



Diabetes Mellitus Disease Management

Prepared for West Virginia Medicaid by ACS Rx Delivery Services

Initial Study

Follow-up/Restudy

EXECUTIVE SUMMARY

Purpose: To determine opportunities for improving the quality and safety of drug therapy for patients with diabetes mellitus following the 2011 clinical practice recommendations published by the American Diabetes Association.¹

Why Issue was Selected: An estimated 24.1 million people in the United States have diabetes mellitus. The associated yearly cost of diabetes in the US is \$174 billion.² Diabetes is associated with considerable morbidity, such as blindness, end stage renal disease, lower extremity amputations, heart disease, and stroke.

Program Specific Information:	Performance Indicators	Exceptions*
	• Underutilization of Angiotensin Modulating (ACE inhibitor or Angiotensin Receptor Blocker[ARB]) Therapy	742
	• Underutilization of Antilipemic Therapy	3,222
	• Potential Drug-Drug Interactions Involving Diabetes Medications	2
	• Increased Risk of Adverse Drug Events With Oral Diabetes Medications	1,721
	• Compliance With Maintenance Diabetes, Antihypertensive and Antilipemic Medications	1,672
	• Duplicate Therapy With Diabetes Medications	0
	• Increased Risk of Adverse Events – Routine monitoring laboratory values	23,099
	• Increased Risk of Adverse Events – Preventative measures (Annual dilated eye exams)	11,599
	• Increased Risk of Adverse events – Preventative measures (Annual foot exams)	12,226
	• Underutilization of Metformin	1,597
	• Underutilization of Antiplatelet Therapy	6,528
	• Underutilization of Influenza Vaccine	14,299
	• Monitoring Diabetes in Patients Receiving Atypical Antipsychotics	474

*Based on data thru September 2011.

Setting & Population: Adult patients with diabetes will be included in this initiative.

Type of Intervention: Cover letter, cost chart and modified profiles

Main Outcome Measures: The performance indicators in this proposal will be remeasured.

Anticipated Results: Increased use of angiotensin-modulating agents, antilipemics, antiplatelets, influenza vaccine and metformin in appropriate diabetic patients, improved compliance with medications, increased awareness of routine laboratory monitoring and preventative measures, reduction of potential drug-drug interactions, potential adverse drug events, and unintentional duplicate therapy.

PERFORMANCE INDICATORS

Indicator #1: Underutilization Of Angiotensin-Modulating Therapy

Why has this indicator been selected? Clinical studies have shown that ACE inhibitors and certain angiotensin receptor blockers (ARB) (specifically losartan and irbesartan) decrease or stabilize albuminuria in incipient nephropathy and slow the rate of progression to advanced nephropathy.³⁻⁶ They should be utilized in all patients with diabetes and hypertension who do not have a contraindication to receiving them. Further, the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease recommend the use of an ACE inhibitor or an ARB for reducing albuminuria and delaying kidney disease progression in patients with diabetes and kidney disease regardless of blood pressure level.⁷

How will the patients be Selected?

- 1) Patients who have hypertension and diabetes and are not taking an angiotensin modulating agent
- 2) Patients who have chronic kidney disease and diabetes and are not taking an angiotensin modulating agent

Candidates (denominator): Patients a diagnosis of diabetes (ICD-9 code or inferred from drug therapy) and 1) hypertension (submitted ICD-9 code diagnosis required) who are receiving antihypertensive drug treatment or 2) kidney disease (submitted ICD-9 code required) and who do not have a documented contraindication or relative contraindication to angiotensin modulating therapy (i.e., anuric renal failure, renal artery stenosis, pregnancy or a history of angioneurotic edema).

Exception criteria (numerator): Candidates not receiving an angiotensin-modulating agents (ACE inhibitor or ARB).

Indicator #2: Underutilization Of Antilipemic Therapy

Why has this indicator been selected? The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) identified diabetes as a CHD risk equivalent.⁸⁻¹⁰ The onset of CHD in patients with diabetes carries a poor prognosis, both at the time of an acute CHD event and in the post-event period. The NCEP and the American Diabetes Association (ADA) recommend that patients with a history of diabetes maintain LDL cholesterol < 100 mg/dl. In high risk patients with diabetes and overt cardiovascular disease, a lower LDL cholesterol goal of <70 mg/dl, is an option.

How will the patients be Patients with diabetes not receiving antilipemic therapy and without a

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and/or antilipemic drug therapy.

Exception Criteria (numerator): Candidates who received < a 60-day supply of the medication during a 90-day period.

Indicator #6: Duplicate Therapy With Diabetes Medications

Why has this indicator been selected? Combination therapy with diabetes medications with complementary mechanisms of action is often required for adequate glycemic control. However, duplicate within-class drug therapy has not been shown to increase efficacy and may increase the risk of adverse drug events, particularly if coordination of care issues play a role.

