

# Impact of Type 2 Diabetes Medication Cost Sharing on Patient Outcomes and Health Plan Costs

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The last decade has seen a proliferation of payer-driven efforts to contain rising healthcare costs. Prescription drugs have increasingly been subject to utilization management policies, including tiered formularies and patient cost sharing for branded products. However, a large body of literature shows that increased cost sharing can have unintended consequences of patient noncompliance to prescribed medication regimens,<sup>1,7</sup> and may delay treatment initiation in patients newly diagnosed with chronic illness, including diabetes, hypertension, high cholesterol, and multiple sclerosis.<sup>8,9</sup> This has prompted concern that increased cost sharing may worsen outcomes for patients.<sup>10-12</sup>

If high cost sharing worsens patient medication adherence, it could lead to costly complications that partially or completely offset payers' pharmacy savings. For example, a study of patients with high cholesterol suggested that higher cost sharing reduced drug adherence and worsened outcomes for patients at high risk of complications, subsequently increasing overall costs.<sup>13</sup> However, the relationships between cost sharing, medication adherence, and outcomes are sensitive to drug class and patient condition.<sup>4,5</sup> More disease-specific estimates on the implications of cost sharing for patient outcomes and plan-spending are needed.<sup>6,14</sup> In particular, in the case of diabetes, there have been a number of innovations over the past 10 years, and more information is needed on whether the relationship between cost sharing, adherence, and outcomes has changed as a result.

Disruptions to therapy caused by high cost sharing can be particularly harmful for patients with diabetes. Successful blood glucose control in patients with diabetes substantially decreases the risk of numerous complications, including cardiovascular disease (CVD), end-stage renal disease, stroke, retinopathy, and death.<sup>15</sup> Diabetes affects 29.1 million Americans, costs the US healthcare system \$245 billion annually (2012 data), and is projected to increase dramatically over the next 40 years.<sup>16-18</sup> Type 2 diabetes (T2D), which repre-

## ABSTRACT

**Objectives:** To study the association between cost sharing for diabetes medications, adherence, hospitalization rates, and healthcare costs, with relationship to patient risk.

**Study Design:** A retrospective claims analysis of data from 35 large, private, self-insured employers (2004 to 2012).

**Methods:** We examined outcomes for 92,410 patients aged 18 to 64 years with a type 2 diabetes (T2D) diagnosis who filled at least 1 T2D prescription. First, we examined the relationship between adherence, measured as the proportion of days covered, and cost sharing, measured as the out-of-pocket cost to purchase a pre-specified bundle of T2D prescriptions. We then examined the association between adherence and hospital days. Simulations showed the effect of increased cost sharing on adherence and inpatient utilization.

**Results:** A \$10 increase in out-of-pocket cost was associated with a 1.9% reduction in adherence ( $P < .01$ ). In turn, a 10% reduction in adherence was associated with a 15% increase in per-patient hospital days (0.17 days;  $P < .01$ ). For the average plan, switching from low to high cost sharing reduced per-patient medication costs by \$242 and increased per-patient hospitalization costs by \$342, for a net increase of \$100 in plan costs. Increases in per-patient costs were greater for high-risk patients, such as those with heart failure (\$1328).

**Conclusions:** Increased cost sharing for T2D medication was associated with reductions in pharmacy costs, but higher total costs for patients with T2D. This problem is particularly acute for patients with 1 or more cardiovascular comorbidities. The results suggest that increased diabetes cost sharing may hamper efforts to lower the total cost of diabetes care.

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### Take-Away Points

This study investigated the association between cost sharing for type 2 diabetes (T2D) medications and patient outcomes, including medication adherence, hospitalizations, and healthcare costs to payers. Increasing patient out-of-pocket costs decreased patient medication adherence, and poorer medication adherence resulted in increased days spent in the hospital. The long-term hospitalization costs associated with lower adherence were greater than the health plan's prescription drug cost-savings, particularly for high-risk patients. Decreasing out-of-pocket expenses may actually decrease long-term T2D-related costs for payers.

- Higher levels of cost sharing are associated with lower levels of adherence to T2D medications.
- Reduced adherence to T2D medications is associated with an increased number of days spent in hospital.
- Although higher cost sharing reduces T2D drug costs, it raises hospitalization costs and, overall, increases costs to the plan.
- High cost sharing has particularly adverse consequences in high-risk populations, such as those with heart failure or prior myocardial infarction, in terms of patient health and plan costs.

sents 90% to 95% of adult diabetes cases,<sup>16</sup> is a progressive disease, and requires most patients to eventually use drug therapy to achieve blood glucose control.<sup>19</sup> Although antihyperglycemic drugs can effectively control blood glucose levels, research indicates that these drugs are underutilized, with studies finding the percent adherent to T2D medications ranges from 31% to 87%, with sizable groups of nonadherent patients in many populations.<sup>7,20,21</sup>

Given the launch of new classes of antihyperglycemics in a healthcare system increasingly concerned with budget constraints, our study updates past work on cost sharing in diabetes<sup>1,4</sup> in light of the new landscape. Moreover, given that past studies have found that increased cost sharing for diabetes medications may lead to complications which offset the pharmacy cost savings,<sup>1,4</sup> one might wonder whether payers have changed benefit designs such that these offsets are no longer present. To answer these questions, we measured associations between cost sharing of T2D-related medications, patient adherence, and total costs for health plans. To do this, we used retrospective data on medication use, healthcare utilization, and spending among privately insured patients with T2D to simulate the per-patient healthcare spending associated with low-cost (\$10 co-payment) and high-cost (\$50 co-payment) pharmacy plans.

## METHODS

A retrospective cohort design was used to analyze the associations among cost sharing, medication adherence, and per-patient all-cause hospital days. Combining these analyses, it was possible to link cost sharing to hospitalization and estimate the impact of cost sharing on plan costs. Additional detail can be found in the [eAppendix](#) (available at [www.ajmc.com](http://www.ajmc.com)).

