

Medication Policy Manual

Policy No: dru188

Topic: Livalo[®], pitavastatin

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IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Pitavastatin (Livalo[®]) is an oral medication used to treat high cholesterol.

NOTE: Pitavastatin (Livalo) is not yet available from pharmacies.

Policy/Criteria

I. Most contracts require prior authorization approval of pitavastatin prior to coverage. Pitavastatin may be considered medically necessary for treatment of dyslipidemias when all of the following criteria in A and B below are met:

A. Rosuvastatin (Crestor[®]) is ineffective at achieving the LDL-C target after at least two months of treatment or is not tolerated.

AND

B. At least one of the following criteria in 1 or 2 is met.

1. The need for greater than 40% LDL-C reduction is documented.

OR

2. At least one of the following statin products has been ineffective at achieving the LDL-C target after at least two months of treatment or is not tolerated:

a. simvastatin (Zocor[®])

b. pravastatin (Pravachol[®])

c. lovastatin (Mevacor[®], Altoprev[®])

II. Administration and Authorization Period

A. Regence considers pitavastatin to be a self-administered medication.

B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement

- At equipotent dosing, there are no differences in efficacy (measured by LDL-C lowering) between the high potency statin products. ^[5-12, 44-48, 56]
- Additionally, there is no evidence demonstrating significant differences in safety profiles or discontinuation rates among the available high potency statin products. ^[5-12]
- Among the statin products, rosuvastatin (Crestor[®]) and simvastatin provide the highest LDL-C lowering at the lowest cost when greater than 41% LDL-C lowering is needed. Relative to other high potency statin products, atorvastatin (Lipitor[®]), pitavastatin (Livalo[®]) and simvastatin/ezetimibe (Vytorin[®]) do not provide the best value in LDL-C reduction (see Appendix 1).

- At initial starting doses, several statin products may achieve up to 41% LDL-C reduction (see Appendices 1 and 2).
- For patients who need moderate LDL-C lowering (i.e., 40% or less), generic simvastatin, pravastatin and lovastatin provide the best values (see Appendix 1).

Overall Efficacy

- Several outcomes trials have demonstrated that statins reduce the risks of cardiovascular and cerebrovascular events. [13-18, 29-39, 42-43, 49-55]
 - * Rosuvastatin reduced rates of heart attack, stroke, death and the need for revascularization in patients with elevated C-reactive protein levels (a marker of inflammation) but normal LDL-C levels (< 130 mg/dL). [54]
 - * A reduction of LDL-C by 50% and C-reactive protein by 37% was also noted. This study suggested that statin therapy may benefit patients with otherwise normal LDL-C but with elevated indicators of inflammation. Further study is needed to confirm the usefulness of this approach. [54]
- Reductions in cardiovascular and cerebrovascular risk are not unique to any specific statin and have been demonstrated with many of the available statins in a variety of patient populations, such as in patients with coronary heart disease, high cholesterol levels, normal cholesterol levels, hypertension, diabetes and previous stroke. [13-18, 29-39, 42-43, 49-55]
- Several primary or secondary prevention trials with simvastatin, pravastatin, lovastatin, and atorvastatin consistently demonstrate that reductions in cardiovascular events correlate with LDL-C reduction. [13-19, 29-39, 42-43, 49-52]
- The 2004 update to the NCEP ATP III Guidelines recommends aggressive LDL-C lowering in individuals depending on their risk for heart attack or stroke. [40-41]
- Comparative clinical trials have demonstrated that more individuals may achieve NCEP ATP III LDL-C goals with high potency statins (rosuvastatin, atorvastatin, and ezetimibe/simvastatin). [1-4]
- The combination of simvastatin and ezetimibe provides potent LDL-C lowering, without significant increases in adverse events relative to other individual statins. [7,2744, 46]
- Other statins, including simvastatin, pravastatin, pitavastatin and lovastatin have moderate LDL-lowering capacity of up to 41% LDL-C reduction.. [9-11, 56]

Safety

- All marketed statins have safety records that are consistent for the statin class. [6-11, 20-24]