How will the patients be Selected? Patients prescribed multiple antidiabetic medications.

Candidates (denominator): Patients receiving sulfonylureas, thiazolidinediones, meglitinides, or alpha-glucosidase inhibitors.

Exception Criteria (numerator): Candidates receiving multiple sulfonylureas, multiple thiazolidinediones, multiple meglitinides, or multiple alpha-glucosidase inhibitors.

Indicator #7: Increased Risk of Adverse Event – Routine Monitoring of Laboratory Values

Why has this indicator been selected? Obtaining routine laboratory values (Basic Metabolic Panel [BMP] or Comprehensive Metabolic Panel [CMP]), A1C, Microalbumin, Fasting Cholesterol Panel and Serum Creatinine) at recommended frequencies¹ is one of the ways providers can assist their patients in managing their diabetes. In addition to the patient's self monitoring of blood glucose, these routine laboratory tests will assist the provider in determining whether medications are functioning appropriately, additions or deletions of medications need to be made, or further evaluation is necessary.

How will the patients be selected? Patients with diabetes (submitted ICD-9 or inferred from drug therapy) and lack the documentation (via CPT codes) for routine laboratory monitoring

Candidates (denominator): Patients with diabetes (submitted ICD-9 diagnosis code for diabetes or inferred from drug therapy).

Exception Criteria (numerator): Candidates with no documentation of the chemistries/laboratory monitoring (CPT codes) within the recommended frequency range. (see Appendix, Table 3).

Indicator #8: Increased Risk of Adverse Events – Preventative Measures (Eye Examinations)

Why has this indicator been selected? Diabetic retinopathy is the leading cause of blindness among adults aged 20-74 years. Annual dilated eye examinations are recommended for all patients with diabetes.¹ This examination serves as a measure for early detection of retinopathy and early intervention with laser photocoagulation surgery to reduce the risk of vision loss. In addition, patient education is critical in assisting the provider in preventing this complication. Patients with diabetes can help to reduce their risk for retinopathy if they are educated about their disease and learn and practice the skills necessary to optimize blood glucose and blood pressure control.

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How will the patients be selected?	Patients with diabetes (submitted ICD-9 code for diabetes or inferred from drug therapy) and lack the documentation (via CPT and/or ICD-9 codes) for eye examinations
Candidates (denominator):	Patients with diabetes (submitted ICD-9 diagnosis code for diabetes or inferred from drug therapy).
Exception Criteria (numerator):	Candidates without documentation of eye examinations by respective CPT and/or ICD-9 codes (see Appendix, Table 4).

Indicator #9: Increased Risk of Adverse Events – Preventative Measures (Foot Examinations)

Why has this indicator been selected?	Foot ulcers are a major predictor of future lower-extremity amputation in patients with diabetes. Preventing foot ulcers and other foot complications can improve function and quality of life, control infection, help maintain health status, prevent amputations and reduce costs. ¹¹
How will the patients be selected?	Patients with diabetes (submitted ICD-9 code for diabetes or inferred from drug therapy) who lack the documentation for foot examinations. Patients with a history of other foot conditions/ diseases (e.g. onychomycosis, dermatophytosis,), codes suggestive of foot evaluation (e.g. nail trimming, radiographs of the foot), or with inferred foot care treatment (prescriptions for becaplermin [Regranex [®]]) will be excluded.
Candidates (denominator):	Patients with diabetes (submitted ICD-9 diagnosis code for diabetes or inferred from drug therapy).
Exception Criteria (numerator):	Candidates without documentation of foot examinations or a history of other foot conditions/diseases suggestive of foot evaluation, as indicated in Table 5 (see Appendix, Table 5).

Indicator #10: Metformin Underutilization

Why has this indicator been selected?	A consensus statement from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes recommends early intervention with metformin in combination with lifestyle changes. ¹ This recommendation is based upon metformin's effect on glycemia, absence of weight gain or hypoglycemia, generally low level of side effects, high level of acceptance, and relatively low cost. Furthermore, the UKPDS demonstrated a beneficial effect of metformin therapy on cardiovascular disease. ^{1,12} Per the metformin prescribing information, patients should be titrated, as tolerated, to a dose of at least 850mg twice daily in order to realize the benefits of metformin therapy.
How will the patients be selected?	Patients with type 2 diabetes who are not receiving metformin therapy who do not have a contraindication to such therapy. Patients who have been treated exclusively with insulins for the past year will be excluded.
Candidates (denominator):	Adult patients with type 2 diabetes without contraindications to metformin.

Exception Criteria (numerator): Candidates who have 1) not received metformin in the past year 2) discontinued metformin in the past 90 days, or 3) received a dose <1700 mg/day on the most recent prescription.

