The Cost and Quality Gap in Diabetes Care: An Actuarial Analysis

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Commissioned by AT&T Services, Inc.

January 30, 2012

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EXECUTIVE SUMMARY

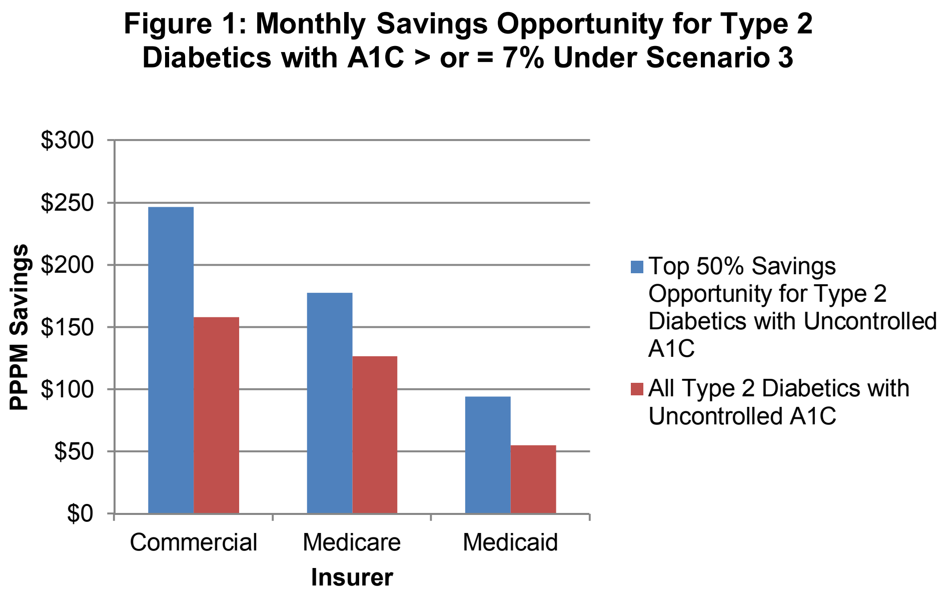
Diabetes has emerged as one of the major health problems of the early 21st Century. It is often associated with obesity and physical inactivity and can lead to devastating complications such as heart attack, stroke, end stage renal disease, blindness and amputations. As an example of the public concern, Medicare, commercial and Medicaid payers are measured on how well their members have diabetes controlled through HEDIS and similar metrics.

Diabetes prevalence is rising in the United States, with an increase in diagnosed diabetes from 6.5% in 1999 to 7.8% in 2006 [1]. The rising prevalence is projected to continue with estimates that diagnosed and undiagnosed diabetes will almost double between 2009 and 2034 [2].The portion of the national healthcare expenditure attributed to people with type 2 diabetes is expected to increase from 10 percent in 2011 to 15 percent in 2031. [3]

Of particular concern is suboptimal management of diabetes, specifically control of essential clinical metrics including hemoglobin A1C (glycemic control), blood pressure and blood lipid levels. Although control rates for these metrics improved in recent years, the control rates for diabetics analyzed in NHANES 2003-2006 (combined series 2003-2004 and 2005-2006) still remained low at 57% control for A1C (A1C < 7%), 45% for blood pressure (BP < 130/80) and 47% for LDL (LDL under 100) [1]. In addition, only 12.2% of diabetics in NHANES 2003-2006 were reported to have all three metrics simultaneously controlled [1].

Our analysis quantifies the current diabetes control rates for A1C, blood pressure and lipids and models the impact of better control of these metrics on diabetes complication rates and complication costs for commercially insured, Medicare and Medicaid populations. We use the United Kingdom Prospective Diabetes Study (UKPDS) modeling tool to project complication rates under status quo A1C, blood pressure and lipid levels and complication rates under better management. We monetize the impact of reducing complications using commercial and Medicare claims data. Our modeling is limited to the impact of better diabetes management on reducing UKPDS diabetes complications, which account for 20% of total diabetes medical costs. We do not consider reduction in the 80% of medical costs other than these complications. Neither do we consider potential reduction in indirect costs of diabetes, such as lost work time, productivity, and disability, which are reported to be 33% of the total U.S. estimated $174 billion (2007 $) cost associated with diagnosed diabetes.[4]

For the subset of type 2 diabetics with A1C ≥ 7% (from our NHANES analysis: 47% of commercially insured, 38% of Medicare and 41% of Medicaid type 2 diabetes lives) we modeled the impact of better control defined as control of A1C, blood pressure, and lipids. In Figure 1 we provide the savings potential for all type 2 diabetics with A1C ≥ 7% under our scenario 3: reducing A1C by 1.5%, BP by 30mm/Hg for those with BP above goal, total cholesterol by 50% for those with TC above goal and increasing HDL by 50% for those with HDL below goal. This produces a per patient per month (PPPM) savings opportunity of $158, $126 and $55 respectively for commercial, Medicare and Medicaid type 2 diabetics with A1C ≥ 7%. If we focus on the 50% of diabetics with A1C ≥ 7% with the most opportunity for savings (representing 24% of the commercially insured, 19% of the Medicare and 21% of the Medicaid type 2 diabetic population), the savings potential PPPM is $247, $178 and $ 94 respectively for commercial, Medicare and Medicaid type 2 diabetics with A1C ≥ 7%.



Source: Milliman modeling of MarketScan 2006-2009 and NHANES 2005-2008, demographically adjusted to Milliman *Health Cost Guidelines*. Scenario 3: for those with values not at goal, reducing A1C by 1.5%, BP by 30mm/Hg for those with BP above goal, total cholesterol by 50% for those with TC above goal and increasing HDL by 50% for those with HDL below goal. PPPM: per diabetes patient with A1C > or = 7% per month

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A broad spectrum of brand and generic drugs, devices and programs are available to help control diabetes, yet control rates remain disappointing. In reflecting on this situation, the authors are led to suggest that system change and new ways of delivering care and encouraging patient compliance are at least as important as new therapies. Perhaps, broadly speaking, successful system change can result in better diabetes control.

This report was commissioned by AT&T Services, Inc. AT&T is involved in mobile telephone approaches to managing diseases including diabetes. The findings reflect the research of the authors; Milliman does not intend to endorse any product or organization. If this report is reproduced, we ask that it be reproduced in its entirety, as pieces taken out of context can be misleading. As with any economic or actuarial analysis, it is not possible to capture all factors that may be significant. Because we present national average data, the findings should be interpreted carefully before they are applied to any particular situation. Two of the co-authors, Pyenson and Iwasaki, are Members of the American Academy of Actuaries and meet its qualification standards to issue this report.

BACKGROUND: SYSTEMS APPROACHES TO DIABETES

Diabetes prevalence is rising in the United States, with reports that diagnosed diabetes increased from 6.5% in 1999 to 7.8% in 2006 [1]. Of particular concern is suboptimal management of diabetes, specifically control of essential clinical metrics including hemoglobin A1C (glycemic control), blood pressure and blood lipid levels. Although control rates for these metrics improved in recent years, the control rates for diabetics analyzed in NHANES 2003-2006 (combined series 2003-2004 and 2005-2006) still remained low at 57% control for A1C (A1C < 7%), 45% for blood pressure (BP < 130/80) and 47% for LDL (LDL under 100) [1]. In addition, only 12.2% of diabetics in NHANES 2003-2006 were reported to have all three metrics simultaneously controlled [1].

Individuals with diabetes have a dramatically higher rate of microvascular and macrovascular disease, including coronary artery disease (CAD), stroke, peripheral vascular disease (associated with amputation), end stage renal disease (ESRD), and retinopathy (associated with blindness), and have higher mortality and morbidity with an age-adjusted risk of death nearly twice that of people without diabetes [5]. Landmark studies consistently report that lower rates of these complications are associated with lower A1C levels [6-8]. Additionally, medical cost impact studies report reduced medical costs for diabetics with improved glycemic control [9], [10], [11].