### Sample

The study sample was assembled using a longitudinal database of medical and pharmacy claims from 2004 to 2012 from 35 self-insured employers. The data set was constructed at the person-year level to reflect a person's experience in a specific health plan.

Patients with T2D were identified for the study based on 1 or more inpatient or ambulatory visit with a T2D diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes 250.x0 or 250.x2). To create a working-age sample and exclude patients also covered by Medicare—for whom the claim history

may be incomplete—the sample was restricted to patients aged 18 to 64 years at baseline. To ensure sufficient follow-up for analysis, patients were required to have had continuous health plan and pharmacy benefit enrollment during the first observed year with a T2D diagnosis, and for at least 1 year afterward.

Patients excluded from the study included those with less than 1 year of follow-up, those pregnant, and those with gestational diabetes. Additionally, patients using an insulin pump were excluded due to the difficulty in measuring adherence in claims data; however, patients using insulin, not on a pump device, were included. Because this study examined adherence to T2D medications, person-year data were retained only for years in which the patient filled 1 or more T2D prescriptions. Data from the first year with a T2D diagnosis were excluded because the patient may not have had T2D for the entire year. Finally, we excluded outlier patient data in terms of cost sharing and hospital days, as well as patients in small plans (<10 total enrollees with T2D). Additional details on outlier exclusions are available in the eAppendix.

### Measures

Data were collected for the following covariates: patient age, gender, indicators for each of the Charlson comorbidities<sup>22</sup> during the previous year, medical cost sharing faced by the patient in the given year, and indicators for each year in the study period.<sup>4,6,8</sup> Medical cost sharing was defined as the average portion of medical (ie, inpatient, outpatient, and emergency department) services that individuals in a given plan paid out of pocket (OOP).

The key explanatory variable was cost sharing for T2D medications, measured as the average patient OOP cost of purchasing a T2D drug prescription in a given plan.

Specifically, the OOP costs to obtain a fixed bundle of T2D prescriptions were averaged across the individuals in a plan, and the result was divided by the number of drugs in the bundle to obtain the average OOP cost per T2D prescription. Total T2D drug costs were defined as the total amount the plan and patient spent on T2D drugs in a given year.

The key outcome measures were patient medication adherence and number of hospital days. Adherence was measured as the proportion of days covered (PDC) (ie, the fraction of days in the year in which the patient had a supply of at least 1 T2D medication on hand). For example, a PDC of 0.75 indicates that a patient had T2D medications on hand for about 9 months of the year. PDC was selected over another common adherence measure—the medication possession ratio—which has a tendency to overestimate adherence. Hospital days were defined as the number of days an individual spent in hospital in a given year. Hospital stays in which a patient was admitted and discharged in a single day were counted as a full day.

### Statistical Analysis

Linear regression models were used to estimate the relationship between cost sharing, adherence and hospital days at the patient-year level. First, adherence was estimated as a function of drug cost sharing, then days in hospital were estimated as a function of adherence. Adjusted analyses controlled for age, gender, each of the Charlson comorbidities, and the year (to absorb time trends). Because patient adherence to T2D medications may also depend on OOP spending for other healthcare services, the analysis of adherence, as a function of T2D medication cost sharing, also controlled for medical cost sharing.

We used these estimates in a 2-step process to predict total plan costs (ie, plans' drug plus hospitalization costs) at high and low levels of T2D drug cost sharing. Low cost sharing and high cost sharing were defined as an average OOP cost per T2D prescription of \$10 and \$50, which approximately corresponded to the 10th and 90th percentiles of cost sharing, respectively. Regression models were used to predict adherence and hospital days at the low and high cost-sharing levels, holding covariates at their mean values. Payer hospitalization cost was determined by multiplying the predicted number of days in hospital by the average payer cost of a hospital day. Costs were inflated to 2012 US dollars using the Consumer Price Index for All Urban Consumers. By combining the analyses linking cost sharing to adherence and adherence to days in hospital, we predicted the plan's T2D drug costs and hospital costs at high and low cost-sharing levels, and es-

timated how total plan cost would vary with cost sharing.

These predictions were performed for several scenarios. The base case used the full study sample. Subsequent analyses were performed on subsamples defined by patient risk: specifically, the presence of CVD, congestive heart failure (CHF), prior myocardial infarction (MI), renal disease, or prior hospitalization. Additional subsamples included lower-risk patients, including those in none of the above risk groups, and those with no comorbidities. Finally, because our plan-level cost-sharing measure was potentially subject to measurement error in smaller plans, the analyses were repeated based on plan size subsamples. Our base-case analysis included all T2D patients in plans with 10 or more patients with T2D that year; subanalyses also examined plans with greater than 20, 50, 100, and 500 patients with T2D.

## RESULTS

### Descriptive Statistics

From more than 7 million covered lives in the database, 727,476 had at least 1 claim with a T2D diagnosis. After applying exclusion criteria, 92,410 patients from 1514 health-care plans were eligible for study inclusion. Plans had an average of 8776 members and 144 patients with T2D in the study cohort. **Table 1** shows the personal characteristics of patients included in the study overall, as well as those in low and high cost-sharing plans (defined by the 10th and 90th percentiles of cost sharing). The sample was mostly male (56.1%), aged between 50 to 64 years (71.4%), and had an average of 1.17 Charlson comorbidities at baseline.

The mean annual per patient OOP amount for T2D drugs was \$242 (SD = \$337) and the mean OOP amount per individual T2D prescription was \$22.70 (SD = \$16.70). Only 10% of patients had an average OOP per T2D prescription cost exceeding \$54, and 10% had an average OOP cost below \$11.

The average adherence to T2D medications, measured as PDC, was 67% (SD = 29.1%). Patients with T2D spent an average of 1.15 (SD = 7.70) days in hospital each year. In a given year, 1 in 6 (16.6%) patients with T2D was hospitalized. Adherence in the sample ranged from 0.27% to 100%. (No one had a zero PDC because individuals were required to fill  $\geq 1$  prescription for cohort inclusion.) Individuals in low cost-sharing plans had an average adherence of 69%, whereas in high cost-sharing plans, the average adherence was 63%.