Indicator #11: Underutilization of Antiplatelet Therapy

Why has this indicator been selected? The American Diabetes Association recommends the use of aspirin therapy (75-162 mg/d) as a primary prevention strategy in diabetic individuals at high-risk for CVD and as a secondary prevention strategy in diabetic individuals with a history of CVD.¹ Other antiplatelet agents (e.g., clopidogrel, dipyridamole/ASA, ticlopidine) are recommended alternatives for patients who are not candidates for aspirin therapy (e.g., contraindications, allergy).

How will the patients be selected? Patients with diabetes who are candidates for either primary or secondary prevention with antiplatelet therapy who are not receiving antiplatelet therapy (aspirin or an alternative if contraindications to aspirin exist).

Candidates (denominator): Adult patients age 30 years or older with type 2 diabetes.

Exception Criteria (numerator): Candidates who are not receiving antiplatelet therapy (aspirin or an alternative if contraindications to aspirin exist) in the past 45 days.

Indicator #12: Underutilization of the Influenza Vaccine

Why has this indicator been selected? Persons with diabetes are at high risk for developing severe complications from influenza. In a case-control series, influenza vaccine was shown to reduce diabetes-related hospital admissions by as much as 79% during flu epidemics. The American Diabetes Association recommends that all diabetic patients 6 months of age or older receive an annual influenza vaccination.¹

How will the patients be selected? Patients with diabetes who are 6 months of age or older who have not received an influenza vaccination in the past year.

Candidates (denominator): Patients with diabetes who are 6 months of age or older.

Exception Criteria (numerator): Candidates who have not received an influenza vaccination in the past year.

Indicator #13: Monitoring Diabetes in Patients Receiving Atypical Antipsychotics

Why has this indicator been selected? Atypical antipsychotics are associated with metabolic adverse effects that include destabilization of blood glucose levels. While different agents have different risk levels, routine assessment of glucose control is recommended in all patients being treated with atypical antipsychotics.

How will the patients be selected? Patients with diabetes receiving antidiabetic medications and atypical antipsychotics who have not received a hemoglobin A1C in the past 180 days.

Candidates (denominator): Patients with diabetes receiving antidiabetic medications and atypical antipsychotics.

Exception Criteria (numerator): Candidates who have not received a hemoglobin A1C in the past 180 days.

REFERENCES

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9. American Diabetes Association. <http://diabetes.org>. Management of dyslipidemia in adults with diabetes. *Diabetes Care*. 2003;26(1):83-86.
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APPENDIXES

Table 1. Diabetes Drug Interactions

Anti-diabetic Drug	Interacting Drug
Acarbose	<ul style="list-style-type: none"> • Digestive enzymes • Digoxin
Miglitol	<ul style="list-style-type: none"> • Digestive enzymes
Repaglinide	<ul style="list-style-type: none"> • Gemfibrozil

Table 2. Diabetes Drug Disease Interactions

Anti-diabetic Drug	Medical Condition
Acarbose	<ul style="list-style-type: none"> • Cirrhosis • GI disease
Miglitol	<ul style="list-style-type: none"> • GI disease
Chlorpropamide	<ul style="list-style-type: none"> • Age >70
Pioglitazone Pioglitazone/Glimepiride Pioglitazone/Metformin Rosiglitazone Rosiglitazone/Metformin Rosiglitazone/ Glimepiride	<ul style="list-style-type: none"> • Active liver disease • Heart failure • Macular edema
Rosiglitazone	<ul style="list-style-type: none"> • Myocardial ischemia
Metformin Rosiglitazone/Metformin Glipizide/Metformin Glyburide/Metformin Pioglitazone/Metformin	<ul style="list-style-type: none"> • Renal disease or renal dysfunction • Age ≥ 80 years • Heart failure • Acute or chronic metabolic acidosis • Hepatic disease or hepatic impairment

Table 3. Laboratory Codes

CPT Procedure Code Definitions		Minimum Recommended Frequency
Hemoglobin, glyated (A1c)	83036	Quarterly <ul style="list-style-type: none"> • Uncontrolled patients Biannually <ul style="list-style-type: none"> • Controlled patients
Microalbumin/Macroalbuminuria	82042 82043 82044 84155 84160 84165	Annually
Creatinine, blood <i>OR</i> General Health Panel <i>OR</i> Renal Function Panel <i>OR</i> Basic metabolic panel <i>OR</i> Comprehensive metabolic panel a	82565 80050 80069 80048 80053	Annually
Lipid Panel (fasting) – including:	80061	Annually
<ul style="list-style-type: none"> • Total Cholesterol 	82465	Annually

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• HDL	83718	Annually
• LDL	83721 83715 83716	Annually
• Triglycerides	84478	Annually

