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Simulated Value-Based Insurance Design Applied to Statin Use by Medicare Beneficiaries with Diabetes

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ABSTRACT

Objective: To examine cost responsiveness and total costs associated with a simulated "value-based" insurance design for statin therapy in a Medicare population with diabetes. **Methods:** Four-year panels were constructed from the 1997-2005 Medicare Current Beneficiary Survey selected by self-report or claims-based diagnoses of diabetes in year 1 and use of statins in year 2 (N = 899). We computed the number of 30-day statin prescription fills, out-of-pocket and third-party drug costs, and Medicare Part A and Part B spending. Multivariate ordinary least squares regression models predicted statin fills as a function of out-of-pocket costs, and a generalized linear model with log link predicted Medicare spending as a function of number of fills, controlling for baseline characteristics. Estimated coefficients were used to simulate changes in fills associated with co-payment caps from $25 to $1 and to compute changes in third-party payments and Medicare cost offsets associated with incremental fills. Analyses were stratified by patient cardiovascular event risk. **Results:** A simulated out-of-pocket price of $25 [$1] increased plan drug spending by $340 [$794] and generated Medicare Part A/B savings of $262 [$531]; savings for high-risk patients were $558 [$1193], generating a net saving of $249 [$415]. **Conclusions:** Reducing statin co-payments for Medicare beneficiaries with diabetes resulted in modestly increased use and reduced medical spending. The value-based insurance design simulation strategy met financial feasibility criteria but only for higher-risk patients.

Keywords: cost offsets, diabetes, Medicare, medication adherence.

Introduction

Value-based insurance designs (VBID) have been proposed as a means of slowing the dramatic rise in health care spending associated with the treatment of chronic health conditions [1,2]. VBID incorporates financial incentives into prescription drug or other insurance benefits to encourage the initiation of, and adherence to, prevention and treatment regimens for which higher utilization levels are expected to yield clinical benefits that will, in turn, generate downstream savings in the medical care budget. The types of financial incentives that have been suggested include the reduction or complete elimination of cost-sharing, as well as incentives or rewards for high levels of adherence [3].

Evaluating the success of a VBID strategy depends on the perspective taken in the analysis. The societal perspective focuses on the net change in total spending associated with changes in both medication use and spending on other medical care. It may also incorporate the value of any incremental survival or improvement in quality of life associated with increased medication use. However, given that most health insurance is provided through either private markets or public programs with budget constraints, it may be more useful to consider the perspective of the third-party payer. This perspective limits the focus to direct spending and in particular spending by the payer.

Figure 1 illustrates the hypothetical process through which VBID functions. Starting in the upper right, the application of VBID reduces patient cost-sharing for the targeted medication, shifting more of the payment to the third-party payer. Assuming price responsiveness, this reduced out-of-pocket (OOP) price will increase medication use at the margin (upper left). The combination of increased medication use and increased share of payment for all medications (not just the marginal medication use) results in a net increase in third-party spending on medications (lower left). With appropriate targeting, the increased use of medications is presumed to improve health status and reduce the need for medical care services and spending. If the savings in medical spending to third parties are larger than the increase in spending on medications, then VBID is a desirable strategy.

The success of a VBID strategy depends on the magnitude of two key relationships—the behavioral responsiveness of medication use to OOP price and the relationship between medication use and health outcomes that affect medical care spending. VBID may be applied universally—in other words, to all patients for whom a drug might be indicated, or selectively to targeted subgroups of patients most likely to benefit clinically or to respond more readily to benefit design incentives. As the ability to target the benefit structure increases, the larger are the cost savings likely to accrue to the insurer.

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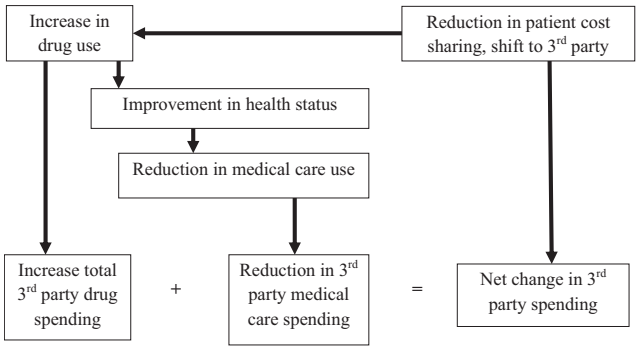

Fig. 1 – Value-based insurance design at the margin, third party perspective.

Treatments for patients with diabetes have become a focus for VBID inquiries because of the evidence of cost savings associated with appropriate medication use. The use of statins to prevent or delay the secondary complications of diabetes has been shown to improve clinical outcomes for older adults [4–7]. There is also increasing evidence that improved adherence to this class of medications reduces medical costs [8–15]. In a recent observational study that included a variety of controls for confounding, Stuart et al. [16] identified a savings of $832 associated with 10% higher adherence to statins when measured over a 3-year period.