Clinical practice guidelines for diabetes care specify target levels for A1C, blood pressure and lipids and protocols for lifestyle and drug therapy treatment to achieve these targets, yet adherence with these recommendations is disappointing. Patient adherence to diabetes drug therapy and lifestyle recommendations, as well as physician practice patterns, are identified as contributors to the poor rate of glycemic control. Research to date has documented wide variances in patient adherence to glycemic control management, including the filling of prescriptions [12-16].

Studies consistently report physician delays in intensifying drug therapy when A1C is above goal, with many patients experiencing A1C levels > 8% resulting in years of glycemic burden [17-21]. This is in light of the progressive nature of the disease: studies report an annual 0.15% increase in A1C even with appropriate management [22].

Because of these challenges, a number of innovative approaches to working with physicians and patients are underway. Diabetes control monitors and patient education are not, by themselves, direct therapy, but these services attempt to address behavioral aspects of compliance and diabetes management.

To address the need for improvement in physician practice patterns for diabetes care, physician pay for performance initiatives have been implemented by many health plans. The target performance is typically tied to HEDIS measures for diabetes which include A1C testing, A1C < 7%, annual eye examinations, annual LDL testing and LDL < 100, annual nephropathy screening, and BP < 130/80. Several studies report improved quality and clinical metrics for diabetics when cared for by physicians in a P4P arrangement compared to those cared for by physicians without a P4P arrangement [23] [24] [25]. Another initiative aimed at improving physician care coordination for diabetics and other chronically ill patients is the *medical home* movement which often incorporates a P4P arrangement. Several Patient Centered Medical Home (PCMH) demonstrations report improvements in quality and clinical outcomes for diabetes patients cared for under this model [26].

Educational and behavior change initiatives are commonly used to improve patient self-management and typically include disease management (DM) programs and diabetes self-management education (DSME) interventions. These two forms of intervention have varying levels of reported success. Diabetes disease management programs are now a mainstay of commercial insurers provided by in-house programs or through contracts with DM vendors. The model for these programs is telephonic outreach, supplemented with diabetes educational mailings, to diabetes members who are identified through claims data or provider referral. Outreach is tailored to the severity level and knowledge base of each diabetes member. Impact on lowering A1C and medical costs is mixed [27] [28] [29] [30] [31]. Outcomes of the Medicare Health Support Disease Management Pilot Program, which enrolled > 100,000 diabetics in the intervention and approximately 60,000 in the control group, were recently reported, with no evident reduction in the utilization of acute care or the cost of care. [32]

DSME is typically performed by diabetes educators and is a covered benefit by Medicare and many commercial payers. The American Association of Diabetes Educators (AADE) represents diabetes educator professionals and provides definitions, standards of care and goals for diabetes educators. Diabetes educators are typically certified diabetes educators (CDE) or board certified in advanced diabetes management (BC-

ADM), most often have a background in nursing and dietetics and, more recently, may include registered pharmacists. The self-management education can take place in individual or group settings. Positive short term impact on reducing A1C and costs has been reported, but the benefit is reported to decline a few months after the intervention ceases [33] [34] [35] [36] [37] [38] [39].

Value based benefit designs (VBBD) for commercially insured populations, in which copays for chronic diabetes drug therapies are significantly reduced, have been associated with improved patient compliance with diabetes drug therapy. Elasticity between utilization of health care services and member copay levels is well established and is the foundation of the VBBD initiatives for improving compliance with chronic disease drug treatment therapies. One VBBD study reported that a 36% reduction in copayments for diabetes medication was associated with a reduction in the number of non-adherent patients by 30% [40].

A variety of web- and phone-based systems are available to help manage diabetes. A new class of systems was cleared by the FDA as a mobile health device for virtual patient coaching. A randomized controlled trial reports statistically-significant A1C reductions for type 2 diabetics using the new patient coaching device compared to type 2 diabetics receiving usual care. The patient coaching system includes diabetes management software that allows patients to enter diabetes self-care data into their PC or mobile phone and receive automated real-time educational, behavioral and motivational messaging specific to the entered data, along with a healthcare provider portal allowing for physicians to access patient data [41]. The increased adoption of electronic medical records and e-prescribing should complement and enhance patient-centric digital solutions.

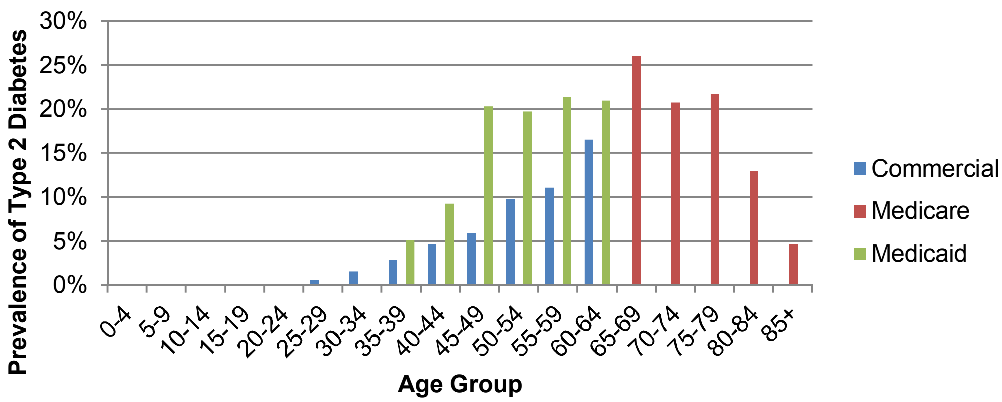
NHANES ANALYSIS

We analyzed the NHANES 2005-2006 and 2007-2008 series to identify characteristics of type 2 diabetics for commercially insured, Medicare and Medicaid populations. The methodology for identifying characteristics of diabetics can be found in Appendix B.

Prevalence of Type 2 Diabetes

The prevalence of type 2 diabetes varies by insurer, age and gender. The overall prevalence is 6.1% in commercially insured adults ages 20-64, 19.4% in Medicare ages 65+ and 11.1% in Medicaid ages 20-64. Figure 2 shows how diabetes prevalence increases with age for the commercially insured and Medicaid population.

Figure 2: Prevalence of Type 2 Diabetes by Insurer



Source: Milliman analysis of NHANES 2005-2008, demographically adjusted to Milliman *Health Cost Guidelines* 2011.

Prevalence of Comorbidities

Type 2 diabetes patients are more likely to have comorbidities such as obesity, hypertension, coronary artery disease (CAD) and hyperlipidemia than the general population. For purposes of comparing the diabetes prevalence and total population prevalence, we adjusted the total population prevalence to reflect the demographics of the diabetes population. The need for managing multiple comorbidities highlights the challenge for diabetes disease management and DSME.