Table 4: Preventative Measures (Eye Examination)

CPT Procedure Code Definitions	
Description Code	
• Repair of retinal detachment, one or more sessions; cryotherapy or diathermy, with or without drainage of subretinal fluid	67101
• Repair of retinal detachment, one or more sessions; photocoagulation, with or without drainage of subretinal fluid	67105
• Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), with or without implant, with or without cryotherapy, photocoagulation, and drainage of subretinal fluid.	67107
• Repair of retinal detachment; with virectomy, any method, with or without air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique	67108
• Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopathy)	67110
• Repair of retinal detachment; by scleral buckling or vitrectomy, on patient having previous ipsilateral retinal detachment repairs(s) using scleral buckling or vitrectomy techniques	67112
• Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage, one or more sessions; cryotherapy, diathermy	67141
• Prophylaxis of retinal detachment (e.g., retinal break, lattice degeneration) without drainage, one or more sessions; photocoagulation (laser or xenon arc)	67145
• Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; cryotherapy, diathermy	67208
• Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; photocoagulation.	67210
• Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; radiation by implantation of source (includes removal of source)	67218
• Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), one or more sessions; cryotherapy, diathermy	67227
• Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), one or more sessions; photocoagulation (laser or xenon arc)	67228
• New patient - Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate	92002
• New patient, one of more visits – Ophthalmology services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive	92004
• Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient	92012
• Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, one or more visits	92014
• Ophthalmological examination and evaluation, under general anesthesia, with or	92018

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without manipulation of globe for passive range of motion or other manipulation to facilitate diagnostic examination; complete	
<ul style="list-style-type: none"> Ophthalmological examination and evaluation, under general anesthesia, with or without manipulation of globe for passive range of motion or other manipulation to facilitate diagnostic examination; limited 	92019
<ul style="list-style-type: none"> Scanning computerized ophthalmic diagnostic imaging (e.g., scanning laser) with interpretation and report, unilateral 	92135
<ul style="list-style-type: none"> Ophthalmic biometry by partial coherence interferometry with intraocular lens power calculation 	92136
<ul style="list-style-type: none"> Ophthalmoscopy, extended, with retinal drawing (e.g., for retinal detachment, melanoma), with interpretation and report; initial 	92225
<ul style="list-style-type: none"> Ophthalmoscopy, extended, with retinal drawing (e.g., for retinal detachment, melanoma) with interpretation and report; subsequent 	92226
<ul style="list-style-type: none"> Fluorescein angiography with interpretation and report 	92230
<ul style="list-style-type: none"> Fluorescein angiography (includes multiframe imaging) with interpretation and report 	92235
<ul style="list-style-type: none"> Indocyanine-green angiography (includes multiframe imaging) with interpretation and report 	92240
<ul style="list-style-type: none"> Fundus photography with interpretation and report 	92250
<ul style="list-style-type: none"> Ophthalmodynamometry 	92260
<ul style="list-style-type: none"> Special anterior segment photography with interpretation and report; with fluorescein angiography 	92287
<ul style="list-style-type: none"> Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist 	G0117
<ul style="list-style-type: none"> Glaucoma screening for high risk patients furnished under the direct supervision of an optometrist or ophthalmologist 	G0118

ICD-9 Code Definitions	
Description	
Code	
<ul style="list-style-type: none"> General and subjective eye exam 	95.0x
<ul style="list-style-type: none"> Examinations of form and structure of eye 	95.1x
<ul style="list-style-type: none"> Objective functional tests of eye 	95.2x
<ul style="list-style-type: none"> Special vision services 	95.3x
<ul style="list-style-type: none"> Examination of eyes and vision 	V72.0

Table 5: Preventative Measures (Foot Examination)

