## Medical Claim Cost Impact of Improved Diabetes Control for Medicare and Commercially Insured Patients with Type 2 Diabetes

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#### ABSTRACT

BACKGROUND: Diabetes prevalence is increasing in the United States, yet the control of critical clinical metrics (e.g., hemoglobin A1c [A1c], blood pressure, and lipids) remains suboptimal. Lower A1c levels have been shown to be associated with lower diabetes complication rates, and reduced medical costs have been reported in individuals with diabetes who have improved glycemic control. While many studies have quantified the impact of A1c control on medical claim costs, this article provides new information on the cost and event impact of better control for all 3 metrics for the commercial population and Medicare population separately.

OBJECTIVES: To (a) quantify current type 2 diabetes control rates for A1c, blood pressure, and lipids and (b) model the impact of scenarios for better control of these metrics on diabetes complication rates and complication costs in people with diabetes in commercially insured and Medicare populations.

METHODS: 858 adults with commercial (n = 392) or Medicare (n = 466) coverage and type 2 diabetes were identified from approximately 10,000 individuals in the National Health and Nutrition Examination Survey (NHANES; combined series 2005-2006 and 2007-2008). Based on each individual's risk factors, the United Kingdom Prospective Diabetes Study modeling tool was used to project rates of 7 diabetes complications under status guo A1c, blood pressure, and lipid levels and complication rates under better management. Three improved management scenarios were created to model the impact of better control in all commercially insured and Medicare individuals with type 2 diabetes who had A1c, blood pressure, or lipids not at goal and in a subset of individuals whose A1c levels were  $\geq$  7%, with or without blood pressure or lipids not at goal. Thomson Reuters MarketScan Commercial Claims and Encounters Database (2006-2009) and Medicare 5% sample data (2006-2009), including the eligibility data for each, were used to develop both the average annual costs and per-patient-per-month (PPPM) costs, adjusted to 2012 dollars, in commercially insured and Medicare fee-for-service patients with diabetes and the cost of diabetesrelated complications to monetize the impact of reducing complications.

**RESULTS:** Analysis of NHANES data showed that type 2 diabetes prevalence is 6.1% in commercially insured individuals aged 20 to 64 years and 19.4% in Medicare beneficiaries aged 65 years and older. Of patients with type 2 diabetes, 47% of commercially insured patients and 38% of Medicare patients were found to have A1c  $\ge$  7%. With improved control of A1c, blood pressure, and lipid levels that were not at goal, as modeled in 3 management scenarios, reductions in the probability of complications across all patients with diabetes ranged from 43% to 67% in the commercial population and 28% to 49% in the Medicare population. The cost savings effect from reduced complications across all patients with diabetes ranged from \$67 to \$105 PPPM in the commercial population and \$99 to \$158 in the Medicare population. The high end of this savings range yielded a reduction of about 10% in total costs when compared with an average of \$1,090 PPPM in commercially insured patients with diabetes and an average of \$1,565 PPPM in Medicare patients with diabetes derived from large claims databases, both in projected 2012 dollars.

CONCLUSION: Results of this analysis suggest that better control of A1c, blood pressure, and lipids is associated with savings opportunities in commercially insured and Medicare patients with type 2 diabetes. A focus on only patients with uncontrolled A1c offers a somewhat higher per-patient cost reduction than for all uncontrolled diabetes patients but greatly diminishes the number of targeted patients.

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#### What is already known about this subject

- Diabetes control rates of critical clinical metrics, such as hemoglobin A1c ([A1c]; glycemic control), blood pressure (BP), and lipids, has improved in recent years but are still suboptimal, with 57% control for A1c (A1c <7%), 45% for BP (<130/80 mm Hg), and 47% for low-density lipoprotein cholesterol (LDL-C <100 mg per dL).</li>
- Improved control of A1c, BP, and lipids is associated with a lower rate of diabetes complications and lower medical costs.
- The United Kingdom Prospective Diabetes Study tools that quantify the probabilities of diabetes complications based on a patient's controllable and uncontrollable risk factors are well established and consider A1c, BP, and lipids.

#### What this study adds

- For people with diabetes, about 20% of the commercial or Medicare costs is due to diabetes complications. For scenarios of improved control over A1c, BP, and lipid levels, cost savings impact from reduced complications across all diabetes patients on a per-patient-per-month (PPPM) basis ranged from \$67 to \$105 in the commercial population and \$99 to \$158 in the Medicare population. The high end of this savings range yielded a reduction of about 10% in total costs relative to an average of \$1,090 PPPM in commercially insured patients with diabetes and an average of \$1,565 PPPM in Medicare patients with diabetes.
- For both the commercial and Medicare populations, the number of people with diabetes who have any of the 3 metrics uncontrolled was about twice the number who have A1c uncontrolled.
- The per-patient savings from better control is similar whether or not A1c is the metric that is uncontrolled. For the commercial population, the per-patient savings from better control for people with diabetes and uncontrolled A1c is 20% to 29% higher than if better control were applied to people with diabetes and any of the 3 metrics uncontrolled. For the Medicare population, the per-patient savings from better control was about 50% higher for patients with uncontrolled A1c compared with the patients with any of the 3 metrics uncontrolled.