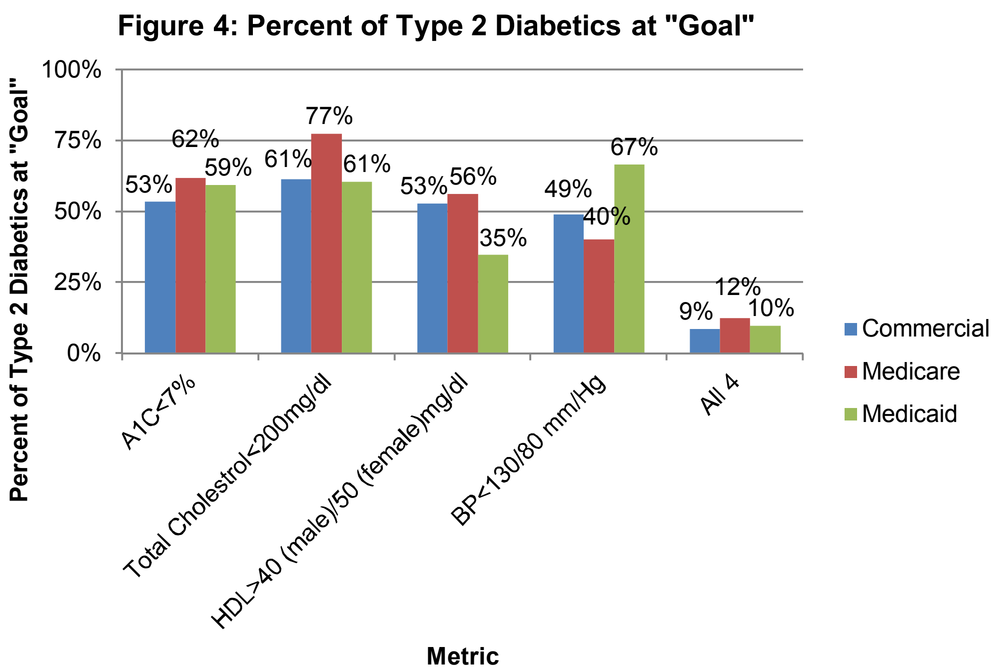
Figure 3: Prevalence of Comorbidities in Type 2 Diabetics

	Commercial		Medicare		Medicaid	
	Diabetes Population	Total Population Adjusted to Diabetes Demographics	Diabetes Population	Total Population Adjusted to Diabetes Demographics	Diabetes Population	Total Population Adjusted to Diabetes Demographics
Obesity	67%	38%	45%	31%	75%	52%
Hypertension	73%	54%	85%	78%	69%	58%
CAD	14%	5%	30%	19%	23%	15%
Hyperlipidemia	56%	22%	71%	47%	51%	25%

Source: Milliman analysis of NHANES 2005-2008, demographically adjusted to Milliman *Health Cost Guidelines* 2011.

Control Rates of A1C, Blood Pressure and Lipids

Because of the association between poorly controlled A1C, blood pressure and lipids, and the higher risk of microvascular and macrovascular complications for type 2 diabetics, treatment is directed at controlling these metrics. The American Diabetes Association recommends the following targets for type 2 diabetics: A1C < 7, BP < 130/80, LDL < 100, total cholesterol < 200, HDL > 40 men/> 50 women [42]. The rate of control for these metrics varies by insurance program, with Medicare beneficiaries having better control for all metrics except blood pressure. Figure 4 shows the low portion of diabetics having all 4 metrics under control, which highlights the opportunity for better control.

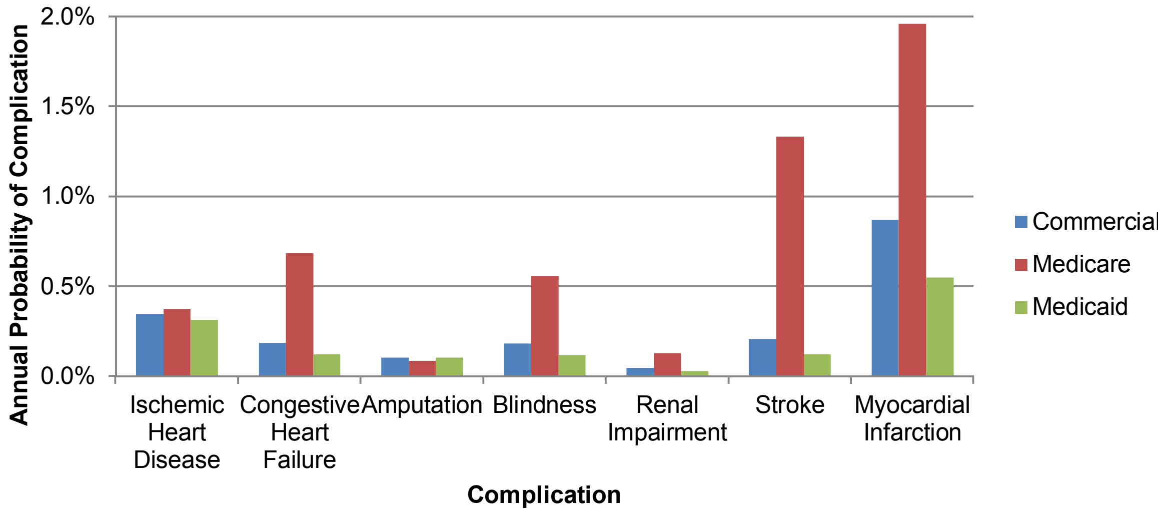


Source: Milliman analysis of NHANES 2005-2008, demographically adjusted to Milliman Commercial *Health Cost Guidelines* 2011, Milliman 65+ *Health Cost Guidelines*.

PROBABILITY OF DIABETES COMPLICATIONS AND POTENTIAL REDUCTIONS

Using the type 2 diabetes subjects from our NHANES analysis, we identified each subject's risk factors needed for the UKPDS risk of complications projections. The UKPDS risk model produces the probability of developing one of seven diabetes complications: ischemic heart disease, congestive heart failure, amputation, blindness, renal impairment, stroke or myocardial infarction (heart attack) based on particular risk factors (see Appendix B for UKPDS risk factors). In particular, A1C, blood pressure and lipid measurements influence an individual's risk for complications: the risk increases as values are further above goal (or below goal for HDL). Figure 5 shows the status quo annual probability of complications.

Figure 5: Annual Probability of Complications for Type 2 Diabetics Under Current Control Rates



Source: Milliman analysis of NHANES 2005-2008, UKPDS Modeling, demographically adjusted to Milliman *Health Cost Guidelines* 2011 UKPDS risk model.

For those with A1C, blood pressure, total cholesterol or HDL not at recommended target, we modified these metrics according to the three scenarios described below. As noted previously in our NHANES analysis, a significant portion of diabetics do not have one or more of these metrics at recommended targets. Figure 6 summaries the clinical targets and improvement scenario amounts.

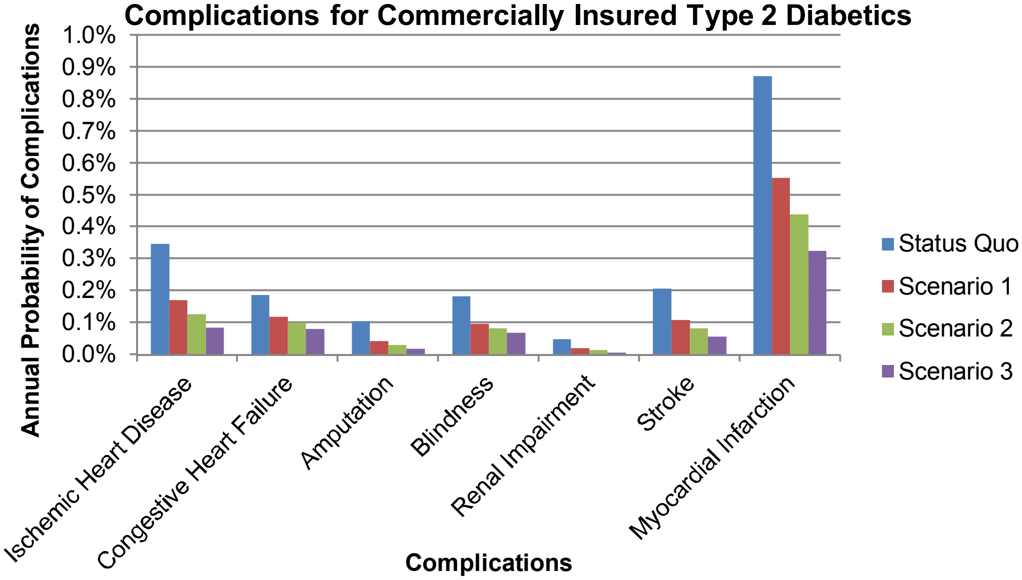
Figure 6: Clinical Targets and Improvement Scenarios

