Attachment B

West Virginia Medicaid Hypertension Management

Educational RetroDUR Mailing	☑Initial Study ❑Follow – up /Restudy

Executive Summary

Purpose:	To determine opportunities for improving the safety and efficacy of drug therapy for patients with hypertension, following the 2014 Evidence-based Guideline for the Management of High Blood Pressure in Adults from the Panel Members Appointed to the Eighth Report of the Joint National Committee (JNC-8)[1] and Clinical Practice Guidelines for the Management of Hypertension in the Community as stated by the American Society of Hypertension and the International Society of Hypertension (ASH/ISH)[2].	
Why Issue was Selected:	Hypertension is the most common condition seen in primary care and leads to myocardial infarction, stroke, renal failure, and death if not detected early and treated appropriately.[1,2]	
Program Specific Information:	Performance Indicators	Candidates
	• Increased Risk of Adverse Event (ADE): Hypertension and no antihypertensive therapy, with presence of condition that can precipitate high blood pressure.	4,884
	• Increased Risk of ADE: Hypertension and no antihypertensive therapy, with concomitant oral corticosteroids.	1,806
	• Increased Risk of ADE: Drug-induced hypertension.	40
	• Increased Risk of ADE: Angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), aliskiren, and triamterene in pregnancy.	12
	• Increased Risk of ADE: Metolazone and impaired hepatic function.	14
	• Increased Risk of ADE: Triamterene and renal or hepatic impairment.	58
	• Increased Risk of ADE: Duplicate therapy with ACE-inhibitors, ARBs and/or combination products.	2
	• Discontinuation of antihypertensive drug therapy.	2,113
	• Non-adherence with antihypertensive drug therapy.	5,309
	• Underutilization of recommended first line therapies (Thiazide diuretic, Calcium Channel Blocker, ACE-inhibitor, or ARBs).	*TBD*

1654 1111,304	• Underutilization of angiotensin modulating agents with the presence of a compelling indication.	*TBD*
	• Underutilization of beta-blocking agents with the presence of a compelling indication.	*TBD*
	• Underutilization of alpha-blockers with the presence of a compelling indication.	931
	• Underutilization of combination products in patients on single entity agents.	*TBD*
	• Increased Risk of ADE: Angiotensin modulating agents, direct renin inhibitors and angioedema history.	97
Setting & Population:	Adult patients with hypertension will be included in this initiative.	
Types of Intervention:	Cover letter and individual profiles	
Main Outcome Measures:	The performance indicators will be re-measured when six months of outcome data are available.	
Anticipated Results:	Increased utilization of antihypertensive therapy in patients not taking antihypertensives who have conditions that precipitate hypertension; more aggressive treatment with antihypertensives in patients on medications that may induce hypertension or make it more difficult to treat; decreased use of angiotensin modulating therapy, aliskiren, and triamterene during pregnancy; decreased utilization of triamterene in patients with liver or renal impairment; decreased utilization of metolazone with hepatic impairment; more frequent blood pressure monitoring in patients with metabolic syndrome or those with other cardiovascular risk factors; improved adherence with antihypertensive medications, re-initiation of discontinued antihypertensive therapy, increased awareness of angiotensin modulating agents and direct renin inhibitors in patients with a history of angioedema; and increased appropriate use of ACE inhibitors, beta-blockers, alpha-blockers, combination antihypertensives, and multidrug antihypertensive regimens.	

Performance Indicator #1: Increased risk of adverse event: Hypertension and no antihypertensive therapy with presence of condition that can precipitate high blood pressure.

Why has this indicator been selected?	Treatment of hypertension has three objectives, one being evaluation and assessment of identifiable causes of high blood pressure. Identifying potential causes of high blood pressure can prevent resistant hypertension and help signal reasons for treatment failure.
How will the patients be selected?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years, who do not have a history of an antihypertensive agent in the past 90 days.
Exception criteria (numerator):	Candidates with a medical claim in the past 2 years for sleep apnea, chronic kidney disease, primary aldosteronism, renovascular disease, Cushing's Syndrome, pheochromocytoma, coarctation of the aorta, or thyroid/parathyroid disease.

Performance Indicator #2: Increased risk of adverse drug event: Hypertension and no antihypertensive therapy, with concomitant oral corticosteroid use.