If improved medication adherence is cost-saving, the question is whether patients are sufficiently responsive to OOP price changes such that reduced co-payments can motivate a sufficiently large increase in medication use. The price elasticity of demand associated with cost-sharing and prescription drug expenditures for the management of chronic conditions generally ranges between −0.2 and −0.6 [17,18], depending on the study design, drug, and population. This indicates that a 10% decrease in OOP spending is associated with a 2% to 6% increase in spending on prescription drugs. Several studies have focused on antidiabetic medications, finding changes in co-payments to be associated with changes in medication use [19–21]. Goldman et al. [22] found a 25% reduction in days supplied of antidiabetic medications when co-payments were doubled. Some studies have examined the response to increases in OOP prices. For example, a longitudinal study of statin users found that a 100% co-payment increase resulted in reduced statin adherence rates of 2.6% and 1.1% for new and continuing users, respectively [23]. In contrast, a 30% reduction in co-payments from a large employer resulted in a 3.4% increased utilization of statins [24]. In general, Medicare beneficiaries purchasing maintenance medications used for the long-term treatment of chronic conditions have been found to have a low level of response to cost-sharing incentives [18]. Chernew et al. [24] reported price elasticities for diabetic drugs (−0.136) and statins (−0.182)—estimates that were at the lower end of the range previously reported for medications in patients with other chronic conditions.

There have been several types of studies focused on demonstrating the potential for VBID interventions. An early study by Rosen et al. [25] used a Markov model to simulate how the elimination of cost-sharing would increase drug use in diabetic patients, reduce disease progression, and ultimately reduce medical care utilization and spending. However, the estimates used to populate various nodes in the model were taken from the literature and may not have been specific to the study sample or environment. Other studies have drawn on VBID interventions, principally observational studies or small convenience samples where single employers, such as Pitney Bowes, implemented a VBID program change [26]. Some more recent studies have included comparison groups [27–29], with results pending for two prospective controlled trials [30,31]. To date, there is evidence that VBID-related reductions in cost-sharing result in small but statistically significant increases in medication use. No studies, however, have demonstrated medical cost offsets to the increased cost borne by the insurer. Furthermore, these studies examine the effects of VBID in employee populations but have not yet addressed the potential for VBID in the Medicare population.

In this study, we explored the potential cost-savings associated with a simulated VBID strategy related to statin adherence for an elderly population with diabetes. Extending prior research examining medical cost-savings associated with statin adherence [16], we used a sample of Medicare beneficiaries with diabetes selected from the nationally representative Medicare Current Beneficiary Survey (MCBS), following them for up to 3 years after baseline assessment. We estimated multivariate models of demand for statins as a function of the OOP price and then estimated the relationship between statin fills and Medicare spending. We used microsimulation to assess the total and Medicare cost-saving potential associated with reductions in cost-sharing for statins. We also stratified our estimates by using a modified application of the Framingham Risk Calculator as a way to examine the role of targeting.

Methods

Data and study sample

Data from the 1997–2005 MCBS were used for this study. The MCBS enrolls approximately 4000 Medicare beneficiaries every year and follows these individuals for up to 3 additional years. Data collected from this survey include self-reports of demographic and socioeconomic characteristics, health and functional status, as well as utilization and cost of all health services including prescription drugs [32]. Information about prescription drug use is provided by the respondent who is asked to keep a log of pharmacy receipts, insurance claims, and used medication containers. Each prescription fill or refill is recorded as a separate event and includes information about the drug name, strength, and quantity of doses. The date of the prescription fill and the number of days of treatment supplied are not recorded. The MCBS is linked to Medicare administrative data including Part A and B claims.

Six pooled panels were constructed of beneficiaries inducted into the MCBS from 1997 to 2002, who had a diagnosis of diabetes in their baseline year. Identification of diabetes cases was based on claims and self-report. An algorithm developed by the Centers for Medicare & Medicaid Services for the Chronic Condition Warehouse was used to identify diabetes cases from claims [33]. The Chronic Condition Warehouse criteria for diabetes include beneficiaries with an *International Classification of Diseases, Ninth Revision,* code for 250.xx (diabetes), 357.2 (polyneuropathy in diabetes), 362.01 (background diabetic retinopathy), 362.02 (proliferative diabetic retinopathy not otherwise specified), or 366.41 (diabetic cataract) on one or more inpatient hospital, skilled nursing facility, or home health claims or two outpatient hospital or physician claims in any position [33]. Patients who reported being given a diagnosis of diabetes by a physician were also included as cases. Self-reported diabetes is considered the gold standard for identifying individuals when clinical indicators are not available [34,35].