	ADA Clinical Targets	Improvement Amount		
		Scenario 1	Scenario 2	Scenario 3
A1C (%)	< 7%	↓1% A1C	↓1.25% A1C	↓1.5% A1C
Systolic Blood Pressure/Diastolic Blood Pressure (mm/Hg)	< 130/80 mm/Hg	↓10 mm/Hg	↓20 mm/Hg	↓30 mm/Hg
High-Density Lipoprotein (mg/dl)	> 40 mg/dl (M); > 50 mg/dl (F)	↑20%	↑35%	↑50%
Total Cholesterol (mg/dl)	< 200 mg/dl	↓20%	↓35%	↓50%

We modeled the impact of reducing these metrics on the status quo diabetes complication rates and on the number of deaths associated with these complications. In figures 7-9, we present the complication reduction impact for each of the scenarios for commercial, Medicare and Medicaid. The scenarios with greater improvements in A1C, blood pressure, HDL and total cholesterol generate fewer events/conditions and associated deaths. The ceiling/floor for each value under scenario 3 is A1C down to 5.5%, BP down to 100/50 mm/Hg, HDL up to 60 mg/dl for men and 75 mg/dl for women and TC down to 100.

For commercially insured type 2 diabetics, a 43%, 55% and 67% reduction in the probability of complications with better diabetes control is expected under scenario 1, 2 and 3 respectively.

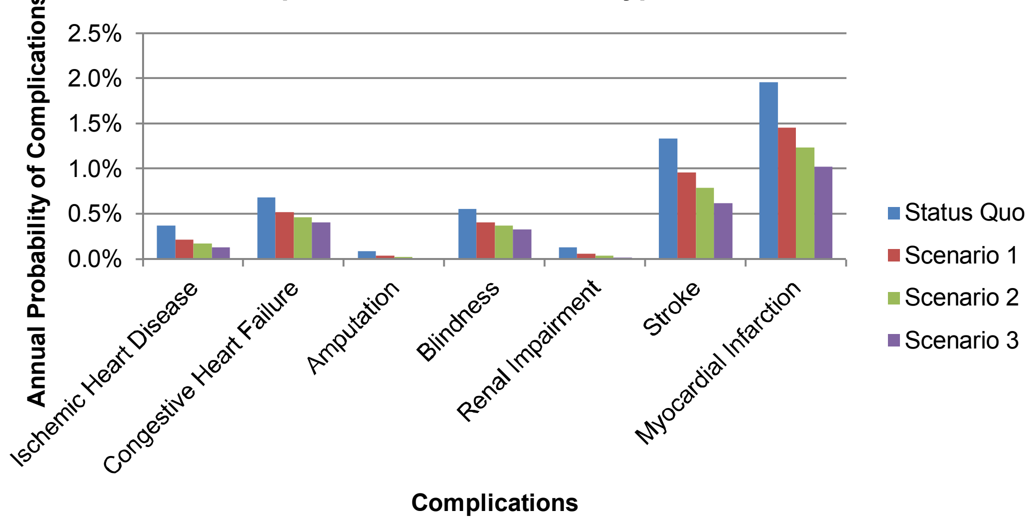
Figure 7: Impact of Better Control on Probability of Complications for Commercially Insured Type 2 Diabetics



Source: NHANES 2005-2008, demographically adjusted to Milliman *Health Cost Guidelines* 2011. UKPDS risk model.

Medicare-age diabetics have a higher probability of developing complications but not as dramatic a reduction in complications, due to age being a significant, unmodifiable risk factor for complications. A 28%, 38% and 49% reduction in the probability of complications with better diabetes control is expected under scenario 1, 2 and 3 respectively.

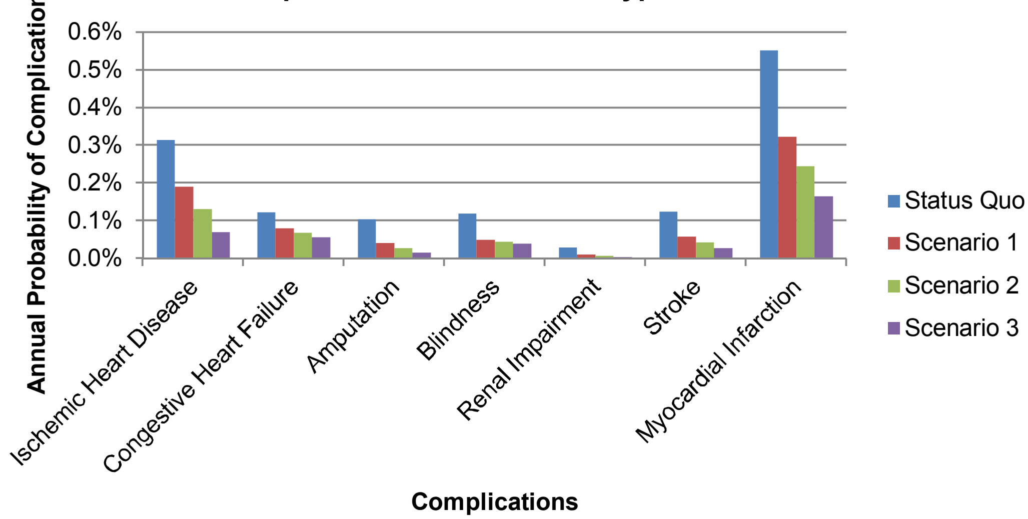
Figure 8:Impact of Better Control on Probability of Complications for Medicare Type 2 Diabetics



Source: NHANES 2005-2008, demographically adjusted to Milliman Medicare *Health Cost Guidelines* 2011. UKPDS risk model.

The opportunities in Medicaid are also significant. A 44%, 58% and 72% reduction in the probability of complications with better diabetes control is expected under scenario 1, 2 and 3 respectively.

Figure 9:Impact of Better Control on Probability of Complications for Medicaid Type 2 Diabetics



Source: NHANES 2005-2008, demographically adjusted to Milliman Medicaid *Health Cost Guidelines* 2008. UKPDS risk model.

CLAIMS DATA COST ANALYSIS AND COST IMPACT OF BETTER DIABETES CONTROL ON REDUCING COMPLICATIONS

For our analysis of diabetes costs, we identified type 2 diabetics in commercial claim data (MarketScan) and Medicare claim data (Medicare 5% sample) and tabulated costs for diabetics with and without specified complications. We assumed that Medicaid price levels are 80% of Medicare. (See Appendix B for claim data methodology.)

Diabetes Costs by Major Service Category by Payer

The allowed cost per type 2 diabetes patient per month (PPPM) in the commercial population claim analysis is approximately $1,090, which compares to an average allowed cost of $448 across the commercially insured adult non-diabetic population and $489 across the total population. The cost of UKPDS complications contributes 20% of the total spending for diabetics. Figures 10 and 11 show the cost summaries for commercial and Medicare. Because of the wide variability in Medicaid costs by state, we do not show a model for Medicaid.

Figure 10: Allowed Cost (PPPM) by Major Service Category in Commercial Population

			PPPM	% in Total
Total			$1,090	100%
	UKPDS Complications		$214	20%
	Other than UKPDS Complications		$876	80%
		Diabetes Prescription Drugs	$86	8%
		Other Prescription Drugs	$188	17%
		Inpatient	$181	17%
		Outpatient	$421	39%

Source: Milliman analysis of MarketScan 2006-2009, demographically adjusted to Milliman *Health Cost Guidelines* 2011. Costs trended to 2012.