Why has this indicator been selected?	Identifying causes of hypertension can prevent treatment failure of the disease. Oral corticosteroids can cause hypertension and make blood pressure more difficult to treat. Patients with hypertension who haven't required medication management should be monitored closely during oral corticosteroid therapy as blood pressure may become elevated, requiring initiation of an antihypertensive.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years, who do not have a history of an antihypertensive agent in the past 90 days.
Exception criteria (numerator):	Candidates receiving prednisone >7.5mg/day or patients receiving 90 or more days out of the past 120 days of oral corticosteroids.

Performance Indicator #3: Increased risk of adverse drug event: Drug-induced hypertension.

Why has this indicator been selected?	The following drug therapies can contribute to resistant hypertension or make hypertension more difficult to treat: stimulants (amphetamines), oral contraceptives, non-steroidal anti-inflammatory drugs, venlafaxine (≥300mg), bromocriptine, erythropoietin, cyclosporine, tacrolimus, cold remedies (pseudoephedrine), and agents to treat migraines. Blood pressure monitoring in this population is essential in preventing progression of disease.
How will the patients be selected?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days.
Exception criteria (numerator):	Candidates with claims history in the past four months for one of the above listed medications (for 90 days with drug-free periods of no more than 10 days) that can worsen hypertension, who have not had a submitted medical or procedural claim, suggesting an office visit, in the past 6 months.

Performance Indicator #4: Increased risk of adverse drug event: ACE-inhibitors, ARBS, Aliskiren, and Triamterene in pregnancy.

Why has this indicator been selected?	ACE modulating products should not be used during pregnancy. Official labeling for ACE-inhibitors warns of use during any trimester, whereas labeling for the ARBs and aliskiren warns of fetal risk during the second and third trimesters.[6,7] Triamterene is a dihydrofolate reductase inhibitor. Medications with this activity have been associated with increased risk of cardiovascular defects and oral clefts in infants.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days, who have a diagnosis in the past 9 months indicating pregnancy (and without a claim indicating delivery or termination).
Exception criteria (numerator):	Candidates with a claim in the past 45 days for an angiotensin modulating containing product or a triamterene containing product.

Performance Indicator #5: Increased risk of adverse drug event: Metolazone and impaired hepatic function.

Why has this indicator been selected?	Metolazone-induced fluctuations in serum electrolyte concentrations can occur rapidly and precipitate hepatic coma in susceptible patients. Metolazone should be used with caution in patients with impaired hepatic function or hepatic disease such as cirrhosis; the drug is contraindicated in patients with hepatic coma or pre-coma.
How will the patients be selected ?	
Candidates (denominator):	Patients with a pharmacy claim for metolazone in the past 45 days.
Exception criteria (numerator):	Candidates with a diagnosis in the past year for chronic hepatic disease, cirrhosis, viral hepatitis, or hepatic coma.

Performance Indicator #6: Increased risk of adverse drug event: Triamterene and renal or hepatic impairment.

Why has this indicator been selected?	Triamterene is contraindicated in patients with severe or progressive renal disease or dysfunction and in severe hepatic disease. Individuals with these conditions should use this drug with caution or use alternative antihypertensives.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days, who have a diagnosis in the past two years of moderate to severe renal impairment or hepatic impairment.
Exception criteria (numerator):	Candidates with a claim in the past 45 days for a triamterene containing product.

erformance Indicator #7: Increased risk of adverse event: Duplicate therapy with ACE-inhibitors, ARBS and/or combination products.

Why has this indicator been selected?	The main objective of hypertension management is to reach and maintain goal blood pressure. When goal blood pressure is not achieved with a single agent the dose of the initial drug should be increased or a second agent should be added.[1] When additive therapy is being considered, ACE inhibitors and ARBs should not be combined. While each of these drug types is beneficial in patients with kidney disease, the combination may actually cause adverse effects on kidney function.[2]
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years who have been on antihypertensive products in the past year.
Exception criteria (numerator):	Candidates with a claim for both an ACE inhibitor and an ARB within the past 45 days, with at least 7 days of overlapping therapy

Performance Indicator #8: Discontinuation of antihypertensive drug therapy.