The prevalence of diabetes is on the rise in the United States, with an increase in diagnosed diabetes from 6.5% in 1999 to 7.8% in 2006.<sup>1</sup> Furthermore, the increase in prevalence is projected to continue; in fact, estimates suggest that diagnosed and undiagnosed diabetes will almost double between 2009 and 2034.<sup>2</sup> Individuals with diabetes face an increased risk of microvascular and macrovascular disease (i.e., coronary artery disease, stroke, peripheral vascular disease, end-stage rental disease, and retinopathy), and the ageadjusted risk of death in individuals with diabetes is nearly twice that of those without diabetes.<sup>3</sup>

Although the control rate of critical clinical metrics, such as hemoglobin A1c (A1c; glycemic control), blood pressure (BP), and lipids, has improved in recent years,<sup>1</sup> the management of diabetes is still suboptimal. A previous analysis of National Health and Nutrition Examination Survey (NHANES) data (combined series 2003-2004 and 2005-2006) shows that control rates remain low: 57% control for A1c (A1c <7%), 45% for BP (BP <130/80 mm Hg), and 47% for low-density lipoprotein cholesterol (LDL-C < 100 milligrams per deciliter [mg/dL]).<sup>1</sup> In addition, only 12.2% of individuals with diabetes in NHANES (2003-2006) were reported to have all 3 metrics simultaneously controlled.<sup>1</sup>

Landmark studies have reported that lower A1c levels are associated with lower rates of diabetes-related complications.<sup>4-6</sup> However, studies do not uniformly report that lower A1c is better at all levels. The ACCORD trial<sup>7</sup> identified higher mortality among patients with A1c < 6% compared with a control group with A1c of 7%-7.9%.

The medical costs associated with type 2 diabetes are substantial, and the portion of the national health care expenditure attributed to its management is expected to increase from 10% in 2011 to 15% in 2031.8 Numerous diabetes management efforts invoke the urgency of controlling health care costs. Several medical cost impact studies have reported that medical costs are lower in individuals with diabetes who have improved glycemic control.<sup>8-14</sup> Results of a retrospective analysis in 6,780 patients with diabetes who were members of a large U.S. health insurance plan showed that predicted total diabetes-related costs were 32% higher in patients with A1c levels >7% than in those with A1c levels  $\leq 7\%$  (\$1,540 vs. \$1,171, respectively; P < 0.001).<sup>9</sup> A regression analysis used to estimate the correlation between glycemic control and medical costs in 3,017 patients with diabetes who were members of a large health maintenance organization (HMO) found that costs increased for every 1% increase above an A1c level of 7%.10 In a study of 34,469 patients with type 2 diabetes identified from a large U.S. managed care organization, a 1-percentage point increase in A1c led to a 4.4% increase (on average) in diabetes-related medical costs, which corresponds to an annual cost increase of \$250 per person.<sup>11</sup> A study investigating the benefit of intensive glycemic control, intensified hypertension control, and

serum cholesterol reduction in a hypothetical cohort of newly diagnosed patients with type 2 diabetes reported incremental cost-effectiveness ratios of \$41,384, -\$1,959, and \$51,889, respectively, per quality-adjusted life-year.<sup>12</sup> In a retrospective study of 2,394 patients with diabetes identified in a multispecialty group clinic, the adjusted rate of inpatient admissions (hospital or skilled nursing facility) over a 3-year period was 13 per 100 patients with good glycemic control (A1c <8%), 16 per 100 patients with fair glycemic control (A1c ranges 8% to 10%), and 31 per 100 patients with poor glycemic control (A1c >10%; P<0.05). The corresponding mean adjusted charges were about \$970, \$1,380, and \$3,040, respectively.13 Results of a retrospective cohort analysis in 9,887 patients with type 1 or type 2 diabetes who received care at a clinic affiliated with a managed care organization showed that the probability of a diabetes-related hospitalization was higher in patients with a mean A1c  $\geq$  10% than in those with a mean A1c <7% (odds ratio = 2.14; 95% confidence interval = 1.36-3.33); the adjusted mean estimated costs of diabetes-related hospitalizations per patient were \$2,792 and \$6,759, respectively.<sup>14</sup> In a systematic review of the literature (January 2000-November 2005) assessing the effect of antidiabetic medications and glycemic control on cost in patients with diabetes who were members of U.S. managed care organizations, investigators identified 8 studies showing that improved glycemic control reduces overall perpatient direct costs; of interest, the pharmacy component usually represented 20% to 30% of overall costs, and about 30% of pharmacy charges were directly correlated with glycemic control.15

The current analysis was based on a hypothetical cohort of commercially insured and Medicare fee-for-service patients with type 2 diabetes who were identified from the NHANES database. Applying the United Kingdom Prospective Diabetes Study (UKPDS) complication risk model to the individual's risk characteristics, the analysis simulated diabetes complication rates under status quo risk factor profiles and complication reductions associated with improved management of A1c, BP, and lipids. Data extracted from large commercial and Medicare administrative databases were used to quantify the average incremental cost of 7 UKPDS diabetes complications for the year of the complication and the 2 years following a complication, with the cost impact presented in per-diabetes patient-per-month (PPPM) dollars. Using the claim costs associated with diabetes-related complications to model the costeffectiveness of improving diabetes care has been suggested by others.7 Previous cost studies examined subsets of managed care diabetes patients, analyzing both claims and clinical data. These studies compared costs among patients with varying levels of A1c and made adjustments to control for confounding variables. The potential selection biases of such approaches are well known, and results can reflect well-motivated patients or regression to the mean. Our approach of examining a

hypothetical cohort of all diabetics sets boundaries for the maximum impact of better diabetes management on complications and cost and considers BP, lipid, and A1c control for a commercially insured population separate from the Medicare population.