The cost PPPM in the Medicare population claim analysis is approximately $1,565, which compares to an average cost of $686 for non-diabetic Medicare beneficiaries and $858 for the total Medicare population. The Medicare 5% sample does not include Part D data. The cost of UKPDS complications contributes 21% of the total spending for diabetics. In a subsequent section, we model the potential for reducing this cost of complications when A1C, blood pressure and lipids are reduced for those above goal.

Figure 11: Allowed Cost (PPPM) by Major Service Category in Medicare Population

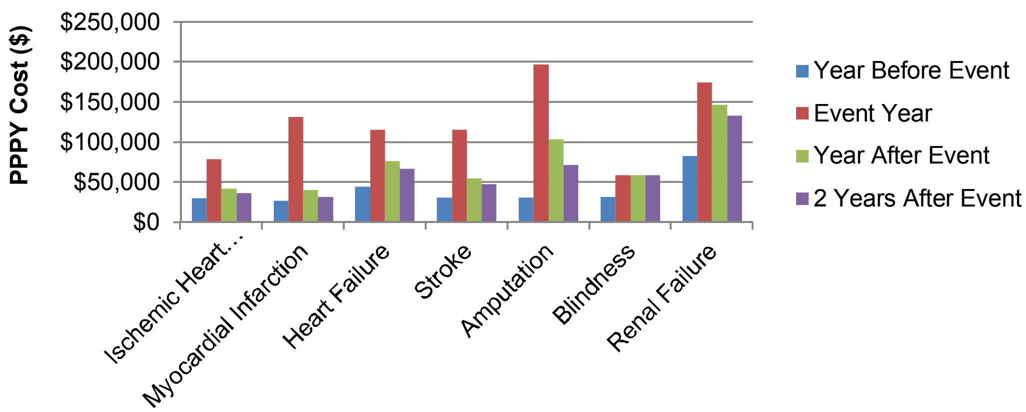
			PPPM	% in Total
Total			$1,565	100%
	UKPDS Complications		$331	21%
	Other than UKPDS Complications		$1,234	79%
		Inpatient	$285	23%
		Skilled Nursing Facility	$62	5%
		Home Health	$57	5%
		Outpatient	$152	12%
		Physician	$336	27%
		Durable Medical Equipment	$64	5%
		Hospice	$18	1%

Source: Milliman analysis of CMS's 5% Medicare sample 2009, demographically adjusted Milliman Medicare *Health Cost Guidelines* 2011. Costs trended to 2012.

Cost of Diabetes Complications

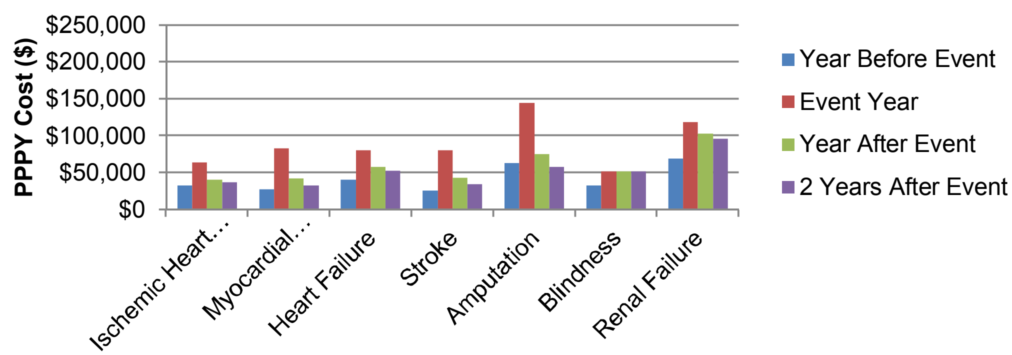
We developed the incremental costs of each diabetes complication in order to monetize the impact of reducing complications. Figures 12 and 13 show the annual costs incurred during the years surrounding an event. The incremental cost of an event is the average annualized costs in the year of the event and the two years after the event, net the costs in the year before an event. The costs in the 2 years after all events remain higher than the costs in the year before the event except for amputation in the Medicare population.

Figure 12: Allowed Cost PPPY by Event in the Commercial Population



Source: Milliman analysis of MarketScan 2006-2009, demographically adjusted to Milliman *Health Cost Guidelines* 2011. Costs trended to 2012.

Figure 13: Allowed Cost PPPY by Event in the Medicare Population



Source: Milliman analysis of CMS's 5% Medicare sample 2006-2009, demographically adjusted to Milliman 65+ *Health Cost Guidelines* 2011. Costs trended to 2012.

Cost Impact of Better Diabetes Control

We monetized the reduction in UKPDS complications under scenario 1, 2 and 3 by reducing total costs by the incremental complication cost for the complications that are avoided. We do not consider the impact on costs other than the avoided UKPDS complications, but these complications account for approximately 20% of diabetics' costs. The portion and type of complications that are avoided varies by the profiles of those in each payer cohort and by reduction scenarios shown in Figure 14. We provide the PPPM and PMPM savings generated by the total diabetes population and the diabetes population with A1C over goal under the 3 improved diabetes management scenarios. The PPPM is the average monthly savings over three years (2012 to 2014) for the target diabetes population while the PMPM is the average monthly savings over three years for the total insured population. We do not assume costs that may be incurred to achieve better control, such as additional prescription drugs, physician services, or other services. For the commercial population, we do not consider the impact on disability costs, lost work time or productivity, which are a significant contributor to diabetes costs. [4]

For the commercial diabetic population, scenario 3 produces a $105.47 PPPM reduction in costs or approximately 10% of the $1090 average monthly costs for diabetics. On a PMPM basis, scenario 3 produces a $4.70 PMPM reduction in costs or approximately 1% of the $489 average monthly costs for all insured members. As noted earlier, Medicare diabetics have higher complication risk but lower potential reduction in complications compared to commercially insured and Medicaid populations. For the Medicare diabetic population, scenario 3 produces a $106.04 PPPM reduction in costs or approximately 7% of the $1565 average monthly costs for diabetics. On a PMPM basis, scenario 3 produces a $16.18 reduction in PMPM costs or approximately 2% of the $858 average monthly costs for all Medicare members.

Commercial

	Target: All Diabetes Patients			Target: Uncontrolled A1C Diabetes Patients		
	Scenario 1	Scenario 2	Scenario 3	Scenario 1	Scenario 2	Scenario 3
Reduction in number of complications	43%	55%	67%	43%	55%	68%
Savings PPPM	$66.73	$86.06	$105.47	$99.44	$128.71	$158.17
Savings PMPM	$2.97	$3.83	$4.70	$2.06	$2.67	$3.28
Savings Per Target Patient over 3 years	$2,400	$3,100	$3,800	$3,600	$4,600	$5,700

Medicare

	Target: All Diabetes Patients			Target: Uncontrolled A1C Diabetes Patients		
	Scenario 1	Scenario 2	Scenario 3	Scenario 1	Scenario 2	Scenario 3
Reduction in complication rate	28%	38%	49%	32%	43%	54%
Savings PPPM	$58.85	$82.33	$106.04	$74.55	$100.38	$126.49
Savings PMPM	$8.98	$12.56	$16.18	$4.35	$5.86	$7.38
Savings Per Target Patient over 3 years	$2,100	$3,000	$3,800	$2,700	$3,600	$4,600