Procedure Code Definitions	
Description	Code
<ul style="list-style-type: none"> Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) the diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (4) patient education 	G0245
<ul style="list-style-type: none"> Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history, (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3) patient education 	G0246
<ul style="list-style-type: none"> Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include, the local care of superficial wounds (i.e., superficial to muscle and fascia) and at least the following if present: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails 	G0247
<ul style="list-style-type: none"> Routine foot care; removal and/or trimming of corns, calluses and/or nails and preventive maintenance in specific medical conditions (e.g., diabetes), per visit 	S0390
Other Foot Conditions/Diseases	
<ul style="list-style-type: none"> Decubitus ulcer of the heel 	707.07
<ul style="list-style-type: none"> Dermatophytosis of the nail, of the foot 	110.1, 110.4
<ul style="list-style-type: none"> Diseases of the nail 	703
<ul style="list-style-type: none"> Trimming of nondystrophic nails, any number Debridement of nail(s) by any method(s); one to five Debridement of nail(s) by any method(s); six or more Avulsion of nail plate, partial or complete, simple; single Avulsion of nail plate, partial or complete, simple; each additional nail plate (List separately in addition to code for primary procedure) Evacuation of subungual hematoma Excision of nail and nail matrix, partial or complete, (eg, ingrown or deformed nail) for permanent removal Excision of nail and nail matrix, partial or complete, (eg, ingrown or deformed nail) for permanent removal; with amputation of tuft of distal phalanx Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure) Repair of nail bed; Reconstruction of nail bed with graft; Wedge excision of skin of nail fold (eg, for ingrown toenail) 	11719-11765
<ul style="list-style-type: none"> Cellulitis and abscess of toe 	681.1
<ul style="list-style-type: none"> Candidiasis of skin and nails 	112.3
<ul style="list-style-type: none"> Specified anomalies of the nails 	757.5
<ul style="list-style-type: none"> Open wound of toe (s) 	893
<ul style="list-style-type: none"> Trimming of dystrophic nails, any number 	G0127
<ul style="list-style-type: none"> Ulcer of heel and midfoot Ulcer of other part of the foot 	707.14-707.15
<ul style="list-style-type: none"> Amputation, foot; midtarsal (eg, Chopart type procedure) 	28800-28825

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<ul style="list-style-type: none"> • Amputation, foot; transmetatarsal • Amputation, metatarsal, with toe, single • Amputation, toe; metatarsophalangeal joint • Amputation, toe; interphalangeal joint 		
<ul style="list-style-type: none"> • Removal of foreign body, foot; subcutaneous • Removal of foreign body, foot; deep • Removal of foreign body, foot; complicated 		28190-28193
<ul style="list-style-type: none"> • Radiologic examination, foot; two views • Radiologic examination, foot; complete, minimum of three views • Radiologic examination; calcaneus, minimum of two views • Radiologic examination; toe(s), minimum of two views 		73620, 73630, 73650, 73660
<ul style="list-style-type: none"> • Foot, arch support, removable, premolded, longitudinal, each • Foot, arch support, removable, premolded, metatarsal, each • Foot, arch support, removable, premolded, longitudinal/metatarsal, each • Foot, arch support, nonremovable, attached to shoe, longitudinal, each • Foot, arch support, nonremovable, attached to shoe, metatarsal, each • Foot, arch support, nonremovable, attached to shoe, longitudinal/metatarsal, each • Hallus-valgus night dynamic splint • Orthopedic shoes, footwear, surgical boots, etc. 		L3040-L3060, L3070-L3100, L3201-L3265
<ul style="list-style-type: none"> • Dislocation of the foot 		838
<ul style="list-style-type: none"> • Amputation, leg, through tibia and fibula • Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast • Amputation, leg, through tibia and fibula; open, circular (guillotine) • Amputation, leg, through tibia and fibula; secondary closure or scar revision • Amputation, leg, through tibia and fibula; re-amputation • Amputation, ankle, through malleoli of tibia and fibula (eg, Syme, Pirogoff type procedures), with plastic closure and resection of nerves • Ankle disarticulation 		27880-27889
<ul style="list-style-type: none"> • Traumatic amputation of toe (s) (complete) (partial) • Traumatic amputation of foot (complete) (partial) • Traumatic amputation of legs (s) (complete) (partial) 		895-897



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Date

<<Name>>
 <<Address>>
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RE: Caring for Your Patients with Diabetes

Dear Dr. Sample:

The goal of this quality management program is to assist you in caring for your patients with diabetes. The American Diabetes Association (ADA) develops standards of medical care that are designed to improve the management of diabetes.¹ Strategies to achieve treatment goals and reduce the risk of long-term complications associated with diabetes are the focus of this initiative.

Claims data indicate that in the West Virginia Medicaid Program there are approximately 65,000 individuals being treated for diabetes. This treatment included 203,871 prescriptions for antidiabetic medications in the past year at a total cost of \$23,654,854.

West Virginia Specific Data

Diabetes Management Indicator Summary	Number of Patients with Opportunities*
• Encourage the use of angiotensin modulating agents in patients with a diagnosis of hypertension or nephropathy and no contraindications to therapy	742
• Encourage the use of antilipemic therapy in patients without contraindications	3,222
• Encourage the use of metformin in patients with type 2 diabetes without contraindications to therapy	1,597
• Promote safe and effective use of antidiabetic agents through identification of potential adverse events and drug interactions	1,721
• Support medication adherence and recognize when discontinuation of therapy may be contributing to treatment failure	1,672
• Encourage recommended laboratory tests and preventative screenings	23,099
• Identify potentially unnecessary duplicate therapy with antidiabetic medications	0
• Encourage the daily use of antiplatelet therapy	6,528
• Promote the use of an annual influenza vaccination	14,299
• Monitor diabetes (i.e., A1C every 6 months) in patients receiving atypical antipsychotics	474

*Based on data thru September 2011.