Compared with their counterparts in low cost-sharing plans, individuals in high cost-sharing plans generally tended to be younger (average age of 50.8 vs 53.2 years) and healthier (eg, fewer comorbidities, fewer days in hospital), consistent with past research.<sup>23</sup> This suggests that

■ **Table 1.** Descriptive Statistics<sup>a,b</sup>

Variable	Full Sample (N = 92,410)		Low Cost Sharing	High Cost Sharing
<b>Demographics (binary)</b>	<b>N</b>	<b>%</b>	<b>%</b>	<b>%</b>
Gender				
Male	51,849	56.1	55.4	60.6
Female	40,561	43.9	44.6	39.4
<b>Demographics (continuous)</b>	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>Mean</b>
Age, years	52.5	7.61	53.2	50.8
Baseline Charlson Comorbidity Index count	1.17	0.50	1.18	1.14
<b>Healthcare expenditures (per patient)</b>	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>Mean</b>
Annual out-of-pocket amount for diabetes drugs	\$242	\$337	\$118	\$564
Annual total paid amount for diabetes drugs	\$1330	\$1568	\$1280	\$1460
Annual out-of-pocket amount for inpatient services	\$904	\$13,713	\$1102	\$385
Annual total paid amount for inpatient services	\$5362	\$43,178	\$5864	\$4049
<b>Diabetes prescription drug usage and cost sharing</b>	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>Mean</b>
Out-of-pocket payment per diabetes Rx	\$22.7	\$16.7	\$10.6	\$54.4
Adherence (proportion of days covered)	67%	29.1%	69%	63%
Medical cost sharing (out-of-pocket amount for medical services)	21.3%	12.6%	22.9%	17.1%
<b>Hospitalization</b>	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>Mean</b>
Days in hospital (per patient per year)	1.15	7.70	1.32	0.721

<sup>a</sup>Patients had an inpatient claim in a given year as follows: 16.6% of patients in the full sample, 18.2% of patients in low cost-sharing plans, and 12.6% of patients in high cost-sharing plans.

<sup>b</sup>Low cost sharing and high cost sharing are defined as the 10th and 90th percentiles of cost sharing for T2D medications, respectively. Values for patients with low and high cost sharing are predicted values from a regression of the given variable on cost sharing, evaluated at the 10th and 90th percentiles of cost sharing.

any negative effects of cost sharing could be understated in our analysis due to selection of healthier patients to less generous plans.

### Unadjusted Linear Regression

Analysis **Figure 1** illustrates the negative association between cost sharing and adherence for T2D prescription drug therapy. The figure, which reports the unadjusted average co-payment per prescription to the average medication adherence per plan, shows that a \$10 increase in the OOP cost of T2D drugs was associated with 1.6 percentage points lower medication adherence ( $P < .01$ ). The average PDC in the plan was 67%, which means a \$10 increase in OOP costs is associated with a  $-2.4\%$  change in adherence (or 1.6 percentage points out of 67).

### Adjusted Linear Regression Analyses

**Cost sharing and adherence.** Although **Figure 1** shows a negative relationship between adherence and cost sharing, it does not account for differences across patients within the plan. After adjusting for observed patient characteristics, the negative relationship between cost sharing for T2D prescriptions and adherence to T2D drug therapy persisted. Based on the regression, a \$10 increase in the OOP cost of T2D drugs was associated with a lower PDC of 1.3 percentage points ( $P < .01$ ), or a  $-1.94\%$  change in drug adherence for a plan with the average PDC of 67% (or 1.3 percentage points out of 67).

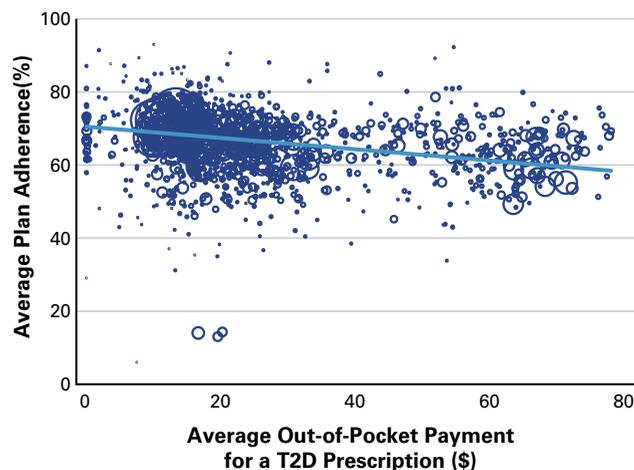
**Adherence and all-cause hospitalization.** Increased adherence was associated with reduced all-cause hospital days. Each 10% point increase in adherence was associated with a 0.17-day reduction in the number of days a patient was expected to spend in hospital annually ( $P < .01$ ) (**Figure 2**). For a plan with 100,000 members with T2D, this equates to a reduction of 17,000 patient-days in hospital annually. This represented a 14.8% decrease in the mean 1.15 hospital days per patient, per year.

**Cost sharing and per-person plan costs.** Increased cost sharing for T2D drugs was associated with increased payer hospitalization costs. Raising the average OOP cost per T2D prescription from \$10 to \$50 was associated with a \$242 reduction in per-person payer costs for T2D prescriptions and an increase of \$342 per person of payer hospitalization costs, as shown in **Figure 3**.

**Impact of increased cost sharing by risk group and plan size.** As shown in **Table 2**, increased cost sharing was associated with higher total plan costs across a variety of plan sizes and patient populations. Increasing the average OOP payment per T2D prescription from \$10 to \$50 resulted in increased overall payer costs (combined drug and hospitalization costs) for all high-risk and 1 of 2 low-risk patient populations. The largest increase in plan costs was for patients with T2D and CHF (\$1328 per patient, per year). The only patient risk group for which increased cost sharing did not increase overall plan costs was patients with no comorbidities other than diabetes.