Medicaid

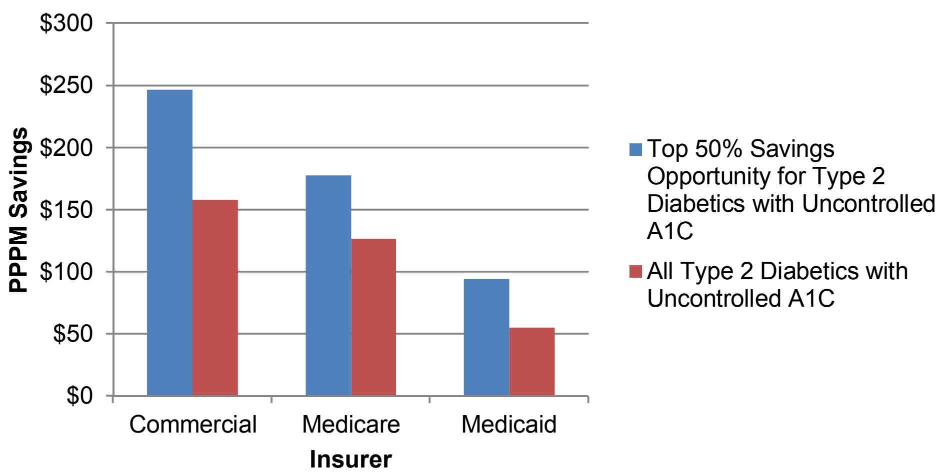
	Target: All Diabetes Patients			Target: Uncontrolled A1C Diabetes Patients		
	Scenario 1	Scenario 2	Scenario 3	Scenario 1	Scenario 2	Scenario 3
Reduction in complication rate	44%	58%	72%	49%	62%	75%
Savings PPPM	$30.00	$39.00	$48.03	$36.15	$45.71	$55.32
Savings PMPM	$0.83	$1.08	$1.33	$0.54	$0.69	$0.83
Savings Per Target Patient over 3 years	$800	$1,100	$1,300	$1,300	$1,600	$2,000

Source: Milliman modeling on NHANES 2005-2008, MarketScan 2006-2009, Medicare 5% Sample 2008, Milliman Health Cost Guidelines, Commercial, Medicare and Medicaid.

Stratification of Diabetics by Potential Cost Reduction

The potential for reduced costs through better control does not occur uniformly across all patients. The following chart shows the savings opportunity for type 2 diabetics with uncontrolled A1C which we note from our NHANES analysis as 47% of the commercially insured, 38% of Medicare and 41% of Medicaid lives. We modeled the impact of better control defined as control of A1C, blood pressure, and lipids and provide the savings potential for all type 2 diabetics with A1C $\geq$ 7 under our scenario 3 (reducing A1C by 1.5%, BP by 30mm/Hg for those with BP above goal, total cholesterol by 50% for those with TC above goal and increasing HDL by 50% for those with HDL below goal) which shows a PPPM savings opportunity of $158, $126 and $55 respectively for commercial, Medicare and Medicaid type 2 diabetics with A1C $\geq$ 7. If we focus on the 50% of diabetics with A1C $\geq$ 7 with the most opportunity for savings (24% of the commercially insured, 19% of the Medicare and 21% of the Medicaid type 2 diabetic population), the savings potential PPPM is $247, $178, $ 94 respectively for commercial, Medicare and Medicaid type 2 diabetics with A1C $\geq$ 7.

Figure 15: Savings Opportunity for Type 2 Diabetics with A1C > or = 7% Under Scenario 3



Source: Milliman modeling of MarketScan 2006-2009 and NHANES 2005-2008, demographically adjusted to Milliman *Health Cost Guidelines*.

Our modeling demonstrates that considering multiple, modifiable risk factors—A1C, blood pressure, lipids—and their interaction with non-modifiable factors such as age and sex, enables a highly concentrated patient stratification. Both clinical recommendations and system change advocates recognize the importance of managing the whole patient. Indeed, our models suggest the health status improvement and cost reduction of this approach is greater than with any one particular metric. As a practical matter, the "system approach" discussed above will work best when applied to individual patients' risk factors.

PAYER PRICES AND COSTS OF DIABETES MANAGEMENT APPROACHES

The shortfall in diabetes control is not for a lack of treatment options. In this section, we list the main diabetes management products and services along with their prices and cost to payers. Most benefit plans cover a broad spectrum of options, including a variety of prescription drugs classes, both generic and brand insulins, monitors, pumps, clinician education for diabetics, and disease management programs. Costs for the options vary widely. Clearly, the collection of options is not sufficient to solve the diabetes problem. Nevertheless, the payer spending speaks to the cost, if not value, of attempts to control diabetes.

Little data is available that compares the efficacy of different treatment options. There are “head-to-head” trials that compare the A1C reduction of particular drugs [43] [44]. As with gaps in other chronic condition care, gaps in controlling diabetes seem to be more about compliance and inadequate systems of care rather than lack of efficacy.

The use of multiple diabetes drugs with or without insulin is common among type 2 diabetics. Figure 18 provides the distribution of commercial diabetes patients by the number of distinct drug classes the patients filled in one year. The table splits the diabetes population into new and existing diabetics, as those who are newly diagnosed would be expected to use less intense therapy. In the table, those using multiple drug classes include patients who may have switched among different drugs and are not taking all drugs simultaneously.

Figure 18. Distribution of Diabetes Patients Taking Diabetes Drugs in a Commercial Population

Number and Type of Diabetes Drugs by Class	Distribution of New and Existing Type 2 Diabetics	Distribution of New Type 2 Diabetics	Distribution of Existing Type 2 Diabetics
No Drugs	14%	29%	11%
1 Oral Class	31%	46%	28%
2 Oral Classes	21%	15%	22%
3 Oral Classes	10%	3%	12%
Insulin Only	7%	2%	7%
Insulin + 1 Oral Class	8%	3%	8%
Insulin + 2 Oral Classes	6%	2%	7%
Insulin + 3 Oral Classes	4%	1%	4%
Total	100%	100%	100%

Source: Milliman analysis of MarketScan 2009 for a commercial population. Amylinomimetic and incretin included as orals. Numbers may not add to 100% due to rounding

Figure 19 describes the use of brand drugs and their cost. For a typical commercial population, 53% of diabetics use one or more oral brand drugs or insulin in a year. While generic drugs are generally very low price, the price of brand diabetes medications can be hundreds of dollars per month. The following table provides statistics on the use and average paid amount for eight classes of brand drugs. Because of non-compliance, changes in therapy, and less-than-full-year coverage, not all diabetics fill 12 prescriptions in a year. For example, a patient on a DPP4 drug fills, on average, 0.41 scripts in a month.

Figure 19: Cost and Use of Diabetes Brand Drug Classes in a Commercial Population					
Diabetes Brand Drug Classes	Portion of Diabetics taking drug class	Rx per month	Paid Unit price (30 day supply)	Paid per user per month	Paid/ Allowed
amylinomimetic	1%	0.26	377.34	155.0	93%
DPP4	15%	0.41	139.21	91.8	85%
Incretin	7%	0.35	202.31	109.4	88%
Insulin	24%	0.56	166.71	133.7	88%
Meglitinide	2%	0.34	122.13	68.0	84%
TZD	24%	0.42	151.44	105.6	86%
Total/Average	**53%**	**0.45**	**159.12**	**112.0**	**87%**

Source: Milliman analysis of MarketScan 2009 for a commercial population.

Figure 20 provides the cost and A1C reduction (reported in clinical trials) for commonly used brand drugs within each of the major diabetes drug classes.