- Rhabdomyolysis is a rare side-effect of all statins (0.1%).^[6-11, 23-24]
 - * Myopathy (muscle weakness) and rhabdomyolysis are commonly linked to additional factors that may increase statin serum levels, such as impaired hepatic and renal function, hypothyroidism, or concomitant use of certain medications, such as fibrates or azole antifungals.
 - * Based on clinical trial safety data and world-wide post-marketing adverse reports, the incidence of myopathy and rhabdomyolysis among available statins is similar.
- Dipstick positive proteinuria (greater than 2+) has been reported in a small number of patients with all statins; however, the clinical relevance of this has not been established.^[6,25]
- Hepatotoxicity occurs rarely (less than 1%) with statins.^[6-11]
 - * Statins are contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases.^[5-12]
 - * At equipotent doses, there are no differences in rates of clinically relevant elevations in LFTs among statins.
 - * Prescribing information indicates initial and routine liver function tests (LFTs) are necessary with all statins.
- Risks for certain drug-drug interactions are inherent with all statins (see Appendix 3).
- Dosage adjustment is not needed for any statin in mild to moderate renal dysfunction. Dosage adjustment may be needed in severe renal dysfunction (Creatinine Clearance [ClCr] less than 30 ml/min).^[5-12] (See appendix 4.)

Half Tablet Program

- Simvastatin, pravastatin, lovastatin and rosuvastatin are eligible medications under the RegenceRx Half-Tablet Program.
 - * As part of this program, when higher strength tablets of these statins can be split and used for the prescribed dose, the member pays only one copayment for a two month supply of medication.
 - * More information about the RegenceRx Half-Tablet Program can be found at www.RegenceRx.com.

Appendix 1: Statin Comparison Chart

% LDL- C Lowering (5-12)	Formulary	Statin Name and Strengths	Cost Per Month*
Less than 35%	√	simvastatin (Zocor) 5 mg, 10mg	\$5 - \$7
	√	lovastatin (Mevacor) 10 mg, 20 mg, 40 mg	\$8- \$18
	√	pravastatin (Pravachol) 10 mg, 20 mg, 40 mg	\$8 - \$10
		Livalo 1 mg	\$XX
35% - 40%	√	simvastatin (Zocor) 20 mg	\$7
		Lipitor 10 mg	\$81
		Lescol XL 80 mg	\$95
		Livalo 2 mg	\$XX
41% - 52%	√	simvastatin (Zocor) 40 mg, 80 mg	\$6-\$7
		Vytorin 10 mg/10 mg, 10 mg/20 mg	\$95 - \$97
	√	Crestor 5 mg, 10 mg	\$99 - \$100
		Lipitor 20 mg, 40 mg	\$104 - \$107
		Livalo 4 mg	\$XX
Greater than 52%	√	Vytorin 10 mg/40 mg, 10 mg/80 mg	\$93 - \$96
		Crestor 20 mg, 40 mg	\$95 - \$97
		Lipitor 80 mg	\$101

* Approximate cost estimates based on a 30-day supply as of 12/2008. Actual prices may vary depending on the pharmacy and the amount or strength of the medication dispensed.

Appendix 2: Starting and Maximum Daily Doses for Formulary/Preferred Statins ^[5-12]

	lovastatin (Mevacor)	simvastatin (Zocor)	pravastatin (Pravachol)	Crestor
Initial Dose	20 mg	10 mg – 40 mg	10 mg – 40 mg	5 mg – 10 mg
Maximum Dose	80 mg	80 mg	80 mg	40 mg

Appendix 3: Drug Interactions with Statin Products [5-12, 26, 56]

Concomitant drug	Crestor	Lipitor	Lescol	Livalo	lovastatin (Mevacor)	pravastatin (Pravachol)	simvastatin (Zocor)	Vytorin
amiodarone - may ↑ statin level	--	--	--	--	X	--	X	X
antacids - may ↓ statin level	X	X	--	--	--	--	--	--
azoles (i.e. itraconazole, ketoconazole, fluconazole etc.) - may ↑ statin level	--	X	X	--	X	--	X	X
bile acid sequestrants – (i.e. colestipol, cholestyramine) - may ↓ statin plasma level	--	X*	X*	--	X*	X*	--	--
cimetidine, ranitidine, omeprazole - may ↑ statin level	--	--	X	--	--	--	--	--
cyclosporine - may ↑ statin level	X	--	--	X	--	--	--	--
diclofenac - may ↑ diclofenac levels	--	--	X	--	--	--	--	--
digoxin - may ↑ digoxin levels	--	X	X	--	--	--	X	X
fibrate derivatives (i.e. gemfibrozil) - may ↑ statin level	X	X	X	X	X	X	X	X
glyburide - may ↑ statin conc; may ↑ glyburide level	--	--	X	--	--	--	--	--
grapefruit juice (> 1 quart/day) - may ↑ statin level	--	X	--	--	X	--	X	X
isradipine - may ↓ statin level	--	--	--	--	X	--	--	--
macrolides (i.e. erythromycin, clarithromycin) - may ↑ statin level	--	X	--	X	X	--	X	X
nefazodone - may ↑ statin level	--	X	--	--	X	--	X	X
niacin - may ↑ statin level	X	X	X	X	X	X	X	X
oral contraceptives - may ↑ estrogen and progestin level	X	X	--	--	--	--	--	--
phenytoin - may ↑ statin level; may ↑ phenytoin level	--	--	X	--	--	--	--	--
protease inhibitors (ritonavir, saquinavir) - may ↓ statin plasma level	--	--	--	--	--	X	--	--
protease inhibitors (nelfinavir, ritonavir) - may ↑ statin plasma level	--	X	--	X	X	--	X	X
rifampin - may ↓ statin plasma level	--	--	X	X	--	--	X	X
verapamil - may ↓ statin plasma level	--	X	--	--	X	--	X	X
warfarin - may ↑ INR	X	--	X	--	X	--	X	X