Although plans of all sizes experienced increased overall payer costs, the plan impact of increased cost sharing

**Figure 1.** Association Between Cost Sharing for Diabetes Prescriptions and Adherence to Diabetes Prescription Drug Therapy<sup>a,b</sup>



T2D indicates type 2 diabetes.

<sup>a</sup>These results show the raw correlation in the data for 1514 plans with more than 10 patients with T2D.

<sup>b</sup>Adherence is measured using the proportion of days covered (PDC); mean PDC is 67%.

Smaller bubbles correspond to smaller plans, with the smallest bubbles representing plans with 11 patients with diabetes. Larger bubbles represent larger plans.

was highest in the largest plans. Among plans with more than 500 members with T2D, increased cost sharing was associated with a \$169 increase in per-person plan costs compared with \$100 in plans with 10 or more members with T2D. This means that for a plan with 1 million covered lives and 150,000 members with T2D (assuming 15% prevalence), increasing cost sharing would raise plan costs by \$25 million annually.

## DISCUSSION

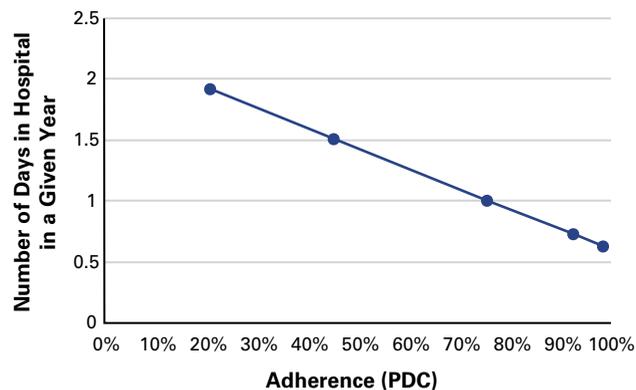
Efforts to contain healthcare costs have led payers to shift the disease management burden to patients through increased prescription drug cost sharing. In this study, we estimated how increased cost sharing affected medication adherence, hospital days, and total per-patient health plan costs for patients with T2D using claims data. We found that each \$10 increase in patient OOP cost was associated with a 1.6 percentage point decrease in adherence (2.4%;  $P < .01$ ); moreover, a 10% reduction in adherence was associated with 15% higher per-patient hospital days. Combining these results, we found that for the average plan, switching from low to high cost sharing would potentially reduce plan per-patient medication costs by \$242 and increase plan per-patient hospitalization costs by \$342, for a net increase in plan cost of \$100. Thus, although higher

cost sharing reduces T2D drug costs to the plan, it may raise hospitalization costs by a greater amount, more than offsetting the savings. For a plan with 150,000 members with T2D, this could amount to an increase of \$25 million in annual plan costs.

High cost sharing has particularly adverse consequences for patient outcomes and plan costs in certain high-risk populations (eg, patients with various comorbidities and/or prior hospitalizations) in our model. In particular, high cost sharing among patients with CHF, CVD, and prior MI led to simulated large increases in per-patient, annual hospitalization costs, at \$1794, \$1220, and \$632, respectively. These costs far outweighed any per-person savings associated with medication cost sharing, at \$466, \$272, and \$149, respectively. Likewise, healthcare plans with more than 500 patients with T2D experienced the highest increase in per-person annual hospitalization costs, at \$550—which was higher than per-person cost savings associated with medication cost sharing, at \$381. On the other hand, for the healthiest patients with no comorbidities during the study period, cost sharing on diabetes medication resulted in modest cost savings. However, the relationship between cost sharing and adherence was consistent across the high-risk and low-risk groups, so it is unclear whether these savings would persist over longer time periods if patients failed to adhere to their medications and their diabetes worsened or led to complications. This should be considered in future work.

These findings are consistent with prior work demonstrating that cost sharing worsens patient medication ad-

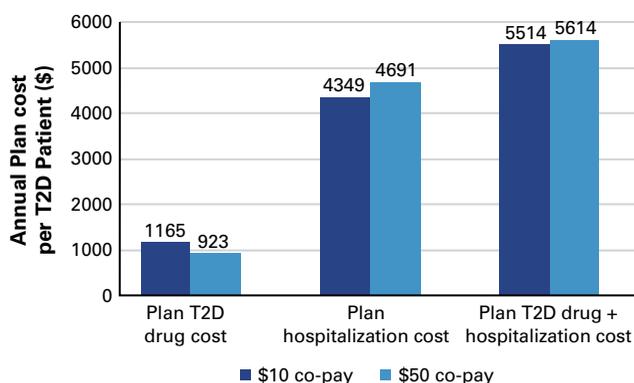
**Figure 2.** Adherence and Number of Days in the Hospital<sup>a</sup>



PDC indicates proportion of days covered.

<sup>a</sup>Results are predicted values from a patient year-level regression of days in hospital on adherence, controlling for patient age, sex, Charlson comorbidities, and medical cost sharing in the patient's plan and year. Each 10% point increase in adherence was associated with a 0.17 day reduction in the number of days a patient was expected to spend in hospital annually ( $P < .01$ ).