Figure 20: Efficacy Statistics for Most Common Prescription in Diabetes Brand Drug Classes							
	Most Common Prescription						
Diabetes Drug Class	**Chemical Name**	**Brand Name**	**Dosage**	**Allowed Cost/30 Day Supply**	**Mean Change in HbA1c over Placebo**	**P-Value**	**95% Confidence Interval**
Amylinomimetic	Pramlintide	Symlin	120mcg subcutaneous solution	$409	-0.4	0.09	Not provided
DPP4	Sitagliptin	Januvia	100mg	$170	-0.8	<0.001	(-1.0, -0.6)
Fixed-dose combo	Pioglitazone + Metformin	Actoplus Met	15-850 mg	$186	-0.45	<0.050	
Incretin	Exenatide	Byetta	10mcg/0.04 mL	$234	-0.7	<0.01	[-1.0, -0.3]
Insulin	Insulin Glargine	Lantus	100 units/mL subcutaneous	$155	-0.6	Not provided	(+0.1, +0.4)
Insulin	Insulin Aspart	Novolog	100 units/mL subcutaneous	$222	-0.3	Not provided	{-0.4, -0.1}
Meglitinide	Nateglinide	Starlix	120 mg oral tablet	$126	-0.7	≤0.004	Not provided
TZD	Pioglitazone	Actos	30 mg oral tablet	$194	-1.0	≤0.05	(-1.6, -0.4)

Sources: Prescribing Information for particular brands [45] [46] [47] [48] [49] [50] [51] [52]

In addition to drugs, payers often cover several diabetes-related services and products (figure 21). These services and products are intended to assist a patient with managing their diabetes. Diabetes Self Management Education (DSME) is often provided when a patient is first diagnosed with diabetes. We provide average payer costs for these services in Figure 21 and 22, based on average utilization of these services in a year and average unit cost identified in our claim data analysis (see Appendix B). The literature reports a wide range of A1C lowering efficacy with DSME, for which we have provided references in the background section. The impact of DSME is reported to decline after the education ceases.

Category	Paid per user per month	Paid/ Allowed
DSME	$23.91	82%
Pump and reservoir	$152.86	88%
Blood glucose testing supplies	$31.21	86%

Source: Milliman analysis of MarketScan 2009 for a commercial population.

Diabetes disease management programs are widely used by commercial payers to engage patients, educate them about self-care, and help them be advocates for their own care. Specialized vendors sell these programs to large employers and insurers, while some payers have their own programs. Prices and content vary considerably from program to program and vendor to vendor. Generally, the programs are sold on a PMPM basis for an entire population, but sometimes vendors will charge a price per patient being managed. Some disease management vendors sell services as a single fee across several disease states. Figure 23 shows a typical range of fees the authors have observed in the market for diabetes disease management services. As noted in the background section, published studies do not report medical utilization or cost reductions with many diabetes disease management programs.

Figure 23: Diabetes Disease Management Costs for a Commercial Population

Basis	Payer Cost
PMPM across all commercial members	$0.75 to $1.25 PMPM
Per Diabetes Patient Being Managed	$25.00 to $50.00 per month per managed patient

Source: Milliman authors' experience.

CONCLUSION

In this paper we contrast the shortfall in diabetes control with the substantial outcome improvements and savings that are possible with better control. The substantial potential savings demonstrated in this paper comes from reducing diabetes complications which account for 20% of total diabetes spend. We do not consider reduction in costs other than specified complications.

One key finding is that potential savings and outcomes improvements are not spread evenly across all diabetics. Larger opportunities are concentrated in patients whose A1C, blood pressure and or lipids are not controlled.

The shortfall in diabetes control is not for a lack of treatment options. Most benefit plans cover a broad spectrum of options, including a variety of prescription drugs classes, both generic and brand, insulins, monitors, pumps, clinician education for diabetics, and disease management programs. Costs for the options vary widely as well as efficacy. Clearly, the collection of options is not sufficient to solve the diabetes problem. Nevertheless, the payer spending speaks to the cost and questions the value of attempts to control diabetes.

Our quantitative findings support the numerous demonstrations and innovations focused on systems of care for diabetics. Both clinical recommendations and system change advocates recognize the importance of managing the whole patient. Indeed, our models suggest the health status improvement and cost reduction of this approach is greater than succeeding with any one particular metric or any one class of drug.

APPENDIX A: DESCRIPTION OF KEY DATA SOURCES AND THEIR APPLICATION

Medicare 5% Sample This limited dataset contains all Medicare paid claims generated by a statistically-balanced sample of beneficiaries. Information includes diagnosis codes, procedure codes, and diagnosis-related group (DRG) codes. It also includes site of service information as well as beneficiary age, eligibility status and an indicator for HMO enrollment. We used Medicare 5% beneficiary sample data in 2005-2009.

Thompson Reuters Medstat database This dataset contains all paid claims generated by more than 20 million commercially-insured lives. Member identification codes are consistent from year to year and allow for multi-year longitudinal studies. Information includes diagnosis codes, procedure codes and DRG codes, NDC codes along with site of service information and the amounts paid by commercial insurers. For this study, we used Medstat 2005 to 2009.

Milliman 2011 Health Cost Guidelines. The Guidelines provide a flexible but consistent basis for the determination of health claim costs and premium rates for a wide variety of health plans. The Guidelines are developed as a result of Milliman's continuing research on healthcare costs. First developed in 1954, the Guidelines have been updated and expanded annually since that time. The Guidelines are continually monitored as they are used in measuring the experience or evaluating the rates of health plans, and as they are compared to other data sources.

NHANES series 2001-2002, 2003-2004, 2005-2006, 2007-2008. This is from the series of National Health and Nutrition Examination Surveys, a department within the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) produces NHANES. Each year, the survey contains information from roughly 5,000 completed forms plus details of laboratory results and physical examinations. A representative sample of the non-institutionalized civilian population ages 12 and older is selected by using a stratified, multistage sampling design. The data items list contains well more than 1,000 items of an individual's clinical, demographic and health status.

UKPDS Risk Engine. The UKPDS Risk Engine is a type 2 diabetes specific risk calculator based on 53,000 patient years of data from United Kingdom Prospective Diabetes Study [53].

APPENDIX B: METHODOLOGY

NHANES Analysis

We used the insurance identifier provided for each individual in NHANES 2005-06 and 2007-08 to distinguish the primary payer for commercial insurance, Medicare or Medicaid. We used the following identification criteria to identify type 2 diabetics and their characteristics for each payer cohort.

Diabetes - answering yes to any one of the following questions:

DIQ010	Other than during pregnancy, has a doctor ever told you that you have diabetes?
DIQ050	Are you now taking insulin?
DIQ070/DID070	Do you take diabetes pills to lower blood sugar?

Type 1 diabetics are identified and excluded from the analysis if they answer that they are less than 31 years old at time of diabetes diagnosis and answer no to taking oral diabetes pills and yes to taking insulin.

DIQ040	How old were you when a doctor or other health professional first told you that you had diabetes or sugar diabetes?
DIQ070/DID070	Do you take diabetes pills to lower blood sugar?
DIQ050	Are you now taking insulin?

Diabetes comorbidities

Hypertension - answering yes to either of the following:

BPQ050A	Are you now taking prescribed medicine for HTN?

Elevated blood pressure	≥130 mmHg systolic: (BPXSBP)
	Or
	≥80 mm Hg diastolic blood pressure: (BPXDBP)

Hyperlipidemia - answering yes to any one of the following:

BPQ100D: Are you now taking prescribed medicine for cholesterol?
Do you have a drug file prescription for a lipid-lowering drug (see antihyperlipidemic drug tab)?

Obesity - having BMI 30+:

BMXBMI	Body Mass Index (kg/m^2)
BMI 30+	Obese

CAD - answering yes to any one of the following:

MCQ160C	Has a doctor ever told you that you had CAD?
MCQ160D	Has a doctor ever told you that you had angina?
MCQ160E	Has a doctor ever told you that you had a heart attack?