*Dosing with a statin should occur at least greater than 1 hour before or greater than 4 hours after administration of a bile acid sequestrant.

Appendix 4: Dosage Adjustments in Patients with Renal Dysfunction [5-12, 56]

	Crestor	Lipitor	Lescol	Livalo	lovastatin (Mevacor)	pravastatin (Pravachol)	simvastatin (Zocor)	Vytorin
Renal Dysfunction	For CrCl* <30, ml/min start at 5 mg/d & do not exceed 10 mg/d	No adjustment	No adjustment (not studied in severe renal impairment)	For CrCl* <60, ml/min start at 1 mg/d & do not exceed 2 mg/d	For CrCl <30, ml/min use doses > 20 mg cautiously	Closely monitor (lack of good data in renal dysfunction)	Adjustment not needed, in mild-moderate, but caution in severe renal dysfunction (CrCl < 30 ml/min)	Adjustment not needed, in mild-moderate, but caution in severe renal dysfunction (CrCl < 30 ml/min)
% excreted in urine	28%	<2%	~5%	~15%	~10%	~20%	13%	13%

*CrCl = Creatinine Clearance

References

1. Jones PH, Davidson MH, Stein EA. Comparison of efficacy and safety of rosuvastatin versus atorvastatin, simvastatin, and pravastatin across doses (STELLAR trial). *Am J Cardiol* 2003;93:152-60.
2. Ballantyne CM, Blazing MA, King TR, et al. Efficacy and safety of ezetimibe co-administered with simvastatin compared with atorvastatin in adults with hypercholesterolemia. *Am J Cardiol* 2004;93:1487-94.
3. Davidson M, Ma P, Stein EA. Comparison of effects of low-density lipoprotein cholesterol and high-density lipoprotein cholesterol with rosuvastatin versus atorvastatin in patients with type IIa or II b hypercholesterolemia. *Am J Cardiol* 2002;89:268-75.
4. Paoletti R, Fahmy M, Mahla G. Rosuvastatin demonstrates greater reduction of low-density lipoprotein cholesterol compared with pravastatin and simvastatin in hypercholesterolemic patients: A randomized, double blind study. *J Cardiovasc Risk* 2001;8:383-90.
5. Lipitor [package insert]. New York, NY: Pfizer, Inc.;. November 2007.
6. Crestor [package insert]. [Wilmington](#), DE: AstraZeneca Pharmaceuticals; October 2008.
7. Vytorin [package insert]. North Wales, PA: MERCK/Schering-Plough Pharmaceuticals; July 2008.
8. Lescol/Lescol XL [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2006.
9. Mevacor [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2008.