#### Methods

## **Data Sources**

Two NHANES series (2005-2006 and 2007-2008), with a total sample size of approximately 10,000 individuals, were analyzed to identify the prevalence of type 2 diabetes and distribution of risk characteristics in commercially insured and Medicare populations (see Appendix A for identification criteria [available in online article]). NHANES is produced by the National Center for Health Statistics, a department within the Centers for Disease Control and Prevention, and is based on a sample of the noninstitutionalized civilian population aged 12 years and older. The data items in NHANES include more than 1,000 items pertaining to an individual's clinical, demographic, and health status. Individuals were selected from NHANES using a stratified multistage sampling design. An insurance identifier provided for each individual in NHANES was used to select individuals whose primary payer was commercial insurance or Medicare.

The Thomson Reuters MarketScan Commercial Claims and Encounters Database (2006-2009) and Medicare 5% sample data (2006-2009) were used to develop both the average annual costs and the PPPM and per-member-per-month (PMPM) costs in commercially insured and Medicare fee-for-service patients. PMPM costs were developed for the entire commercial and Medicare populations; PPPM costs were developed for patients with diabetes as were the per-patient cost of diabetes-related complications. The Thomson Reuters MarketScan database contains all paid claims generated by more than 20 million commercially insured lives annually. Member identification codes are consistent from year to year and allow for multiyear longitudinal studies. The database contains information about International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes; procedure codes and diagnosis-related group (DRG) codes; national drug codes (NDCs); and site of service information and the amounts paid by commercial insurers. We identified costs as falling into the inpatient setting, outpatient setting, or prescription drugs based on assignments in MarketScan. The Medicare 5% sample contains Medicare paid claims generated by a balanced sample of approximately 2.2 million beneficiaries. The sample contains information about ICD-9-CM diagnosis, procedure, and DRG codes, as well as site of service information, beneficiary age, eligibility status, and an indicator for HMO enrollment. We categorized costs into inpatient facility, outpatient facility, professional (inpatient or outpatient), skilled nursing facility, home health, and durable medical equipment (DME) or hospice, based on categories assigned in the Medicare 5% sample. Claims for prescription drug benefits, which are paid through Medicare Part D, are not included in the Medicare 5% sample data and do not appear in our analysis. The 2 claims databases, the Medicare 5% sample, and MarketScan were separately used as sources for Medicare and commercially insured lives, respectively, to generate estimated cost per diabetes complication in the year of the complication and in the 2 subsequent years.

The Milliman Health Cost Guidelines 2011 were used to adjust the NHANES population demographics to reflect typical age-sex distributions of Medicare 65+, non-Medicaid, and commercial beneficiaries. 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.

#### Population Sample

The NHANES database was used to identify patients with diabetes. Patients were considered to have diabetes if they answered "yes" to any of the following survey questions:

- Other than during pregnancy, has a doctor told you that you have diabetes? (NHANES field DIQ010)
- Are you now taking insulin? (NHANES field DIQ050)
- Do you take diabetes pills to lower blood sugar? (NHANES fields DIQ070, DID070)

NHANES does not specify whether a patient has type 1 or type 2 diabetes; therefore, we used previously published logic to exclude patients presumed to have type 1 diabetes.<sup>16</sup> Patients answering "yes" to the first 2 questions and "no" to the third question below were excluded:

- 1. Were you younger than the age of 31 years at the time of diabetes diagnosis? (DIQ040)
- 2. Are you now taking insulin? (DIQ050)
- 3. Do you take diabetes pills to lower blood sugar? (DIQ070/ DID070)

The diabetes sample included 466 commercially insured individuals aged 20-64 years (mean age, 53 years [SD, 9.2 years]; females, 53%) and 392 Medicare beneficiaries aged 65 years and older (mean age, 73.5 years [SD, 5.5 years]; females, 46%; Figure 1).

To establish baseline costs for diabetics and diabetes complications, 2006-2009 Thomson Reuters MarketScan and Medicare 5% sample claims data were analyzed. For the baseline cost of diabetics, a patient was considered to have diabetes if he or she had 1 of the following: 1 inpatient claim, 1 emergency room (ER) claim, or 2 physician evaluation and management claims on separate days during January 2008 through December 2009 with ICD-9-CM 250.xx code as either the primary or secondary code. MarketScan includes pharmacy claims data, and for commercial members, we used the additional Healthcare Effectiveness Data and Information



well populated in blood pressure/body mass index. NHANES=National Health and Nutrition Examination Survey.