Why has this indicator been selected?	There is a close relationship between blood pressure levels and the risk of cardiovascular events, strokes, and kidney disease.[2] Clinical evidence has shown that antihypertensive therapy has been associated with reductions in the incidence of stroke averaging 35%-40%; myocardial infarction 20%-25%; and heart failure more than 50%. Patients may discontinue therapy for many reasons, both intentional and non-intentional.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years who have been on antihypertensive products in the past year.
Exception criteria (numerator):	Candidates without claims history for antihypertensives in the most recent 90 days.

Performance Indicator #9: Non-adherence with antihypertensive drug therapy.

Why has this indicator been selected?	Non-adherence with antihypertensives can lead to perceived treatment failure and increased risk of adverse events due to escalating doses of antihypertensives.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 45 days.
Exception criteria (numerator):	Candidates who have antihypertensive therapy in the most recent 45 days as well as 90 to 135 days ago, but less than 60 days of antihypertensive therapy in the most resent 90 days.

Performance Indicator #10: Underutilization of recommended first line therapies (Thiazide diuretic, CCB, ACE-inhibitor, ARB)

Why has this indicator been selected?	Initial antihypertensive drug choice should be based on the patient's age, ethnicity, and other clinical characteristics. In past guidelines thiazide diuretics have been the basis of antihypertensive therapy in outcomes trials and have been virtually unsurpassed in preventing cardiovascular complications of hypertension. However, calcium channel blockers (CCBs),[8] ACE inhibitors, and ARBs yield comparable effects on overall mortality and cardiovascular, cerebrovascular, and kidney outcomes.[1] For this reason, initial therapy may include either a thiazide type diuretic, CCB, ACE inhibitor, or ARB.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days, who do not have additional comorbidities, and do not have anuria, gout, hyponatremia, are not pregnant, or are not on dialysis.
Exception criteria (numerator):	Candidates who do not have a claims history for a thiazide-containing product, CCB, ACE inhibitor, or ARB in the past 2 years.

Performance Indicator #11: Underutilization of Angiotensin Modulating Agents with the presence of a compelling indication.

Why has this indicator been selected?	ACE inhibitors and angiotensin receptor blockers have demonstrated favorable effects on the progression of diabetic and non-diabetic renal disease. Additionally, they have been proven beneficial in diabetic nephropathy and in reducing albuminuria. Studies in patients with stroke indicate angiotensin modulating therapy lowers recurrent stroke rates when given in combination with a thiazide diuretic. Specifically, perindopril (Aceon), both alone and in combination with a diuretic, has been shown to reduce the risk of stroke in patients with and without hypertension, who have a history of stroke or transient ischemic attack.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days.
Exception criteria (numerator):	Candidates with a diagnosis of chronic renal disease, diabetes, or stroke in the past 2 years, without a contraindication to angiotensin modulating therapy (i.e. renal artery stenosis, renal dialysis, angioedema, renal failure), who have not been on angiotensin modulating therapy.

Performance Indicator #12: Underutilization of Beta-Blocking agent with the presence of a compelling indication.

Why has this indicator been selected?	Beta-blockers reduce cardiac output and decrease the release of renin from the kidney. have been shown to be beneficial in patients with history of myocardial infarction and heart failure. Beta-blockers are also indicated and have been proven beneficial when used as preventative agents in patients with migraine. Patients with hypertension and comorbidities such as myocardial infarction, heart failure, and migraine benefit from the use of beta blockers.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days.
Exception criteria (numerator):	Candidates with a diagnosis in the past 2 years of myocardial infarction, angina, or migraine, a pharmacy claim for a first line antihypertensive therapy and without a contraindication to beta-blocker therapy (i.e. asthma, COPD, depression, 2nd or 3rd degree AV block), who are on more than one antihypertensive agent but not on beta-blocking therapy.

Performance Indicator #13: Underutilization of Alpha-Blocker agent with the presence of a compelling indication.

Why has this indicator been selected?	Alpha-blocking antihypertensives can have favorable effects on other comorbidities such as benign prostatic hyperplasia.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days.
Exception criteria	Candidates with a diagnosis in the past 2 years of benign prostatic hyperplasia, a

(numerator):	pharmacy claim for a first line therapy and who are on more than one antihypertensive agent but not alpha-blockers in the past 45 days.