**Figure 3.** Relationship Between Plan Costs and Diabetes Prescription Cost Sharing



T2D indicates type 2 diabetes.

herence, resulting in costly complications. For example, previous studies have shown that patient cost sharing leads to decreased medication adherence and can compromise health in patients with T2D and other chronic conditions.<sup>1,4,7,24</sup> Results such as these led the Congressional Budget Office to change its scoring system, such that every 10% increase in prescription medication use reduces estimated medical costs by 2%.<sup>25</sup> This study confirms these findings

and further demonstrates that decreasing cost sharing for patients with T2D may be advantageous for payers. Specifically, lower patient OOP expenses for T2D medications may improve access and adherence, leading to improved long-term patient outcomes and decreased overall costs.<sup>6</sup> On the other hand, increased medication cost sharing may decrease adherence and associated total payer costs.<sup>26</sup>

These findings demonstrate the importance of a comprehensive approach to benefit design incorporating costs, value, and patient outcomes. As T2D prevalence increases in the United States, the cost burden of T2D care will increase for payers,<sup>18</sup> stimulating further efficiencies in healthcare delivery systems. As plans experiment with cost sharing and tiered prescription plan designs to lower payer costs, some patients may face substantial, and sometimes prohibitive, OOP costs.<sup>9,27</sup> Plans may also sort newer T2D therapies into higher cost-sharing tiers, with possible consequences for drug initiation and adherence, as well as overall plan costs.<sup>9</sup> Our findings suggest that, rather than imposing policies that limit or disrupt T2D care, payers may see greater benefit from policies that carefully consider cost sharing and adherence promotion. More generally, formulary policy, like all aspects of healthcare delivery, should be designed to encourage the

**Table 2.** Adherence, Cost, and Hospitalization Impact of Increasing the Average Out-of-Pocket Payment per Diabetes Prescription From \$10 to \$50 by Risk Group and Plan Size<sup>a</sup>

Sample	Adherence (PDC), %	Plan Diabetes Drug Costs, \$	Plan Hospitalization Costs, \$	Plan Drug + Hospitalization Costs, \$
All	-5.32	-242	342	100
High-risk groups				
CVD <sup>b</sup>	-5.52	-272	1220	949
CHF	-5.72	-466	1794	1328
Prior MI	-5.00	-149	632	482
Renal disease	-0.62	-31	223	192
Prior hospitalization	-3.58	-204	659	455
Low-risk groups				
No CVD, no CHF, no prior MI, no renal disease, no prior hospitalization	-5.61	-242	268	26
No Charlson comorbidities except diabetes	-5.32	-241	195	-46
By plan size				
More than 10 patients <sup>c</sup>	-5.32	-242	342	100
More than 20 patients	-5.32	-245	341	96
More than 50 patients	-5.44	-266	352	86
More than 100 patients	-5.68	-281	377	96
More than 500 patients	-7.16	-381	550	169

CHF indicates congestive heart failure; CVD, cardiovascular disease; MI, myocardial infarction; PDC, proportion of days covered.

<sup>a</sup>Plan size categories are not mutually exclusive. For example, a plan with >100 patients with type 2 diabetes (T2D) also has >50 patients with T2D.

<sup>b</sup>CVD includes myocardial infarction, CHF, peripheral vascular disease, and cerebrovascular disease.

<sup>c</sup>Number of patients with T2D.

use of services that foster quality, improve outcomes, and offer the most value to patients and society.<sup>26</sup>

### Limitations

Our study had several limitations. The data were limited to patients aged 18 to 64 years; therefore, findings in other patient populations are uncertain. Second, we focused on the impact on patients receiving T2D medications, not the complications or costs related to the delay of treatment initiation from increased cost sharing. This is particularly salient in T2D care, where early treatment initiation has been associated with improved long-term patient outcomes. Third, we examined 5 high-risk and 2 low-risk groups of patients; future research should explore additional patient risk groups and ideally, incorporate important clinical benchmarks unavailable in our claims data (eg, glycated hemoglobin). Also of interest for future work is the potential interaction of cost sharing with personal characteristics. Fourth, we included costs for both generic and branded drugs, whereas OOP costs and the impact of cost sharing may be higher among branded drugs. Future research should investigate whether the effects of cost sharing change with greater generic entry.

Lastly, the methods employed in this study show associations but do not prove causality. For example, patients with prior hospitalization are more likely to be hospitalized again in the future. If they are also more likely to discontinue their T2D medication, this would falsely suggest a negative correlation between adherence and hospitalization. However, because the relationships among cost sharing, adherence, and hospitalization are identified based on differences in cost sharing across plans, this mitigates this potential bias. Plan populations will generally be more homogeneous than individual patients, and many employers offer only 1 pharmacy benefit, thereby reducing the possibility of selection bias. Moreover, experimental data have shown a negative relationship between cost sharing and utilization,<sup>28-30</sup> consistent with the link we found between higher cost sharing and reduced adherence.

### CONCLUSIONS

The cost of healthcare in the United States is putting pressure on health plans to trim spending. However, this claims-based data analysis illustrates that in the case of T2D, high medication cost sharing may be counterproductive, associated with decreased medication adherence. Poor adherence counteracts drug costs savings, increasing hospital costs, and leading to a higher cost burden for plans. This is even more relevant for patients with comorbidities or a

history of hospitalization. Rather than increasing OOP spending for patients with T2D, plans should consider other policy options, such as value-based care, which may reduce cost sharing for certain T2D medications.

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**Authorship Information:** Concept and design (JL, JTS, SS, DG, YW, SM); acquisition of data (JTS, DG); analysis and interpretation of data (JL, JTS, SS, YW, SM); drafting of the manuscript (JTS, SS, YW); critical revision of the manuscript for important intellectual content (JL, JTS, SS, DG, YW, SM); statistical analysis (JTS, SS, YW); obtaining funding (JL, DG, SM); administrative, technical, or logistic support (JL, SM); and supervision (JL, JTS, DG, SM).

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## eAppendix

This eAppendix provides additional detail on the study methods beyond that which was provided in the main study text. First, information on type 2 diabetes (T2D) diagnosis codes and drugs is given. Second, additional detail on the construction of the study cohort is provided. Third, a schematic of the study approach is given. Fourth, additional detail is provided on key study variables, namely, cost sharing, adherence, and days in hospital. Fifth, additional results figures are provided.

The following diagnosis codes were used in the construction of the study sample.