Set (HEDIS) diabetes identification criteria, 1 physician evaluation and management claim coded with ICD-9 250.xx as either the primary or a secondary code and 1 or more prescription claim(s) for a diabetes drug to determine if a patient had diabetes for this cohort. (NDC list available from HEDIS.) The Medicare data did not include prescription drug information, and we did not use this additional criteria for Medicare. Women having 1 or more claims coded with pregnancy-related diabetes (ICD-9-CM codes 630.xx-679.1 and 760.xx-779.9) were excluded from the diabetes cohort. The number of diabetics identified for the baseline costs from the commercial MarketScan analysis was 174,886 and for the Medicare 5% analysis 260,682.

To calculate the cost of complications, 2006-2009 claims data were used to allow for calculation of the cost in the year prior to and the 2 years after the complication. The sample size of diabetics with each of the 7 complications is presented in Table 1.

TABLE 1     Sam       Com	ple Size of Diabeti plications	cs with
Diabetes Complication	MarketScan	Medicare 5% Sample
Ischemic heart disease	27,635	48,064
Myocardial infarction	1,773	5,710
Congestive heart failure	12,328	40,189
Stroke	954	5,231
Amputation	636	2,294
Blindness	1,549	3,806
Renal failure	7,590	13,041
Source: Authors' analysis of M	arketScan and Medicare 5	% sample 2006-2009.

#### Study Measures

The probability of developing a diabetes complication was calculated for each NHANES diabetes patient using the UKPDS risk model. The UKPDS risk model, a type 2 diabetes-specific risk calculator based on 53,000 patient-years of data from the UKPDS,<sup>17</sup> determines the probability of developing each of 7 diabetes complications: ischemic heart disease, myocardial infarction, congestive heart failure (CHF), stroke, amputation, blindness, and renal impairment. The model includes formulae for calculating comorbidity incidence, estimates of probability for coronary heart disease (CHD) complications, and the relative risks correlated with potential risk factors, as well as equations for absolute risk that incorporate the effect of multiple risk factors to produce overall event rates.17 The UKPDS model includes the patient's A1c, systolic BP, and lipid levels as risk factors, in addition to age, sex, ethnicity, smoking status, and time since diabetes diagnosis.17 The NHANES risk factor fields used as inputs to UKPDS are presented in Appendix A (available in online article).

Costs of complications were developed by examining the actual claims costs of individuals having events. For each patient having an event, costs were tabulated in the year before the event, the year of the event, and 2 years after the event. Index year 2007 was used to identify the 7 diabetes complications (see Appendix B for coding logic used to identify complications [available in online article]). In order to represent the cost of each newly developed complication, 2006 was used to perform a 12-month look back from the index complication date to exclude patients from the cost calculation having claims coded with each of the 7 diabetes complications. The years 2008 and 2009 were used to follow the costs in the 2 years after the index complication.

We considered the complication costs that could be avoided to be the incremental cost of each complication—that is, the cost associated with the complication above the background cost of the diabetes patient. The incremental cost of each diabetes complication was the net of the costs in the year of the complication and the year prior to the complication and likewise for each of the 2 years after the complication, since

TABLE 2         Clinical Targets	and Improvemer	nt Scenarios			
				Improvement Amount	
	ADA Clinic	al Targets	Scenario 1	Scenario 2	Scenario 3
Alc (%)	<7	%	<b>↓</b> 1% A1c	↓1.25% Alc	↓1.5% Alc
Systolic BP/diastolic BP (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)	<b>†</b> 20%	<b>†</b> 35%	<b>†</b> 50%
Total cholesterol (mg/dL)	<200 r	ng/dL	↓20%	↓35%	↓50%
A1c=hemoglobin A1c; ADA=American Diabetes Association; BP=blood pressure; F=female; M=male; mg/dL=milligrams per deciliter; mm Hg=millimeter of mercury.					

patient costs rarely revert to precomplication costs. PPPM costs (i.e., the average monthly costs for the patient experiencing the event) were developed, and costs were trended from 2006-2009 to 2012 using a 5% annual trend. The 5% annual trend was chosen to approximate the combined effect of unit price and utilization trends across the commercial and Medicare populations during this period, although we note reports of higher and lower trends.<sup>18,19</sup> Appendix C (available in online article) contains an algebraic presentation of the incremental cost calculation.

We did not include the additional costs of the pharmaceutical treatments or care management services that would be needed to achieve the improved outcomes we modeled. The availability of many generic drugs for glycemic, BP, and lipid control suggests relatively low additional costs are possible for the pharmaceutical treatments, at least for many patients. Care management programs come in many varieties and include electronic interfaces as well as more traditional telephonic outreach to patients by nurses. A full consideration of these costs is outside the scope of this analysis.

#### **Modeling Analysis**

Using the hypothetical cohort of commercially insured and Medicare fee-for-service patients with diabetes identified in the NHANES analysis as described earlier, the probability of diabetes-related complications for each patient was estimated using the UKPDS risk model. Using each patient's "status quo" (as appears in NHANES) risk factors, the probability of developing each complication was calculated, and that calculation was repeated for 3 improvement scenarios. The 3 improvement scenarios modified clinical metrics in patients with A1c, BP, total cholesterol, or high-density lipid protein cholesterol (HDL-C) not at recommended targets. The impact of reducing these metrics on status quo diabetes complication rates and the number of deaths associated with these complications was modeled in commercially insured and Medicare populations. The 3 improvement scenarios (Table 2) are based on American Diabetes Association (ADA) targets, and reductions in each of the 3 values are consistent with reductions generally achievable with initiation, titration, or add-on drug class therapy.