10. Pravachol [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2007.
11. Zocor [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2008.
12. Zetia [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2008.
13. The Long Term Intervention with Pravastatin in Ischemic Disease (LIPID) Study. Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. *N Engl J Med* 1998;339:1349-57.
14. Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole TG, Brown L et al. The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. *N Eng J Med* 1996;335:1001-9.
15. Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, Macfarlane PW, McKillop JH et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. *N Eng J Med* 1995;333:1301-7.
16. The Scandinavian Simvastatin Survival Group. Randomized trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian simvastatin survival study (4S). *Lancet* 1994;344:1383-9.
17. Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol lowering with simvastatin in 20 536 high-risk individuals: a randomized placebo-controlled trial. *Lancet* 2002;360:7-22.
18. Downs JR, Clearfield, M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A et al. Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels. Results of AFCAPS/TexCAPS. *JAMA* 1998;279:1615-22.
19. Illingworth DR. Management of hypercholesterolemia. *Med Clin N Am* 2000;84:23-42.
20. Shepherd J, Hunninghake DB, Stein EA, Kastelein JJ, Harris S, Pears J, Hutchinson HG. Safety of rosuvastatin. *Am J Cardiol* 2004;94:882-8.
21. Knopp RH. Drug treatment of lipid disorders. *N Engl J Med* 1999;341:498-511.
22. Astra-Zeneca Letter. October 5, 2004. Data on file.
23. Thompson PD, Clarkson P, Karas RH. Statin-associated myopathy. *J Am Med Assoc* 2003;289:1681-90.
24. Ballantyne CM, Corsini A, Davidson MH et al. Risk from myopathy with statin therapy in high-risk patients. *Arch Int Med* 2003;163:553-64.
25. Vidt DG, Cressman MD, Harris S, Pears JS, Hutchinson HG. Rosuvastatin-induced arrest in progression of renal disease. *Cardiology* 2004;102:52-60.

26. Lin JC, Ito MK, Stolley SN, Morreale AP, Marcus MB. The effect of converting from pravastatin to simvastatin on the pharmacodynamics of warfarin. *J Clin Pharmacol* 1999;39:86-90.
27. Davidson MH, McGarry T, Bettis R for the Ezetimibe Study Group. Ezetimibe co-administered with simvastatin in patients with primary hypercholesterolemia. *J Am Coll Cardiol* 2002;40:2124-35.
28. Hodaas H, Fellstrom B, Jardine AG, Holme I, Nyberg G, Fauchald P, Gronhagen-Riska C et al. Effect of fluvastatin on cardiac outcomes in renal transplant recipients: a multicentre, randomized, placebo-controlled trial. *Lancet* 2003;361:2024-31.
29. The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. Major outcomes in moderately hypercholesterolemic, hypertensive patients randomized to pravastatin vs usual care. *JAMA* 2002;288:2998-3007.
30. Sever PS, Dahlof B, Poulter NR, Wedel H, Beevers G, Caulfield M, Collins R et al. Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower than average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial-Lipid lowering arm (ASCOT-LLA): a multicentre randomized controlled trial. *Lancet* 2003;361:1149-58.
31. Colhoun HM, Betteridge DJ, Durrington PN, Hitman G, Neil HAW, Livingstone SJ, Thomason MJ et al. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the collaborative atorvastatin diabetes study (CARDS): multicentre randomized placebo-controlled trial. *Lancet* 2004;685-96.
32. Riegger G, Abletshauer C, Ludwig M, Schwandt P, Widimsky J, Weidinger G, Welzel D. The effect of fluvastatin on cardiac events in patients with symptomatic coronary artery disease during one year of treatment. *Atherosclerosis* 1999;144:263-70.
33. Asselbergs FW, Diercks GFH, Hillege HL, van Boven AJ, Janssen WMT, Voors AA, de Zeeuw D et al. Effects of fosinopril and pravastatin on cardiovascular events in subjects with micro albuminemia. *Circulation* 2004;110:2809-16.
34. Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, et al. Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomized controlled trial. *Lancet* 2002;360:1623-30.
35. Cannon CP, Braunwald E, McCabe C, Rader DJ, Rouleau JL, Belder R, Joyal SV et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *N Eng J Med* 2004;350:1495-504.
36. de Lemos JA, Blazing MA, Wiviott SD, Lewis EF, Fox KA, White HD, Rouleau JL et al. Early intensive vs a delayed conservative simvastatin strategy in patients with acute coronary syndromes. Phase Z of the A to Z trial. *JAMA* 2004;292:1307-16.