The enclosed patient profiles reflect the above issue and are provided as a chart reminder for when your patients return for their next appointments.

We acknowledge that there may be clinical variables influencing an individual patient's management that are not apparent in claims data or that a patient may have been inadvertently identified as being under your care. However, we believe the issues identified will assist you in caring for your patient(s). We thank you for reviewing this information and caring for West Virginia Medicaid's patients and welcome the opportunity to discuss any comments or concerns you may have about our quality management program. Please feel free to call our office at _____ with questions or concerns.

Sincerely,

Medical Director

Diabetes Management Indicator Summary

- **Encourage the use of angiotensin modulating agents** in diabetic patients with hypertension who are without contraindications to receiving angiotensin-modulating therapy to reduce the risk of diabetic
- **Encourage the use of antilipemic therapy if needed to maintain an LDL cholesterol <100 mg/dl.** According to the National Cholesterol Education Program (NCEP) guidelines and the American Diabetes Association (ADA) clinical practice recommendations, patients with a history of diabetes should maintain LDL cholesterol < 100 mg/dl. Additionally, findings from the Heart Protection Study suggest that statin therapy may be appropriate to achieve an LDL reduction of ~30% regardless of the baseline LDL in people with diabetes over the age of 40 years with a total cholesterol ≥ 135 mg/dl.^{1,2} In high risk patients with diabetes and overt cardiovascular disease, a lower LDL cholesterol goal of <70
- **Encourage the use of metformin in patients with type 2 diabetes without contraindications to therapy.** The American Diabetes Association (ADA) and the European Association for the Study of Diabetes recommend early intervention with metformin in combination with lifestyle changes due to its effect on glycomia, absence of weight gain, and potentially beneficial effects on cardiovascular disease.³
- **Promote safe and effective use of antidiabetic agents through identification of adverse events and drug interactions.** Certain medical conditions and/or medications may predispose patients receiving antidiabetic agents to adverse drug events. If the combination cannot be avoided for clinical reasons, monitor for toxicity and altered glycemc response.
- **Support medication adherence and recognize when discontinuation of therapy may be contributing to treatment failure.** Adherence to maintenance antidiabetic, antihypertensive and antilipemic medications is necessary to achieve therapy goals: A1C <7%, blood pressure (BP) <130/80 mmHg, and LDL cholesterol of <100 mg/dl (optional goal of <70 mg/dl in patients with
- Identify **potentially unnecessary duplicate therapy** with antidiabetic medications.
- **Encourage daily use of antiplatelet therapy.** The American Diabetes Association recommends the use of aspirin therapy (75-162 mg/day) as a primary prevention strategy in diabetic individuals at increased risk for developing cardiovascular disease (CVD) and as a secondary prevention strategy in diabetic individuals with a history of CVD. Patients considered to have a 10-year risk of CVD >10% include most men at least 50 years of age or women at least 60 years of age who have at least one additional major CVD risk factor (i.e., family history of CVD, hypertension, dyslipidemia, smoking, or albuminuria). Clopidogrel is recommended as an alternative for patients who are not candidates for aspirin therapy (e.g., contraindications, allergy).¹
- **Promote the use of an annual influenza vaccination.** Persons with diabetes are at high risk for developing severe complications from influenza. The American Diabetes Association recommends that all diabetic patients 6 months of age or older with diabetes receive an annual influenza vaccine.¹



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Hyperlipidemia

Prepared for West Virginia Medicaid by Affiliated Computer Services, Inc.

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 NCEP guidelines.^{1,2}

Why Issue was Selected: Coronary heart disease caused 1 of every 6 deaths in the United States in 2007. 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 25 seconds, an American will have a coronary event, and approximately every minute, 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	Exceptions
	• Underutilization of lipid lowering therapy	6,222
	• Potential drug-drug interactions involving lipid lowering therapy	752
	• Potential adverse drug events related to lipid lowering therapy	1,455
	• Non-Adherence with lipid lowering therapy	2,378
	• Simvastatin 80mg – Consider alternative therapy	742

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.

Type of Intervention: Cover Letter, Individual Patient Profiles

Main Outcome Measures: Re-measure performance indicators

Anticipated Results:

- Increased utilization of lipid lowering therapy
- 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

PERFORMANCE INDICATORS**Indicator #1: Underutilization of lipid lowering therapy**

Why has this indicator been selected?

Clinical studies have shown the benefits of lipid lowering therapies, particularly HMG-CoA reductase inhibitors, in patients with coronary heart disease, as well as patients with borderline cholesterol levels and no clinically evident disease. As stated above, there are large groups of patients who are either not treated or undertreated.^{4,11}

How will the patients be selected?