**Table A1.** Diagnosis Codes Used

<b>Condition</b>	<b>ICD-9-CM Diagnosis Codes<sup>a</sup></b>
Type 2 diabetes (T2D)	250.x0 or 250.x2
Pregnancy	630-79, V22 or V23, V28.x, V61.6, V61.7
Gestational diabetes	648.83
Use of insulin pump	V45.85, V53.91, V65.46, and 996.57

*ICD-9-CM* indicates *International Classification of Diseases, Ninth Revision, Clinical Modification*; T2D, type 2 diabetes.

<sup>a</sup>*ICD-9-CM* diagnosis codes 250.x0 or 250.x2.

The following table lists the T2D medications considered when defining cost sharing and adherence for this study.

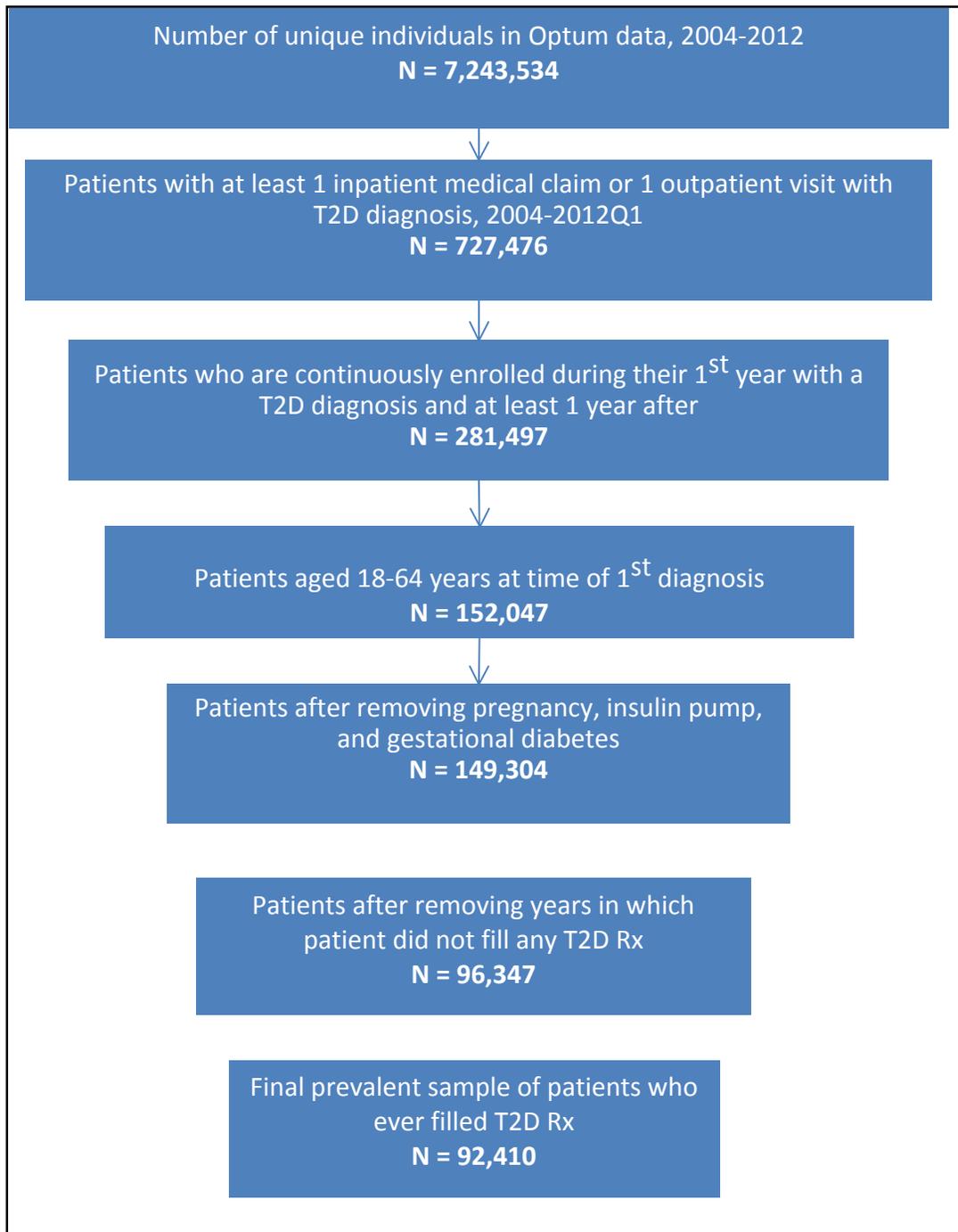
**Table A2.** List of Diabetes Medications, by Therapy Class and Active Ingredients

<b>Therapy Class</b>	<b>Active Ingredients</b>
Alpha glucosidase inhibitor	Acarbose; miglitol
Amylinomimetic	Pramlintide acetate
Biguanide	Metformin
Biguanides and meglitinides, combination	Metformin and repaglinide
Biguanides and sulfonylureas, combination	Metformin and glipizide; glyburide and metformin
Bile acid sequestrant	Colesevelam hydrochloride
DPP-4 inhibitor	Alogliptin; linagliptin; saxagliptin; sitagliptin
DPP-4 inhibitor and biguanides, combination	Sitagliptin and metformin; linagliptin and metformin; alogliptin and metformin
DPP-4 inhibitor and HMG-CoA reductase inhibitor (statin), combination	Sitagliptin and simvastatin
GLP-1 agonist	Liraglutide; exenatide
Intermediate acting insulin	Neutral Protamine Hagedorn (NPH: Humulin N, Novolin N)
Long acting insulin	Insulin detemir; insulin glargine
Meglitinide	Nateglinide; repaglinide
Pre-mixed insulin	50% insulin lispro protamine and 50% insulin lispro; 75% insulin lispro protamine and 25% insulin lispro; 70% NPH and 30% insulin regular
Rapid acting insulin	Insulin glulisine; insulin aspart
Regular or short acting insulin	Humulin R, Novolin R
Sodium-glucose 2 transporter inhibitor	Canagliflozin; dapagliflozin
Sulfonylurea	Chlorpropamide; glimepiride; glipizide glyburide; tolazamide; tolbutamide
Thiazolidinedione	Rosiglitazone; pioglitazone
Thiazolidinedione and biguanide combination	Rosiglitazone and metformin; pioglitazone and metformin
Thiazolidinedione and sulfonylurea combination	Rosiglitazone and glimepiride

DPP-4 indicates dipeptidyl-peptidase 4; GLP-1, glucagon-like peptide-1; HMG-CoA, 3-hydroxy-3-methylglutaryl-coenzyme A; NPH, neutral protamine hagedorn; T2D, type 2 diabetes;

The diagram below outlines the sample size at each stage of the construction of the study cohort.