#### Results

The overall prevalence of type 2 diabetes in NHANES 2005-2008 is 6.1% in commercially insured adults aged 20 to 64 years and 19.4% in Medicare beneficiaries aged 65 years and older.

According to our analysis of NHANES data (2005-2008), the portion of individuals with type 2 diabetes attaining ADA recommended targets (A1c <7%; BP <130/80 mm Hg; LDL-C <100 mg/dL; total cholesterol <200 mg/dL; and HDL-C >40 mg/dL in men and >50 in women)<sup>20</sup> remains low. As shown in Figure 2, the A1c goal was attained by 53% of commercially insured patients and 62% of Medicare beneficiaries; total cholesterol, 61% and 77%, respectively; HDL-C, 53% and 56%, respectively; and BP, 49% and 40%, respectively. Only 9% of commercially insured patients and 12% of Medicare beneficiaries had met all 3 target metrics.

#### Diabetes Costs by Major Service Category by Payer

The allowed PPPM cost in adult individuals with type 2 diabetes in the commercial population was found to be \$1,090, which compared with an average allowed PPPM cost of \$448 across the commercially insured adult population without diabetes and \$489 across the total adult population. The cost of the complications we analyzed (UKPDS complications) contributed 20% of the total spending in individuals with diabetes (Table 3).

Based on our analysis, the PPPM cost in the Medicare population claims analysis was found to be \$1,565, which compared with an average cost of \$686 for Medicare beneficiaries without diabetes and \$858 for the total Medicare population—each of these Medicare figures do not include spending on drugs. The cost of UKPDS complications contributed 21% of the total spending for individuals with diabetes (Table 4).

#### Probability of Diabetes Complications and the Impact of Better Diabetes Control on the Probability of Complications

In the commercial population, improved management scenarios 1, 2, and 3 (see Table 2) produced reductions in the probability of diabetes-related complications of 43%, 55%, and 67%, respectively. In the Medicare population, the scenarios produced reductions in the probability of diabetes-related complications of 28%, 38%, and 49%.



#### Medical Claim Cost Impact of Improved Diabetes Control for Medicare and Commercially Insured Patients with Type 2 Diabetes

#### Source: Authors' analysis of NHANES 2005-2008 data.

A1c=hemoglobin A1c; BP=blood pressure; HDL=high-density lipoprotein; mg/dL=milligrams per deciliter; mm Hg=millimeter of mercury; NHANES=National Health and Nutrition Examination Survey.

TABLE 3	Allowed Cost PPPM I Category in Comme	by Major S rcial Popul	ervice ation
			Total

			PPPM (\$)	Percentage
Total			1,090	100
	UKPI	DS complications	214	20
	Othe	r than UKPDS complications	876	80
		Diabetes prescription drugs	86	8
		Other prescription drugs	188	17
		Inpatient, including inpatient professional	181	17
		Outpatient, including outpatient professional	421	39

Source: Authors' analysis of MarketScan 2006-2009, demographically adjusted to Milliman Health Cost Guidelines 2011.<sup>52</sup> Costs trended to 2012.

PPPM=per patient per month; UKPDS=United Kingdom Prospective Diabetes Study.

Figures 3 and 4 provide the comparison of probability rates under the status quo and 3 management scenarios.

#### **Cost Impact of Better Diabetes Control**

The reduction in UKPDS complications was monetized under the 3 improvement scenarios. UKPDS complications were shown to account for approximately 20% of costs in individuals

# TABLE 4 Allowed Cost PPPM by Major Service Category in Medicare Population

			PPPM (\$)	Total Percentage
Total			1,565	100
	UKPI	DS complications	331	21
	Othe	r than UKPDS complications	1,234	79
		Inpatient facility	285	23
		Skilled nursing facility	62	5
		Home health services	57	5
		Outpatient facility	152	12
		Physician professional	336	27
		Durable medical equipment	64	5
		Hospice	18	1

Source: Authors' analysis of Centers for Medicare and Medicaid Services' 5% Medicare sample 2009, demographically adjusted to Milliman Medicare Health Cost Guidelines 2011.<sup>52</sup> Costs trended to 2012.

PPPM=per patient per month; UKPDS=United Kingdom Prospective Diabetes Study.

with diabetes. The portion and type of complication avoided varied by the profile of each payer cohort and the reduction scenarios (Table 5). The cost savings impact from reduced complications across all diabetes patients on a PPPM basis ranged from \$67 to \$105 in the commercial population and \$99 to





NHANES = National Health and Nutrition Examination Survey; UKPDS = United Kingdom Prospective Diabetes Study.

\$158 in the Medicare population. The high end of this savings range yielded a reduction of about 10% in total costs relative to an average of \$1,090 PPPM in commercially insured patients with diabetes and an average of \$1,565 PPPM in Medicare patients with diabetes.