Performance Indicator #14: Underutilization of combination products in patients on single entity agents.

Why has this indicator been selected?	Utilization of combination antihypertensive products may improve compliance and reduce costs.
How will the patients be selected ?	
Candidates (denominator):	Patients with a diagnosis of hypertension in the past 2 years and claims history of antihypertensives in the past 90 days.
Exception criteria (numerator):	Candidates with pharmacy claims history in the past 45 days for two single agent entities available as a combination product.

Performance Indicator #15: Increased risk of adverse event: Angiotensin Modulating Agents, Direct Renin Inhibitors and angioedema history.

Why has this indicator been selected?	Anaphylactoid reactions have occurred with the angiotensin modulating agents and direct renin inhibitors and may involve angioedema of the face, extremities, lips, tongue, glottis and/or larynx. This reaction can occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors or angiotensin receptor antagonists. Patients with a history of angioedema unrelated to these therapies may be at increased risk while receiving an angiotensin modulator or direct renin inhibitor.
How will the patients be selected ?	
Candidates (denominator):	Patients with a pharmacy claim in the past 45 days for an angiotensin modulating agent or a direct renin inhibitor (aliskiren).
Exception criteria (numerator):	Candidates with a history of angioedema in the past 2 years.

References

1) James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel members Appointed to the Eighth Joint National Committee (JNC 8). JAMA 2014 February 311(5):507-520.
2) Weber MA, Schiffrin EL, White WB, et al. Clinical Practice Guidelines for the Management of Hypertension in the Community. J Clin Hypertens 2014 Jan16;(1): 14-26.
3) Bender SR, Fong MW, Heitz S, et al. Characteristics and management of patients presenting to the emergency department with hypertensive urgency. J Clin Hypertens 2005 Jan;8(1):12-8.
4) Krakoff LR. Cost-effectiveness of ambulatory blood pressure: a reanalysis. Hypertension 2006 Jan;47(1):29-34.
5) Fischer MA, Avorn J. Economic implications of evidence-based prescribing for hypertension: can better care cost less? JAMA 2004 Apr 21;291(15):1850-6.
6) Fretheim A, Aaserud M, Oxman AD. The potential savings of using thiazides as the first choice antihypertensive drug: cost-minimization analysis. BMC Health Serv Res 2003 Sep 8;3(1):18.
6) Cooper WO, Hernandez-Diaz S, Arbogast PG, et. al. Major congenital malformations after first-trimester exposure to ACE inhibitors. NEJM 2006 June 8;354:2443-2451.
7) Aliskiren (Tekturna) prescribing information. Novartis Pharmaceuticals, East Hanover, NJ. Available at: www.pharma.us.novartis.com. Accessed March 21, 2007.
8) ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial: major outcomes in the high-risk hypertensive patients randomized to angiotensin-converting inhibitor or calcium channel blocker vs diuretic. JAMA 2002; 288(23):2981-2997.

West Virginia Medicaid
Hyperlipidemia Management

Educational RetroDUR Mailing	☑Initial Study ☐Follow – up /Restudy

Executive Summary

Purpose:	To analyze medical and prescription claims data to determine opportunities for improving coronary heart disease (CHD) prevention with lifestyle modifications and lipid lowering drug therapies following ACC/AHA and NHLBI guidelines.[1,2]	
Why Issue was Selected:	Coronary heart disease caused 1 of every 6 deaths in the United States in 2010. CHD makes up more than half of all cardiovascular events in men and women less than 75 years old. Nearly 33% of deaths due to cardiovascular disease occurred before the age of 75 years, which is well before the average life expectancy of 77.9 years. Approximately every 34 seconds, an American will have a coronary event, and approximately every 1 minute and 23 seconds, someone will die of one.[3] Lowering high LDL cholesterol is known to lower the risk for developing CHD and should therefore be a primary target for prevention. Clinical studies have shown that patients with established CHD (secondary prevention) and those with risk factors for CHD (primary prevention) benefit from lipid lowering therapy.[4-11]	
Program Specific Information:	Performance Indicators	Candidates
	• Underutilization of lipid lowering therapy	8,046
	• Underutilization of lipid lowering therapy in diabetics	8,052
	• Potentially inappropriate lipid lowering therapy in children	22
	• Potentially inappropriate lipid lowering therapy with an agent other than an HMG-CoA reductase inhibitor	381
	• Potential drug-drug interactions involving lipid lowering therapy	125
	• Potential adverse drug events related to lipid lowering therapy	2,663
	• Non-Adherence with lipid lowering therapy	245
	• Simvastatin 80mg – Consider alternative therapy	7
Setting & Population:	All patients currently receiving lipid lowering therapy. Also, patients with medical, procedure and/or pharmacy claims inferring atherosclerotic disease or risk factors for atherosclerotic disease, and those patients lacking medical and/or procedure claims inferring atherosclerotic disease or risk factors for atherosclerotic disease.	
Types of Intervention:	Cover letter and individual patient profiles	
Main Outcome Measures:	The performance indicators will be re-measured when six months of outcome data are available.	
Anticipated Results:	• Increased utilization of lipid lowering therapy in targeted populations • Decreased risk of drug interactions and adverse events with lipid lowering therapy	