**Figure A1.** Optum Database Sample Construction



T2D indicates type 2 diabetes.

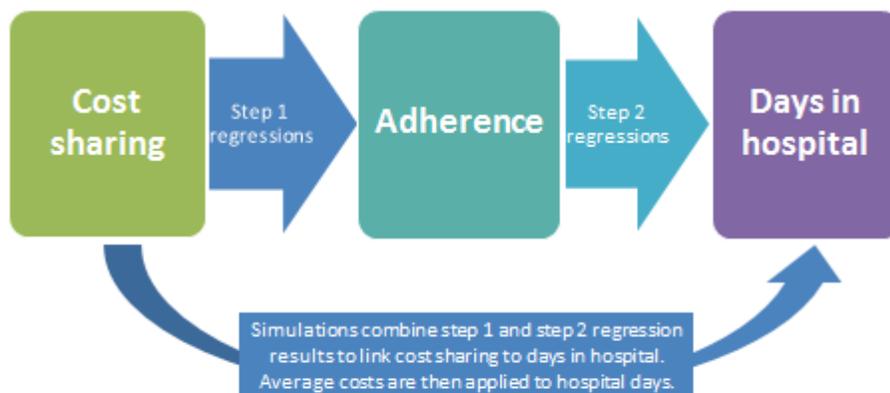
## Description of Outliers Excluded From Study Sample

In order to remove outliers, 3937 patients (4%) were excluded from the study sample according to the following criteria:

- person-years in which the patient was in a small plan (fewer than 10 enrollees with T2D),
- patients in a plan which reported that more than 100% of medical costs were paid out of pocket (OOP),
- person-years in which the patient had more than \$1 million in OOP drug costs,
- person-years in which the patient spent more than 300 days in the hospital, and
- person-years in which the patient's plan had extremely high cost sharing (greater than the top 1% of the sample).

A diagram of the study schematic is below. This diagram shows how regression results from steps 1 and 2 are combined in the simulations in order to link cost-sharing to days in hospital.

**Figure A2.** Study Schematic



## **Construction of Cost-Sharing Measure**

The key explanatory variable was drug cost-sharing, which was measured for every plan based on observed OOP diabetes medication costs for plan participants. To accomplish this, a bundle of diabetes medications weighted by actual usage rates was created based on observed treatment patterns. For example, if there were 10 type 2 diabetes (T2D) patients across all plans in a given year and 80 metformin prescriptions and 20 glipizide prescriptions were observed for the 10 patients, that year's bundle would comprise 8 metformin prescriptions and 2 glipizide prescriptions per patient. This cost-sharing measure represents a given plan's average OOP cost to purchase the bundle. This approach to developing a cost-sharing measure has been used in previous studies.<sup>1,2,3</sup> For ease of interpretation, we normalized the cost-sharing measure by dividing it by the number of diabetes prescriptions in the bundle, resulting in an average OOP cost of a diabetes prescription in a given plan. Prescriptions represented a 30-day supply. A mail-order prescription (ie, a 90-day supply) was counted as three 30-day prescriptions.

In presenting the average OOP costs, low and high cost-sharing OOP payments were defined as \$10 and \$50. These values approximately correspond to the 10th and 90th percentiles of cost-sharing values that patients face, or OOP costs of \$11 and \$54 per prescription, respectively.

## **Measurement of Adherence**

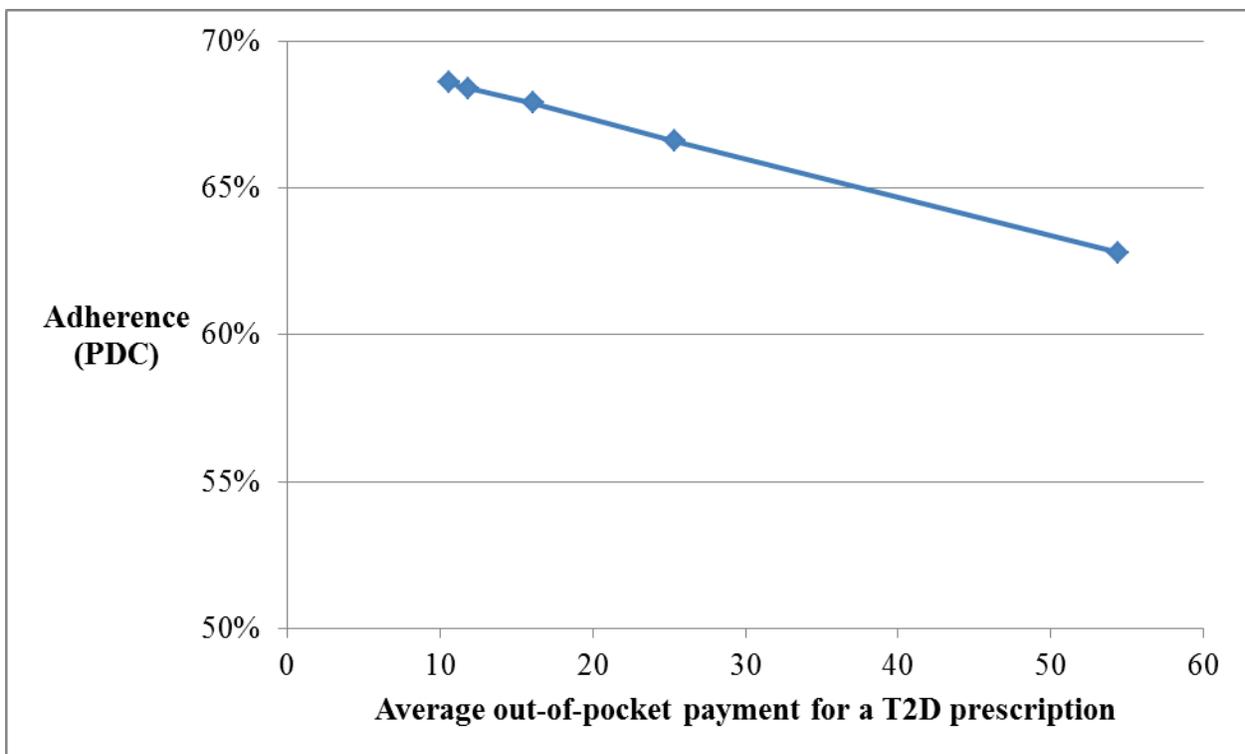
Adherence was measured as the proportion of days covered (PDC), which measures the fraction of days in the year in which the patient had a supply of diabetes medication on hand. PDC was selected over another common adherence measure, the medication possession ratio (MPR), because unlike the MPR, the PDC does not tend to overestimate adherence. The MPR may be >1 when a patient switches medications (and hence temporarily has a double supply on hand) or when a patient takes >1 diabetes medication (eg, metformin and sulfonylureas). By construction, the PDC is never >1, and therefore does not have this shortcoming.