In the commercial population, scenario 3 produced a \$105.47 PPPM reduction in costs (about 10% of the \$1,090 average monthly costs) in individuals with diabetes and a \$4.70 PMPM reduction in costs (about 1% of the \$489 aver-

age monthly costs) across all insured members. As noted previously, the Medicare population with diabetes has higher complication risks but lower potential reduction in complications, compared with commercially insured populations. In the Medicare population with diabetes, scenario 3 produced a \$106.04 PPPM reduction in costs (about 7% of the \$1,565 average monthly costs) in individuals with diabetes and a \$16.18 reduction in PMPM costs (about 2% of the \$858 average monthly costs) across all Medicare members.

TABLE 5         Cost Impact of	of Better Diabetes	s Control				
	Target: All Diabete	Farget: All Diabetes Patients with Any Uncontrolled Metric <sup>a</sup>			trolled A1c Dia	betes Patients
Commercial Population	Scenario 1	Scenario 2	Scenario 3	Scenario 1	Scenario 2	Scenario 3
Reduction in complication rate	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
	Target: All Diabete	Patients with Any Uncontrolled Metric <sup>a</sup>		Target: Uncontrolled A1c Diabetes Patients		
Medicare	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

Source: Authors' modeling using NHANES 2005-2008, MarketScan 2006-2009, Medicare 5% sample 2008, Milliman Health Cost Guidelines 2011,<sup>52</sup> commercial and Medicare.

<sup>a</sup>Uncontrolled A1c or blood pressure or lipids.

NHANES = National Health and Nutrition Examination Survey; PMPM = per member per month; PPPM = per patient per month.

Table 6 shows the application of these scenarios to a commercial plan with 100,000 members and an estimated 4,454 patients with diabetes. The probabilities reflect the underlying fluctuation of outcomes relative to the status quo forecast.

#### Discussion

This study modeled the impact on diabetes of multiple points of control that are important for people with diabetes. Clinical practice guidelines for diabetes care specify target levels for A1c, BP, and lipids and protocols for lifestyle and drug therapy to achieve these targets, yet adherence to these recommendations is low.

Much of the research in diabetes control is funded by the pharmaceutical industry. Not surprisingly, much of the research focuses on the important metrics and outcomes associated with classes of drugs of interest to particular manufacturers, especially glycemic control. Indeed, patient adherence to diabetes drug therapy, lifestyle recommendations, and physician practice patterns are identified as contributors to the poor rate of glycemic control. Research to date has documented wide variance in patient adherence to glycemic control management, including the filling of prescriptions.<sup>21-25</sup> Studies consistently report physician delays in intensifying drug therapy when A1c is above goal, with many patients experiencing levels >8%, resulting in years of glycemic burden.<sup>26-30</sup> Furthermore, diabetes is a progressive disease, with studies reporting an annual 0.15% increase in patients' Alc, even with appropriate management.<sup>31</sup> However, as we identify, focusing on diabetes patients with poor glycemic control ignores a large number of uncontrolled patients and misses large opportunities for improved outcomes. Because of these challenges, numerous innovative approaches to working with physicians and patients are underway.

To address the need for improvement in physician practice patterns in diabetes care, physician pay for performance (P4P) initiatives have been implemented by many health plans. Several studies have reported improved quality and clinical metrics in individuals with diabetes when cared for by physicians in a P4P arrangement, compared with those cared for by physicians without a P4P arrangement.<sup>32-34</sup> Another initiative aimed at improving physician care coordination for individuals with diabetes and other chronically ill patients is the medical home movement, which often incorporates a P4P arrangement. Several patient-centered medical home demonstrations have reported improvements in quality and clinical outcomes in diabetes patients cared for under this model.<sup>35</sup>

Educational and behavioral change initiatives are commonly used to improve patient self-management and typically include disease management (DM) programs and diabetes self-management education (DSME) interventions. Varying levels of success have been reported with DM and DSME interventions. Diabetes DM programs are now a mainstay of commercial insurance programs and are 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. The impact of lowering A1c on medical costs is mixed.<sup>36-41</sup> The recently reported outcomes of the Medicare Health Support Disease Management Pilot Program, which enrolled more than 100,000 individuals with diabetes in the intervention and approximately 60,000 in the control group, showed no evident reduction in the utilization of acute care or the cost of care.42

DSME is typically performed by diabetes educators and is a covered benefit by Medicare and many commercial payers. The

		Target: All Diabetes Patients			
		Status Quo	Scenario 1	Scenario 2	Scenario 3
Annual complicat	ion rate	1.9%	1.1%	0.9%	0.6%
Reduction in com	plication rate relative to status quo		43%	55%	67%
	Probability <sup>a</sup> of scenario results > status quo		0.0007	< 0.0001	< 0.0001
PPPM	· · · · · · · · · · · · · · · · · · ·	\$1,089.95	\$1,023.22	\$1,003.89	\$984.47
Savings PPPM			\$66.73	\$86.06	\$105.47
	Probability <sup>a</sup> of scenario results > status quo		0.0502	0.0154	0.0035
<sup>a</sup> Probabilities were Number of member Estimated number Coefficient of Var	calculated based on a commercial plan with: ers = 100,000 r of diabetes patients = 4,454 intion (CV) of diabetes patients PPPM = 2.6				

PPPM = per patient per month.