	• Increased compliance with lipid lowering therapy • Reduced utilization of simvastatin 80mg due to concerns for adverse events • Reduced risk of adverse events in children on certain cholesterol lowering agents.

Performance Indicator #1: Underutilization of lipid lowering therapy

Why has this indicator been selected?	Clinical studies have shown that the HMG-CoA reductase inhibitors consistently reduce ASCVD events in patients with coronary heart disease. Current treatment guidelines, based on these studies, identified certain groups of individuals who are most likely to benefit from HMG-coA reductase inhibitor therapy, particularly at appropriate intensity of HMG-CoA reductase inhibitor therapy. [1]
How will the patients be selected ?	
Candidates (denominator):	1. Patients ≥ 21 years of age with diagnoses or procedures indicative of clinical ASCVD in their medical history: • Acute coronary syndrome • Myocardial Infarction • Angina • Coronary artery bypass grafting (CABG) • Percutaneous transluminal coronary angioplasty (PTCA) • Stent placement • Atherectomy • Cerebral ischemia • Peripheral artery disease
Exception criteria (numerator):	Candidates who did not receive atorvastatin 40-80mg or rosuvastatin 20-40mg in the past year and have no contraindications to HMG-CoA reductase inhibitor therapy.

Performance Indicator #2: Underutilization of lipid lowering therapy in diabetics

Why has this indicator been selected?	Clinical studies have shown that the HMG-CoA reductase inhibitors consistently reduce ASCVD events in patients with coronary heart disease. Current treatment guidelines, based on these studies, identified certain groups of individuals who are most likely to benefit from HMG-CoA reductase inhibitor therapy, particularly at appropriate intensity of HMG-CoA reductase inhibitor therapy. One such group is diabetic patients. [1]
How will the patients be selected ?	
Candidates (denominator):	2. Patients with a diagnosis or drugs indicative of diabetes in their medical and pharmacy claims history: • Age 40-75 • Diabetes • Antidiabetic therapy • No claims for Welchol (colesevelam) in the past year
Exception criteria (numerator):	Candidates who did not receive an HMG-CoA reductase inhibitor in the past year and have no contraindications to HMG-CoA reductase inhibitor therapy.

Performance Indicator #3: Potentially inappropriate lipid lowering therapy in children

Why has this indicator been selected?	NHLBI guidelines for cardiovascular health in children and adolescents recommend that children less than 10 years of age should not be treated with a lipid-lowering medication unless they have a severe primary hyperlipidemia or a high-risk condition that is associated with serious medical morbidity, such as homozygous hypercholesterolemia, primary hypertriglyceridemia with TG ≥ 500 mg/dL, evident CVD in the first two decades of life or postcardiac transplantation.[1,2]
How will the patients be selected ?	
Candidates (denominator):	Patients <10 years old lacking a diagnosis of hypercholesterolemia, hypertriglyceridemia, diabetes mellitus (Type 1 or 2), chronic kidney disease, Kawasaki disease, or cardiac transplant.
Exception criteria (numerator):	Candidates who received lipid lowering therapy in the past year.

