4; OATP1B1) by cyclosporine (CYP3A4, OATP1B1 inhibitor)	avoid adjunctive therapy, if possible; if combined therapy necessary, monitor for signs/symptoms of MYO, RHAB; use lowest recommended HMG doses; fluvastatin may be alternative as metabolized by CYP2C9 and not affected by OATP1B1	major, moderate (DrugReax) 2-major (CP)
HMGs	fibric acid derivatives (e.g., fenofibrate, gemfibrozil)	adjunctive administration may elevate HMG serum levels, with increased risk of severe MYO, RHAB, due to inhibition of HMG metabolism (CYP2C8; OATP1B1) by gemfibrozil (CYP2C8, OATP1B1 inhibitor), or additive myopathy risk (fibrates)	avoid combination, if possible; if concurrent therapy necessary, use cautiously, closely monitor creatine kinase and observe for MYO, RHAB; use lowest recommended HMG doses	major (DrugReax) 2-major (CP)
HMGs	protease inhibitors	adjunctive administration may increase HMG serum levels and elevate potential for enhanced pharmacologic/adverse effects (e.g., MYO, RHAB) due to CYP3A4 inhibition and other unknown mechanisms	avoid combination therapy, if possible; if combined therapy necessary, monitor for increased adverse effects (e.g., MYO, RHAB) and use lowest recommended HMG dose; may consider pravastatin, an HMG not metabolized by CYP3A4	contraindicated, major, moderate (DrugReax) 1-severe, 2-major, 3-moderate (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
Select HMGs	amiodarone	combined administration may increase risk of HMG adverse effects [e.g., myopathy (MYO), rhabdomyolysis (RHAB)] most likely due to inhibition of HMG metabolism (CYP3A4, CYP2C9) by amiodarone (CYP3A4, CYP2C9 inhibitor)	monitor for MYO, RHAB; use lowest recommended HMG doses; consider using HMG not metabolized by CYP3A4 or CYP2C9, such as pravastatin, if drug combination necessary	major, moderate (DrugReax) 2-major, 3-moderate (CP)
Select HMGs	azole antifungals	combined administration may lead to increased HMG concentrations and potential for enhanced pharmacologic/adverse effects (e.g., MYO, RHAB) due to inhibition of HMG metabolism (CYP3A4) by azole antifungals (CYP3A4 inhibitor); fluvastatin with increased risk of adverse effects when prescribed with fluconazole, voriconazole (CYP2C9 inhibitors)	posaconazole-HMG combination is contraindicated due to increased risk of MYO/RHAB; avoid adjunctive therapy, if possible with other combinations; if combined therapy necessary, monitor for signs/symptoms of MYO, RHAB; may consider using HMG not metabolized by CYP3A4, CYP2C9 such as pravastatin	contraindicated, major (DrugReax) 1-severe, 2-major, 3-moderate (CP)
Select HMGs	macrolide antibiotics	macrolides (CYP3A4, OATP1B1 inhibitors) prescribed with HMGs metabolized by CYP3A4 or OATP1B1 may increase HMG serum levels and elevate potential for enhanced pharmacologic/adverse effects (e.g., MYO, RHAB)	avoid macrolides with HMGs metabolized by CYP3A4, OATP1B1, if possible; pravastatin, rosuvastatin not metabolized by CYP3A4 and may be alternative HMGs; if combination necessary, monitor for MYO, RHAB	major (DrugReax) 1-severe, 2-major (CP)
Select HMGs	other CYP3A4 inhibitors (e.g., diltiazem, imatinib, nefazodone, verapamil)	CYP3A4 inhibitors administered with HMGs metabolized by CYP3A4 may increase HMG serum levels and elevate potential for enhanced pharmacologic/ adverse effects (e.g., MYO, RHAB)	avoid CYP3A4 inhibitors with HMGs metabolized by CYP3A4, if possible; pravastatin, rosuvastatin not metabolized by CYP3A4 and may be alternative HMGs; if combination necessary, use lowest recommended dose and monitor for MYO, RHAB	contraindicated, major, moderate (DrugReax) 1-severe, 2-major, 3-moderate (CP)

Target Drug	Interacting Drug	Interaction	Recommendation	Clinical Significance Level
Select HMGs	select NNRT inhibitors (delavirdine, efavirenz)	combined administration of delavirdine (CYP3A4 inhibitor) with HMGs metabolized by CYP3A4 may increase HMG serum levels and elevate potential for enhanced pharmacologic/adverse effects (e.g., MYO, RHAB); alternately, concurrent administration of efavirenz (CYP3A4 inducer) with HMGs metabolized by CYP3A4 may decrease HMG serum levels and potentially decrease therapeutic efficacy	monitor for increased adverse effects (e.g., MYO, RHAB) or decreased HMG efficacy; may alter HMG dose or add other lipid-lowering therapy; consider alternative HMGs not metabolized by CYP3A4	major, moderate (DrugReax) 1-severe, 2-major, 3-moderate (CP)

- *CP = Clinical Pharmacology
- HMG = HMG CoA reductase inhibitor
- MYO = myopathy
- NNRT = non-nucleoside reverse transcriptase
- RHAB = rhabdomyolysis

5 References

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