Clinical metrics and goals for type 2 diabetes A1C, lipids (LDL, total cholesterol and HDL) and hypertension (blood pressure)

	NHANES Field	Goal for Diabetics
A1C	LBXGH	<7.0%
LDL	LBDLDL	<100 mg/dl
Total cholesterol	LBDTCSI	< 200 mg/dl
HDL	LBDHDDSI	>40 mg/dl men/50 mg/dl women
Blood Pressure	BPXSBP/BPXDBP	<130/80 mm/Hg

UKPDS Risk Variables

We used the UKPDS risk model to find the probability of each complication for each diabetic [53]. The risk model assigns a weighting to each risk factor to calculate the probability of seven diabetes complications. The risk factors used in UKPDS include those below and are identified in NHANES with the following fields:

Input	NHANES Field	NHANES Descriptor
Ethnicity	RIDRETH1	Race/Ethnicity
Gender	RIAGENDR	Gender
Age at (diabetes) diagnosis (y)	DID040	Age when first told you had diabetes
Duration of diabetes (y)	DIQ220	When was your diabetes diagnosed
Weight (kg)	BMXWT	Weight (kg)
Height (m)	BMXHT	Standing Height (cm)
Atrial Fib.	BPXPULS: answer # 2	pulse irregular (yes)
PVD		not available in NHANES
Smoking	SMQ040	Do you now smoke cigarettes (yes)
Chol (mmol/l)	LBDTCSI	Total Cholesterol(mmol/L)
HDL (mmol/l)	LBDHDDSI	Direct HDL-Cholesterol (mmol/L)
Sys BP(mmHg)	BPXSBP	Systolic BP
Diastolic BP (mmg/Hg)	BPXDBP	Diastolic BP
HbA1c (%)	LBXGH	Glycohemoglobin (%)
IHD	MCQ160D	Ever told you had angina/angina pectoris (yes)
CHF	MCQ160B	Doctor told you had CHF (yes)
Amputation		not available in NHANES
Blind	VIQ017	Blind in both eyes (yes)
Renal	KIQ022	Ever told you had weak/failing kidneys (yes)
Stroke	MCQ160f	Stroke (yes)
MI	MCQ160e	Heart Attack (Myocardial Infarction) (Yes)

Commercial and Medicare 5% Sample Claim Data Analysis

Diabetics were identified using the following criteria:

Over a two-year period (2008-2009) individuals with one inpatient or one ER or two physician E&M codes on separate dates coded with ICD9 250.xx in any position of the claim
OR for commercial claim database (no Part D data available in Medicare 5% sample), individuals with one or more claim (inpatient, ER or physician E&M code) coded with ICD9 250.xx in any position of the claim and one or more prescription claims for diabetes drug, commercial only for Rx drugs (NDC list available upon request)

Pregnant women were excluded using the following logic:
Women having one or more claims (any claim) for 630.xx-679.1 or 760.xx-779.9

Due to coding practices we believe our population includes some Type 1 diabetics

Adverse Event/Conditions Costs were identified using the following logic:

We used 2007 as the index year for identifying the seven diabetes complications. We used 2006 to perform a twelve-month look back for each individual to exclude those with claims for CHF, AF, ESRD stroke, CAD, amputation and blindness. We calculated the average cost during the year before the index event, during the year of the index complication and for two years after the index complication.

We identified complications using the following identification criteria:
Stroke: one ER or IP claim with stroke in the primary position of the claim

ICD-9 Ischemic Stroke:

433.01 Occlusion and stenosis basilar artery w cerebral infarct
433.11 Occlusion and stenosis carotid artery w cerebral infarct
433.21 Occlusion and stenosis vertebral artery w cerebral infarct
433.31 multiple and bilateral w cerebral infarct
433.81 other specified precerebral artery w cerebral infarct
433.91 unspecified precerebral artery w cerebral infarct
434.01 Cerebral Thrombosis with Cerebral infarction
434.11 Cerebral Emobolism with Cerebral Infarction
434.91 Cerebral Artery Occlusion, Unspecified, with cerebral infarction
436.xx Ischemic stroke

ICD-9 Hemorrhagic stroke

430.xx Subarachnoid hemorrhage
431.xx Intracerebral Hemorrhage
432.0 -432.9 Other & Unspecified Intracranial Hemorrhage

CAD event: inpatient admission with ICD-9 code of 410.xx for myocardial infarction in any position of the claim OR any claim with CPT or ICD9 procedure code for coronary revascularization:

CPT – 33140, 92980-92982, 92984, 92985, 92986, 92995, 92996, 33510-33523, 33533-33536, 33572
ICD9 Procedure codes - 00.66, 36.0x, 36.1x, 36.2x

Atrial fibrillation: one IP, or one ER or one physician E&M claim with AF ICD9 427.31 in primary position of the claim

CHF: one IP, or one ER or one physician E&M claim with CHF ICD9 428.xx in the primary position of the claim

Amputation: one IP claim with an ICD-9 procedure code in primary position: 84.1, 84.10-84.17

OR any individual with CPT codes: 27590-27598, 27880, 27881, 27882, 27884, 27886, 27888, 27889, 28800, 28805, 28810, 28820, 28825

ESRD: Any claim coded with one or more of the following CPT codes: 90918-90925, 90935, 90937, 90940, 90951-90970

Ischemic Heart Disease (IHD): one inpatient, one ER or two physician E&M claims with any of the following ICD 9 codes in any position of the claim:
411.1x, 411.8x, 413.xx or 414.0x in any position of the claim.

Blindness: one inpatient, or one ER or two physician E&M claims with ICD 9 369.xx, in any position of the claim

Comparative cost models:
We calculated the PPPM and PMPM cost of diabetes educators, insulin pens, insulin pumps, insulin strips, and continuous glucose monitoring devices from claims with the following coding:

Educators: (OP only)

CPT Codes:	98960-98962, 97802-97804, 99078*, 99605-99607, 96152, 96153
HCPCS Codes:	G0108, G0109, G0270, G0271, S9140-S9141, S9145, S9155, S9460, S9465, S9470
V-Codes:	V65.3, V58.67, V18.0, V53.91, V53.91, V77.1

Insulin pens/pumps/strips:

HCPCS Codes Pumps:	A4221, A4230, A4231, A4232, A4245, A4247, A4364, A4365, A4450, A4455, A6257, A6258, E0784, K0552, K0601
HCPCS Codes for Pens:	A4215, A9274, E1399, J3490
HCPCS Codes for Syringes:	A4206
HCPCS Codes Strips:	A4253, A4255, A9275

Glucose Monitoring

HCPCS Codes for CGM:	A9276-A9279, A4245, A4247, A4364, A4365, A4450, A4455, A6257, A6258
CPT Codes for Continuous Glucose Monitoring:	95250, 95251 (CGM)
HCPCS for Glucose Monitors:	E0607, E2100, E2101, A4256
HCPCS for Lancet:	A4258, A4259

Cost Assumptions

We developed the diabetic patients' cost and the incremental costs of complications using MarketScan 2007-2009 and Medicare 5% 2007-2009. We developed complication costs by examining the actual claim costs of individuals having events in the year before the event, the year of the event and two years after the event. We developed per patient per month (PPPM) costs, which are the average monthly costs for the patients experiencing the event. Costs were trended to 2012 using a 5% annual trend factor from the 2009 claim costs.

We did not include costs for improved diabetes therapy, although costs for the current level of drug treatments are included. Diabetes therapy includes diet and exercise, as well as pharmaceutical medications (generic and brand medications). The additional costs of drugs should be considered in evaluating the projected cost savings.

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