Performance Indicator #4: Potentially inappropriate lipid lowering therapy with an agent other than an HMG-CoA reductase inhibitor

Why has this indicator been selected?	According to the 2013 ACC/AHA blood cholesterol guidelines, a review of randomized controlled trials of non-statins used as monotherapy as well as combination therapy with statins found no data that supported the routine use of non-statin drugs to reduce ASCVD events. As such, the guidelines recommend that non-statins be reserved for high-risk patients who have a less-than-anticipated response to statins or are unable to tolerate a statin.[1]
How will the patients be selected ?	
Candidates (denominator):	Patients ≥ 21 years of age lacking a diagnosis of ASCVD or diabetes.
Exception criteria (numerator):	Candidates with a history of a non-statin in the past 45 days with no history of a statin in the past year.

Performance Indicator #5: Potential drug-drug interactions involving lipid lowering agents

Why has this indicator been selected?	Patients with potential drug-drug interactions are at an increased risk of having an adverse drug event. Only Level 1 (most significant) drug-drug interactions, as defined by FirstData Bank, or lipid-lowering therapy with doses exceeding specified daily limits listed in the package inserts are identified.[14-16]
How will the patients be selected?	
Candidates (denominator):	Patients receiving a lipid lowering medication in the past 45 days.
Exception criteria (numerator):	Candidates concomitantly receiving an interacting drug (see Appendix A) with >/= 7 days overlap.

Performance Indicator #6: Potential adverse drug events related to lipid lowering therapy

Why has this indicator been selected?	Patients with potential drug-disease interactions are at increased risk of having an adverse drug event. Only Level 1 (most significant) drug-drug interactions, as defined by FirstData Bank are identified.[14,15]
How will the patients be selected ?	
Candidates (denominator):	Patients receiving niacin, an HMG-CoA product, a fibrate or colesevelam in the past 45 days.
Exception criteria (numerator):	Candidates receiving: 1. A niacin-containing product with a history of peptic ulcer disease in the past 90 days or hepatic impairment or hepatitis in the past year. 2. An HMG-CoA product with a history of hepatic dysfunction in the past year, renal dysfunction in the past year, myopathy in the past year or current pregnancy. 3. A fibrate with a history of hepatic dysfunction or renal dysfunction in the past year. 4. Colesevelam with a history of bowel obstruction in the past year.

Performance Indicator #7: Non-Adherence with lipid lowering therapy

Why has this indicator been selected?	Adherence with prescribed maintenance drug regimens is paramount to successful patient outcomes. More than $100 billion is spent yearly for problems related to non-adherence. Over half of written prescriptions are taken incorrectly.[12]
How will the patients be selected ?	
Candidates (denominator):	Patients receiving lipid lowering therapy in the most recent 45 days and 90 to 135 days ago.
Exception criteria (numerator):	Candidates who received <60 days' supply of the medication in the past 90 days.

Performance Indicator #8: Simvastatin 80mg – consider alternative therapy

Why has this indicator been selected?	Due to concerns for increased risk of myopathy, including rhabdomyolysis, with simvastatin 80mg compared with other statin therapies with similar or greater LDL-C lowering efficacy and compared with lower doses of simvastatin, use of the 80mg dose of simvastatin should be restricted to patients who have been taking that dose chronically (e.g., for 12 months or more) without evidence of muscle toxicity.[13]
How will the patients be selected ?	
Candidates (denominator):	Patients with a claim in the past 45 days for a simvastatin 80mg-containing product (i.e., simvastatin 80mg or Vytorin® 10mg/80mg).
Exception criteria (numerator):	Candidates with <9 months of therapy with a simvastatin 80mg-containing product in the last 12 months.