37. Schwartz GG, Olsson AG, Ezekowitz MD, Ganz P, Oliver MF, Waters D, Zeiher A et al. Effects of atorvastatin on early recurrent ischemic events in acute coronary syndromes. The MIRACL Study: a randomized controlled trial. *JAMA* 2001;285:1711-8.
38. Amarenco P, Bogousslavsky J, Callahan A 3rd, Goldstein LB, Hennerici M, Rudolph AE, Silleesen H et al. High-dose atorvastatin after stroke or transient ischemic attack. *N Engl J Med* 2006;355:549-59.
39. Amarenco P, Labreuche J, Lavale P, Touboul PJ. Statins in stroke prevention and carotid atherosclerosis: systematic review and up-to-date meta-analysis. *Stroke* 2004;35:2902-9.
40. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III): Executive Summary. NIH Publication No. 01-3670. US Department of Health and Human Services; 2001.
41. Grundy SM, Cleeman JI, Baird Merz CN, Brewer HB, Clark LT, Hunninghake DB, Pasternak RC, et al. Implications of recent clinical trials for the national cholesterol education program adult treatment panel III guidelines. *Circulation* 2004;110:227-39.
42. Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, et al. Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomized controlled trial. *Lancet* 2002;360:1623-30.
43. Lewis SJ, Moye LA, Sacks FM, Johnstone DE, Timmis G, Mitchell J, Limacher M, et al. Effect of pravastatin on cardiovascular events in older patients with myocardial infarction and cholesterol levels in the average range. Results of the cholesterol and recurrent events (CARE) trial. *Ann Intern Med* 1998;129:681-9.
44. Constance C, Westphal S, Chung N, et al. Efficacy of ezetimibe/simvastatin 10/20 and 10/40 mg compared with atorvastatin 20 mg in patients with type 2 diabetes mellitus. *Diabetes Obes Metab.* 2007 Jul;9(4):575-84.
45. Deedwania PC, Gupta M, Stein M, Ycas J, Gold A; IRIS Study Group. Comparison of rosuvastatin versus atorvastatin in South-Asian patients at risk of coronary heart disease (from the IRIS Trial). *Am J Cardiol.* 2007 Jun 1;99(11):1538-43.
46. Pearson T, Ballantyne C, Sisk C, Shah A, Veltri E, Maccubbin D. Comparison of effects of ezetimibe/simvastatin versus simvastatin versus atorvastatin in reducing C-reactive protein and low-density lipoprotein cholesterol levels. *Am J Cardiol.* 2007 Jun 15;99(12):1706-1713.
47. Ballantyne CM, Weiss R, Moccetti T, et al.:EXPLORER Study Investigators. Efficacy and safety of rosuvastatin 40 mg alone or in combination with ezetimibe in patients at high risk of cardiovascular disease (results from the EXPLORER study). *Am J Cardiol.* 2007 Mar 1;99(5):673-80.

48. Asztalos BF, Le Maulf F, Dallal GE, et. al. Comparison of the effects of high doses of rosuvastatin versus atorvastatin on the subpopulations of high-density lipoproteins. *Am J Cardiol.* 2007 Mar 1;99(5):681-5.
49. Heart Protection Study Collaborative Group. Randomized trial of the effects of cholesterol-lowering with simvastatin on peripheral vascular and other major vascular outcomes in 20,536 people with peripheral arterial disease and other high-risk conditions. *J Vasc Surg.* 2007 Apr;45(4):645-654;
50. Chonchol M, Cook T, Kjekshus J, Pedersen TR, Lindendorf J. Simvastatin for secondary prevention of all-cause mortality and major coronary events in patients with mild chronic renal insufficiency. *Am J Kidney Dis.* 2007 Mar;49(3):373-82.
51. Murphy SA, Cannon CP, Wiviott SD, et al. Effect of intensive lipid-lowering therapy on mortality after acute coronary syndrome (a patient-level analysis of the Aggrastat to Zocor and Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 trials). *Am J Cardiol.* 2007 Oct 1;100(7):1047-51.
52. Ford I, Murray H, Packard CJ, Shepherd J, Macfarlane PW, Cobbe SM; West of Scotland Coronary Prevention Study Group. Long-term follow-up of the West of Scotland Coronary Prevention Study. *N Engl J Med.* 2007 Oct 11;357(15):1477-86.
53. Shepherd J, Kastelein JJ, Bittner V, et. al. Treating to New Targets Investigators. Effect of intensive lipid lowering with atorvastatin on renal function in patients with coronary heart disease: the Treating to New Targets (TNT) study. *Clin J Am Soc Nephrol.* 2007 Nov;2(6):1131-9.
54. Ridker PM, Danielson E, Fonseca FA, et al.; JUPITER Study Group. Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. *N Engl J Med.* 2008 Nov 20;359(21):2195-207.
55. Amarenco P, Bogousslavsky J, Callahan A 3rd, et al. ; Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) Investigators. High-dose atorvastatin after stroke or transient ischemic attack. *N Engl J Med.* 2006 Aug 10;355(6):549-59.
56. Livalo [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; August 2009.

Cross References
Crestor [®] , rosuvastatin, dru138
Vytorin [®] , ezetimibe/simvastatin, dru139
Lipitor [®] , atorvastatin, dru119

Codes	Number	Description
N/A		