American Association of Diabetes Educators 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) and most often have a background in nursing, dietetics, and pharmacy. Self-management education can take place in individual or group settings. A positive short-term impact on reducing Alc and costs has been reported, but the benefit has been shown to decline a few months after the intervention ceases.<sup>39,40,43-47</sup>

Value-based benefit designs (VBBD) for commercially insured populations, in which copayments for chronic diabetes drug therapies are reduced, have been associated with improved patient compliance with diabetes drug therapy.48 Elasticity between utilization of health care services and member copayment level is well established and is the foundation of 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 nonadherent patients by 30%.48

A variety of web- and phone-based systems are available to help manage diabetes. A new class of systems was cleared by the U.S. Food and Drug Administration as a mobile health device for virtual patient coaching. A randomized controlled trial reported statistically significant A1c reductions in individuals with type 2 diabetes using the new patient coaching device compared with such individuals receiving usual care.49 The patient coaching system includes diabetes management software that allows patients to enter diabetes self-care data into their personal computers or mobile phones and receive automated real-time educational, behavioral, and motivational messaging specific to the entered data, along with a health care provider portal allowing physicians to access patient data.49 The increased adoption of electronic medical records and e-prescribing should complement and enhance patient-centric digital solutions.

Despite these management programs and the availability of a broad spectrum of pharmacologic products, diabetes control rates remain low. Yet, the correlation between lower A1c levels and lower diabetes-related complication rates has been well documented.4-6 Furthermore, medical costs have been shown to be reduced in individuals with diabetes who have improved glycemic control.9,10

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 generic and brand prescription drugs classes, insulins, monitors, pumps, clinician patient education, and DM programs. Clearly, the collection of options, which vary widely in terms of costs and efficacy, is not sufficient to solve the diabetes problem.

The quantitative findings in the current study support the value of effective systems of care for individuals with diabetes. Both clinical recommendations and system change advocates recognize the importance of managing the whole patient. Indeed, the current models suggest that 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.

#### Limitations

The present study has several limitations. The diagnosis, procedure, or other codes in administrative data may be incorrect or incomplete, and various biases could affect the claims that are coded. For example, the claims of less severe patients and patients with fewer health system interactions may be less likely to be identified. The costs we present are national averages, but costs in particular systems and situations could be much higher or lower. NHANES is an examination survey, with weights provided for individual data points to allow the researcher to extrapolate results to the U.S. population. Some data points, such as insurance coverage, are based on responses to questions, which could introduce biases.

Modeling in the current study is limited to the impact of improved diabetes management on reducing UKPDS diabetes

complications, which account for 20% of total diabetes medical costs. The analysis does not consider any potential reduction (or increase) in the 80% of medical costs in the target populations other than these complications. In addition, the study does not consider potential reduction (or increase) 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 cost (in 2007 dollars) associated with diagnosed diabetes.<sup>50</sup> Costs for the current level of drug treatments in the commercial analysis were included, but costs for improved diabetes therapy were not. Diabetes therapy includes diet and exercise, as well as pharmaceutical (generic and brand name) medications. The additional costs of medications should be considered in evaluating the projected cost savings.

#### Conclusion

Diabetes is a highly prevalent disease that is often associated with debilitating complications. Of particular concern is the suboptimal management of critical clinical metrics, including A1c, BP, and lipids. Individuals with diabetes have higher rates of microvascular and macrovascular disease and morbidity/ mortality than do individuals without diabetes. Studies show, however, that lower A1c levels are associated with lower diabetes-related complications and reduced medical costs, although the ACCORD trial<sup>7</sup> identified higher mortality among patients with A1c <6%, compared with a control group with A1c of 7%-7.9%, and the ADVANCE trial identified that the reduction in major microvascular and macrovascular events was largely driven by a reduction in nephropathy.<sup>51</sup> Data from the current claims data analysis corroborate these findings, showing that better control of A1c, BP, and lipids is associated with complication rate reductions and savings opportunities in commercially insured and Medicare patients with type 2 diabetes.

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#### DISCLOSURES

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Study concept and design were contributed by Fitch and Iwasaki, with assistance from Pyenson. Iwasaki was responsible for data collection, with assistance from Fitch and Pyenson. Data interpretation and the writing and revision of the manuscript were performed by Fitch and Pyenson, with assistance from Iwasaki.

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## APPENDIX A UKPDS Model Inputs and NHANES Fields

UKPDS Risk Factor Inputs and Their	r Identification in NHANES	
Input to UKPDS Model	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 fibrillation	BPXPULS: answer #2	Pulse irregular (yes)
	d00022	Warfarin (yes)
PVD		Not available in NHANES
Smoking	SMQ040	Do you now smoke cigarettes (yes)
Cholesterol (mmol/L)	LBDTCSI	Total cholesterol (mmol/L)
HDL (mmol/L)	LBDHDDSI	Direct HDL-cholesterol (mmol/L)
Systolic BP(mm Hg)	BPXSBP	Systolic BP
Diastolic BP (mm Hg)	BPXDBP	Diastolic BP
HbA1c (%)	LBXGH	Glycohemoglobin (%)
Ischemic heart disease	MCQ160D	Ever told you had angina/angina pectoris (yes)
Congestive heart failure (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)
Myocardial infarction	MCQ160e	Heart attack (myocardial infarction) (yes)
UKPDS Model Outputs Generated for	r This Report	
UKPDS Model Output	Interpretation	
Ischemic heart disease		
Myocardial infarction	Coronary artery disease	
Congestive heart failure (CHF)		
Stroke	Ischemic or hemorrhagic stroke	
Amputation		
Blindness		
Renal impairment	End-stage renal disease	
BP=blood pressure; cm=centimeter; HDL NHANES=National Health and Nutritio	=high-density lipoprotein; kg=kilogram; m=m n Examination Survey: PVD= peripheral vascu	eter; mm Hg=millimeter of mercury; mmol/L=millimole per liter; lar disease: UKPDS=United Kingdom Prospective Diabetes Study: v=vears