Candidates (denominator):

1. Patients with diagnoses, procedures, or drugs indicative of CHD or other atherosclerotic disease in their medical history:

- Myocardial Infarction
- Angina
- Coronary artery bypass grafting (CABG)
- Percutaneous transluminal coronary angioplasty (PTCA)
- Stent placement
- Atherectomy
- Cerebral ischemia
- Hyperlipidemia
- Nitroglycerin or clopidogrel use

OR

2. Patients who meet two of the three following criteria:

- Positive smoking history (diagnosis)
- Hypertension (diagnosis)
- Age – males \geq 45 years of age or females \geq 55 years of age

OR

3. Patients with CHD risk equivalents

- Diabetes (diagnosis or antidiabetic therapy)
- Peripheral vascular disease (PVD)
- Pentoxifylline or cilostazol use

Exception criteria

(numerator):

Candidates who did not receive lipid lowering therapy in the past year.

Indicator #2: 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, are identified.¹⁴

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).

Indicator #3: 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.

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.

Indicator #4: 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 past 135 days.
 Exception Criteria (numerator): Candidates who received <60 days supply of the medication in the past 90 days.

Indicator #5: 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.

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Appendix A: Hyperlipidemia Therapy Drug-Drug Interactions¹⁴

Simvastatin	Danazol
Simvastatin > 10mg/day	Amiodarone
Simvastatin > 10mg/day	Diltiazem/Verapamil
Simvastatin > 20mg/day	Amlodipine
Simvastatin > 20mg/day	Ranolazine
Simvastatin	Macrolides (Erythromycin, Clarithromycin, Telithromycin)
Simvastatin	Nefazodone
Lovastatin, Pitavastatin, Atorvastatin, Rosuvastatin, Simvastatin	Cyclosporine
Lovastatin	Verapamil
Lovastatin, Rosuvastatin, Simvastatin	Gemfibrozil
Lovastatin, Pitavastatin	Clarithromycin, Erythromycin
Lovastatin, Atorvastatin	Telithromycin
Lovastatin, Atorvastatin, Simvastatin	Antifungals (itraconazole, ketoconazole, posaconazole)
Lovastatin, Pitavastatin, Simvastatin	Protease inhibitors
Lovastatin > 40mg/day	Antiarrhythmics (amiodarone, dronedarone)



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Re: Caring for Your Patients with or at Risk for Coronary Heart Disease

Dear Dr. Sample:

The goal of this quality management program is to assist you in caring for your patients with or at risk for coronary heart disease (CHD) through lipid lowering therapy. In 2001, clinical guidelines for cholesterol testing and management were released by the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III [ATP III]). A 2004 update to the NCEP clinical practice guidelines suggests a more aggressive therapeutic option for patients at very high risk for CHD based on recent clinical trials. This program is based on those guidelines and is designed to assist you in maximizing patient outcomes and promoting patient safety.

Claims data indicates that in the West Virginia program there are 13,101 recipients who are candidates (primary or secondary prevention) for lipid lowering therapy. Approximately 47% (6,222) of these candidates are not currently receiving lipid lowering therapy.

<Client's> Medicaid Data

CHD Management with Lipid Lowering Therapy Indicator Summary	of Patients with Opportunities*
Encourage the use of lipid lowering therapy for primary or secondary prevention of CHD per al guidelines	6,222
Promote safe and effective use of antilipemic agents through identification of potential adverse s and drug interactions	2,197
Support medication adherence and recognize when discontinuation of therapy may be ibuting to treatment failure	2,378
Encourage alternative therapy in patients on simvastatin 80mg < 12 months	742

* based on data thru September 2011

The enclosed patient profiles reflect one or more of the above issues and are provided as chart reminders for when your patients return for their next appointments.

We acknowledge that there may be clinical variables influencing an individual patient's management that are not apparent in claims data or that a patient may have been inadvertently identified as being under your care. However, we believe the issues identified will assist you in caring for your patient(s). We thank you for reviewing this information and caring for West Virginia Medicaid's patients and welcome the opportunity to discuss any comments or concerns you may have about our quality management program. Please feel free to call our office at _____ with questions or concerns.

Sincerely,

Medical Director

CHD Management with Lipid Lowering Therapy

Encourage the use of lipid lowering therapy for primary or secondary prevention of CHD per clinical guidelines

- Clinical trials have demonstrated reductions in morbidity and mortality with LDL lowering therapy, in particular with HMG-CoA reductase inhibitors (statins).² Despite the information from recent trials and the NCEP guidelines, hyperlipidemia is often untreated or undertreated. Patients targeted in this intervention are those at risk for CHD or with established CHD who are not currently receiving lipid

Promote safe and effective use of antilipemic agents through identification of potential adverse events and drug interactions

- Certain drugs considered contraindicated when used concomitantly will be identified. Specific statin combinations increase the risk of myopathy and rhabdomyolysis. This includes specified statins when used in combination with protease inhibitors, Ketek[®] (telithromycin), macrolide antibiotics, cyclosporine, gemfibrozil or imidazole antifungals.
- The use of statin therapy with comorbid conditions that are considered contraindications will be identified.