References

1. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2013. Published online November 12, 2013. Available from: https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf. (Accessed 3/10/14).
2. National Heart, Lung and Blood Institute. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. Available from: http://www.nhlbi.nih.gov/guidelines/cvd_ped/ . (Accessed 3/10/14).
3. American Heart Association. Heart Disease and Stroke Statistics — 2014 Update. Circulation 2014; 129: e28-e292. Published online December 18, 2013. Available from: http://circ.ahajournals.org/content/129/3/e28.full.pdf+html. (Accessed 3/10/14).
4. Shepherd J, Cobbe SM, Ford I, et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia: West of Scotland Coronary Prevention Study Group. N Engl J Med 1995; 333: 1301-1307.
5. Downs JR, Clearfield M, Weis S, et al. Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels: Results of AFCAPS/TexCAPS-Air Force/Texas Coronary Atherosclerosis Prevention Study. JAMA 1998; 279: 1615-1622.
6. Scandinavian Simvastatin Survival Study Group. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: The Scandinavian Simvastatin Survival Study (4S). Lancet 1994; 344: 1383-1389.
7. Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole TG, et al. The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels: Cholesterol and Recurrent Events Trial Investigators. N Engl J Med 1996; 335: 1001-1009.
8. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group. 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: 1349-1357.
9. Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: A randomised placebo-controlled trial. Lancet 2002; 360: 7-22.
10. Sever PS, Dahlöf B, Poulter NR, et al., for the ASCOT investigators. Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower that average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial-Lipid Lowering Arm (ASCOT-LLA): a multicenter randomized controlled trial. Lancet 2003; 361: 1149-1158.
11. The Pravastatin or Atorvastatin Evaluation and Infection Therapy – Thrombolysis in Myocardial Infarction 22 Investigators, Cannon CP, Eugene Braunwald E, McCabe CH, et al. Comparison of intensive and moderate lipid lowering with statins after acute coronary syndromes. N Engl J Med 2004; 350.
12. Berg JS et al. Medication compliance: a healthcare problem. Ann Pharmacother 1993;27(suppl 9): S1-S24.
13. Healthcare professional letter packet. Important Drug Warning. Restricted dosing of simvastatin 80-mg dose and updated drug interaction information due to dose-related risk of myopathy/rhabdomyolysis. Merck, West Point, PA. Available at: http://www.simvastatininfocenter.com/documents/hcpletter.pdf. (Accessed 2/10/13).
14. Source for Level one drug-drug and drug-disease interactions. FirstData Bank, Inc. San Bruno, CA. 2011.
15. Official Prescribing Information. Available at: http://www.fda.gov/Drugs/default.htm. (Accessed 2/15/13).
16. FDA Drug Safety Communication: Important safety label changes to cholesterol-lowering statin drugs, Food and Drug Administration; February 28, 2012. Available from: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/default.htm. (Accessed 2/15/13).

Appendix A: Hyperlipidemia Therapy Drug-Drug Interactions[14-16]

Statin	
Atorvastatin	Ritonavir-boosted tipranavir Telaprevir Telithromycin
Atorvastatin > 20mg/day	itraconazole Fosamprenavir Macrolides (clarithromycin, erythromycin,) Ritonavir-boosted protease inhibitors (darunavir, saquinavir)
Atorvastatin > 40mg/day	Nelfinavir Simeprevir
Fluvastatin > 20mg twice daily	Cyclosporine Fluconazole
Lovastatin	Antifungals (itraconazole, ketoconazole, posaconazole, voriconazole) Hepatitis C Protease Inhibitors (boceprivir, telaprevir) HIV Protease Inhibitors Macrolides (clarithromycin, erythromycin) Nefazodone Telithromycin
Lovastatin > 20mg/day	Danazol Diltiazem Verapamil
Lovastatin > 40mg/day	Amiodarone Dronedarone
Pitavastatin	Cyclosporine
Pitavastatin > 1mg/day	Macrolides (clarithromycin, erythromycin)
Pitavastatin > 2mg/day	Rifampin
Pravastatin > 20mg/day	Cyclosporine
Pravastatin > 40mg/day	Macrolides (clarithromycin, erythromycin)
Rosuvastatin > 5mg/day	Cyclosporine
Rosuvastatin > 10mg/day	Gemfibrozil Ritonavir-boosted protease inhibitors (atazanavir, lopinavir) Simeprevir
Simvastatin	Antifungals (itraconazole, ketoconazole, posaconazole, voriconazole) Cyclosporine Danazol Gemfibrozil Hepatitis C Protease Inhibitors (boceprivir, telaprevir) HIV Protease Inhibitors Macrolides (clarithromycin, erythromycin) Nefazodone Telithromycin
Simvastatin > 10mg/day	Diltiazem Verapamil
Simvastatin > 20mg/day	Amiodarone Amlodipine Ranolazine
Non-Statin	
Fenofibrate	Warfarin
Gemfibrozil	Repaglinide-containing products Warfarin

Template Name: Hyperlipidemia DM 2014