## APPENDIX B Claims Data Identification of Complications

Ischemic stroke: 1 ER or 1 inpatient claim with ICD-9-CM code in the primary position of the claim		
ICD-9-CM Codes	Description	
433.01	Occlusion and stenosis basilar artery with cerebral infarction	
433.11	Occlusion and stenosis carotid artery with cerebral infarction	
433.21	Occlusion and stenosis vertebral artery with cerebral infarction	
433.31	Multiple and bilateral with cerebral infarction	
433.81	Other specified pre-cerebral artery with cerebral infarction	
433.91	Unspecified pre-cerebral artery with cerebral infarction	
434.01	Cerebral thrombosis with cerebral infarction	
434.11	Cerebral embolism with cerebral Infarction	
434.91	Cerebral artery occlusion, unspecified, with cerebral infarction	
436.xx	Ischemic stroke	

#### Hemorrhagic stroke: 1 ER or 1 inpatient claim with ICD-9-CM in the primary position of the claim

ICD-9-CM Codes	Description
430.xx	Subarachnoid hemorrhage
431.xx	Intracerebral hemorrhage
432.0-432.9	Other & unspecified intracranial hemorrhage

Coronary artery disease event: Inpatient admission with ICD-9-CM code of 410.xx for myocardial infarction in any position of the claim OR any claim with CPT or ICD-9-CM procedure code for coronary revascularization

CPT Codes	ICD-9-CM Procedure Codes
33140	00.66
92980-92982	36.0x
92984	36.1x
92985	36.2x
92986	
92995	
92996	
33510-33523	
33533-33536	
33572	

Amputation: 1 inpatient claim with an ICD-9-CM procedure code in primary position or any individual with claim for amputation CPT code

CPT Codes	ICD-9-CM Procedure Codes
27590-27598	84.1
27880	84.10-84.17
27881	
27882	
27884	
27886	
27888	
27889	
28800	
28805	
28810	
28820	
28825	

#### APPENDIX B Claims Data Identification of Complications (continued)

End-stage renal disease: Any claim coded with 1 or more of the following CPT codes		
CPT Codes		
90918-90925		
90935		
90937		
90940		
90951-90970		

Ischemic heart disease: Inpatient, 1 ER, or 2 physician E&M claims with any of the following ICD-9-CM codes in any position of the claim

ICD-9-CD Codes	Description
411.1x	Intermediate coronary syndrome
411.8x	Acute coronary occlusion without myocardial infarction
413.xx	Angina pectoris
414.0x	Coronary atherosclerosis

Congestive heart failure: 1 inpatient, 1 ER, or 1 physician E&M claim with ICD-9-CM code 428.xx in the any position of the claim

Blindness: 1 inpatient, or 1 ER or 2 physician E&M claims with ICD-9-CM code 369.xx in any position of the claim

CPT = Common Procedural Terminology; E&M = evaluation and management; ER = emergency room; ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification.

### APPENDIX C Incremental Cost Calculation

Total incremental cost in calendar year (*CY*) for each of commercial, Medicare, or Medicaid was calculated using the formula below:

 $Total(CY) = \sum_{yr} \sum_{Event} Incr(yr, Event) \times Y(CY, yr, Event)$ 

Here,

*Incr(yr, Event)* = Incremental Cost in Index Year (*yr*) and Event Type (*Event*) Per Event (2012 basis, annual)

Y(CY, yr, Event) = Number of Events in Index Year (yr) and Event Type (Event) in Calender Year (CY)

*CY* = Calender Year (2012, 2013, or 2014)

yr = Index Year (0 [(Event Year),] 1, or 2)

Event = Types of Event, which are:

IHD = ischemic heart disease

MI = myocardial infarction

HF = heart failure

Stroke

AMP = amputation

RF = renal failure

Blindness

Incremental Cost in Index Year (Incr[yr, Event]), which is per event, was calculated using the formula below:

Incr(yr, Event)

= $Cost(yr, Event ECY) \times (1 + t)^{2012-ECY-yr}-Cost(-1, Event, ECY) \times (1+t)^{2012-ECY+1}$ 

Here,

*ECY* = Calendar Year of Event in the database

*Cost* (*yr*, *Event*, *ECY*) = Average Annual Cost of Event Calendar Year (ECY), Index Year (*yr*), and Event Type (*Event*) per Event

t = Annual Cost Trend (5%)

In the case of blindness, we assumed

Cost(yr, Blindness, ECY) = Cost(0, Blindness, ECY) if yr = 1 or 2.