### Measurement of Days in Hospital

Hospital days were defined as the number of days an individual spent in the hospital in a given year. Hospital stays in which a patient was admitted and discharged in a single day were counted as a full day.

The 2 figures below illustrate the relationship between cost sharing and adherence among all T2D patients and those with comorbid cardiovascular disease.

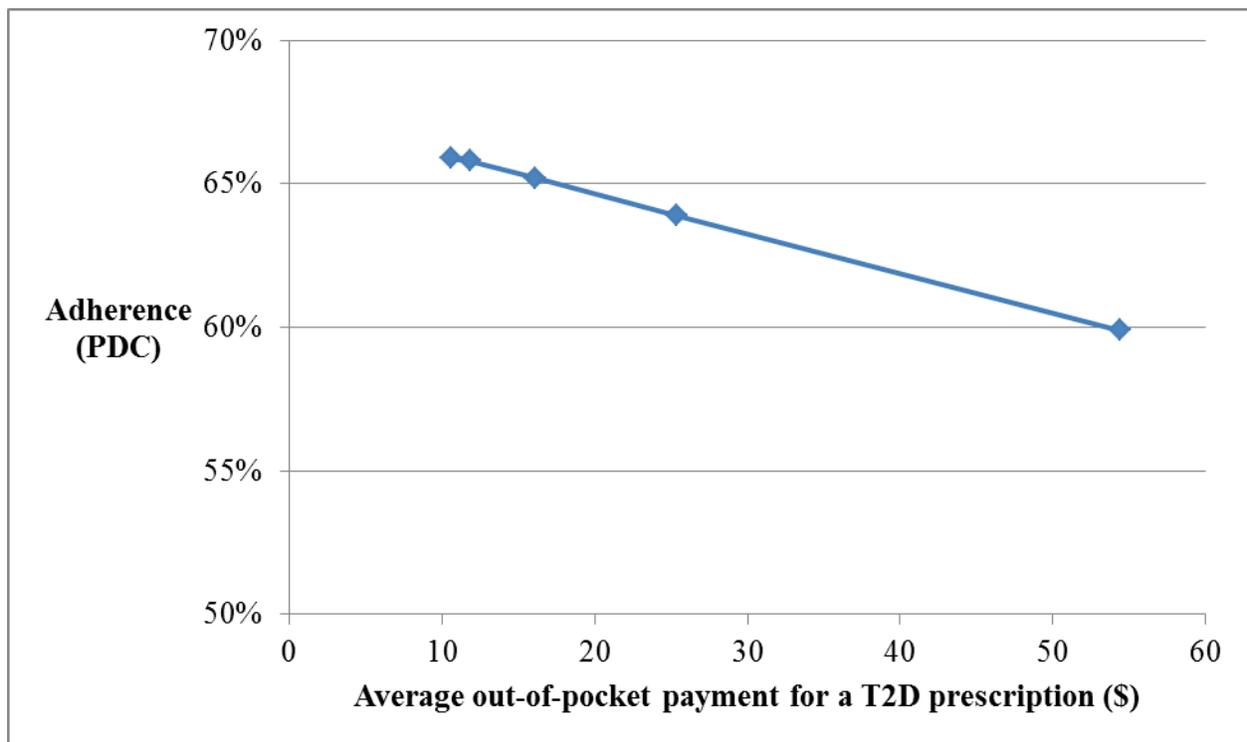
**Figure A3.** Average Out-of-Pocket Payments for T2D Medications and Adherence



PDC indicates proportion of days covered; T2D, type 2 diabetes.

Each \$10 increase in cost sharing is associated with a 1.3 percentage point reduction in adherence, after adjustment for covariates ( $P < .01$ ). Results are predicted values from a patient-year-level regression of adherence on cost sharing, controlling for patient age, sex, Charlson comorbidities, and medical cost sharing in patient's plan and year.

**Figure A4.** Average Out-of-Pocket Payment for T2D Prescriptions and Adherence for Patients With Cardiovascular Disease



PDC indicates proportion of days covered; T2D, type 2 diabetes.

Each \$10 increase in cost sharing is associated with a 1.4 percentage point reduction in adherence, after adjustment for covariates ( $P < .01$ ). Results are predicted values from a patient-year-level regression of adherence on cost sharing, controlling for patient age, sex, Charlson comorbidities, and medical cost sharing in patient's plan and year.

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