Support medication adherence and recognize when discontinuation of therapy may be contributing to treatment failure

- Adherence with prescribed maintenance drug regimens is paramount to successful patient outcomes. Non-adherence can be increased by misunderstanding of the disease, denial of illness, lack of involvement of the patient in the care plan, adverse events, and cost and complexity of the medication regimen. Many of these factors can also lead to discontinuation of lipid lowering therapy. Patients are identified who may be non-adherent to prescribed lipid lowering therapy or who appear to have

Encourage alternative therapy in patients on simvastatin 80mg < 12 months

- Due to concerns for increased risk of myopathy, 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. Consider alternative therapy in patients on simvastatin 80mg < 12 months.

**ATP III LDL-C Goals and Cutpoints for TLC and Drug Therapy in Different Risk Categories
with Proposed Therapeutic Options Based on Recent Clinical Trial Evidence^{1,2}**

Risk Category	LDL-C Goal	Initiate TLC[^]	Consider Drug Therapy
High risk: CHD [^] or CHD risk equivalents [†] (10-year risk >20%)	<100 mg/dl (optional goal: <70 mg/dl) [¶]	≥100 mg/dl [#]	≥100 mg/dl ^{††} (<100 mg/dl: consider drug options) ^{**}
Moderately high risk: 2 or more risk factors [†] (10-year risk 10% to 20%) ^{§§}	<130 mg/dl ^{¶¶}	≥130 mg/dl [#]	≥130 mg/dl (100–129 mg/dl; consider drug options) ^{††}
Moderate risk: 2 or more risk factors [†] (10-year risk <10%) ^{§§}	<130 mg/dl	≥130 mg/dl	≥160 mg/dl
Lower risk: 0–1 risk factor [§]	<160 mg/dl	≥160 mg/dl	≥190 mg/dl (160–189 mg/dl: LDL-lowering drug optional)

[^]Therapeutic lifestyle changes (TLC) remain an essential modality in clinical management. TLC has the potential to reduce cardiovascular risk through several mechanisms beyond LDL lowering. ^{*}CHD includes history of myocardial infarction, unstable angina, stable angina, coronary artery procedures (angioplasty or bypass surgery), or evidence of clinically significant myocardial ischemia. [†]CHD risk equivalents include clinical manifestations of non-coronary forms of atherosclerotic disease (peripheral arterial disease, abdominal aortic aneurysm, and carotid artery disease [transient ischemic attacks or stroke of carotid origin or >50% obstruction of a carotid artery]), diabetes, and 2 + risk factors with 10-year risk for hard CHD >20%. [‡]Risk factors include cigarette smoking, hypertension (BP ≥140/90 mmHg or on antihypertensive medication), low HDL cholesterol (<40 mg/dl), family history of premature CHD (CHD in male first-degree relative <55 years of age; CHD in female first-degree relative <65 years of age), and age (men ≥45 years; women ≥55 years). ^{§§}Electronic 10-year risk calculators are available at www.nhlbi.nih.gov/guidelines/cholesterol. [§]Almost all people with zero or 1 risk factor have a 10-year risk <10%, and 10-year risk assessment in people with zero or 1 risk factor is thus not necessary. ^{¶¶}Very high risk favors an optional LDL-C goal of <70 mg/dl, and in patients with high triglycerides, non-HDL-C <100 mg/dl. ^{¶¶}Optional LDL-C goal <100 mg/dl. [#]Any person at high risk or moderately high risk who has lifestyle-related risk factors (e.g., obesity, physical inactivity, elevated triglyceride, low HDL-C, or metabolic syndrome) is a candidate for therapeutic lifestyle changes to modify these risk factors regardless of LDL-C level. ^{**}When LDL-lowering drug therapy is employed, it is advised that intensity of therapy be sufficient to achieve at least a 30% to 40% reduction in LDL-C levels. ^{††}If baseline LDL-C is <100 mg/dl, institution of an LDL-lowering drug is a therapeutic option on the basis of available clinical trial results. If a high-risk person has high triglycerides or low HDL-C, combining a fibrate or nicotinic acid with an LDL-lowering drug can be considered. ^{‡‡}For moderately high-risk persons, when LDL-C level is 100 to 129 mg/dl, at baseline or on lifestyle therapy, initiation of an LDL-lowering drug to achieve an LDL-C level <100 mg/dl is a therapeutic option on the basis of available clinical trial results.

Selected References (full reference list available upon request):

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