Individuals excluded from the sample included 1) beneficiaries living in long-term care (LTC) facilities during their baseline year, although beneficiaries who were admitted to an LTC in subsequent years were retained, and 2) beneficiaries enrolled in capitated Medicare health plans at any time during participation in the MCBS, as well as dual eligibles who have both Medicaid and Medicare. Individuals in LTC were excluded because of differences in the way the MCBS is administered in these settings. Individuals enrolled in capitated Medicare health plans do not have Part A and

B claims, which were necessary in determining Medicare costs. Last, dual eligibles were excluded because they were found to be disproportionately represented among the higher-risk group and they faced minimal OOP prices.

There were 2949 beneficiaries who had diabetes during their baseline year. Among those, the final sample comprised a cohort of individuals who reported filling prescriptions for statins during their first full year in the MCBS following their fall induction survey (N = 899). This drug user cohort was then followed until they completed their MCBS participation or were lost to follow-up, admitted to an LTC facility for a long-term stay, or died; the final observation year was 2005.

Measures

We had two dependent variables in the multivariate models—the number of 30-day statin fills and Medicare expenditures for Part A and Part B services. Statin prescription fills were determined by drug names and therapeutic class indicators. Although days supply of prescription fills is not available in the MCBS, pill counts are available and were used to measure drug use for each subject. About 16% of medication fills were missing pill counts; these values were imputed on the basis of information in a beneficiary's medication regime by using a two-stage imputation procedure. We divided the number of pills in each fill by 30 to calculate the number of standardized 30-pill fills. Because most statins are dosed once daily, this measure should accurately distinguish the number of monthly fills, with 36 expected to be the maximum over a 3-year period. Medicare expenditures for Part A and Part B services were measured over the same time frame as the statin fills measure. To account for inflation, all dollar values were converted to constant 2005 dollars by using the consumer price index [36].

The key independent variable of interest in the statin fill demand model was the OOP price per fill. To measure this, we summed the OOP payments by beneficiaries associated with statin fills in the base year and divided by the number of 30-pill fills in that year. Ideally, we would have an exogenous price measure, not based on observed prices. Because our question relates to VBID among users of statins, however, the observed OOP price should reflect the price faced at the margin for these users. In the cost-offset model, the key independent variable of interest was the number of statin fills. We did not include the OOP price in the models, but we included indicators for supplemental medical and drug benefits by source of coverage, because these would be expected to have independent effects on medical spending.

There were a number of covariates used in our regression models to control for confounding. These included demographic characteristics such as age, sex, race, marital status, education, income, and census region, which are believed to influence medication use and Medicare spending. A number of health status and disease severity variables were used to avoid indication bias. Self-reported measures used included overall health, height, and weight, which were used to compute body mass index (BMI), number of limitations in activities of daily living, and diabetes type. Medicare administrative data provided variables to identify current and former recipients of Social Security Disability Insurance. Lastly, Medicare claims were used to create measures of diabetes complications (*International Classification of Diseases, Ninth Revision,* codes 250.1x to 250.9x) and various common comorbidities, including chronic renal failure, hypertension, ischemic heart disease, cardiac failure, hyperlipidemia, chronic obstructive pulmonary disease, and osteoarthritis, plus a count of hierarchical coexisting conditions. Finally, we included the number of days followed in the community and dummy variables to capture the reason for any censoring (loss to follow-up, LTC admission, death), as well as year of induction into the MCBS (a proxy for temporal trends in diabetes and availability of treatment options), and a dummy variable that indicated whether the diabetes case was identified by self-report only. Except for the spending, drug utilization, and censoring variables, all covariates were measured during the baseline year.

The analysis was conducted for the full cohort of diabetes patients and then stratified according to 10-year risk of a cardiovascular event (stroke, acute myocardial infarction). The risk stratification used a variant of the Framingham Risk Calculator (based on the Simple Model with Office-Based non-Laboratory Predictors), which assigns points on the basis of the following risk factors: age, BMI, systolic blood pressure (SBP) (untreated and treated), smoking status, and diabetes status [37]. Variables from the MCBS used to create higher- and lower-risk groups included self-reported age, gender, BMI (based on height and weight), current smoking status, and diabetes status as well as claims-based measures of diabetes and hypertension. Because the MCBS does not record SBP measures, it was assumed that individuals with hypertension (70% of the sample) had an untreated SBP of 140 mm Hg. Individuals without hypertension were assumed to have a treated SBP of 120 mm Hg. Points for each item were summed to create a risk score for each beneficiary. According to the Framingham Web site, all participants in this sample were above a 30% 10-year risk of a cardiovascular event. The distribution of risk factor scores was examined by gender and a cut point for the higher-risk group was determined (risk score $\geq$ 21 for men and risk score $\geq$ 24 for women), leaving about 40% of the sample in the higher-risk group (n = 350) and 60% in the lower-risk group (n = 549). This cut point was used to stratify the analysis to determine whether higher-risk individuals were more price responsive to OOP prices for statins and to see whether higher-risk individuals had larger cost-offsets associated with statin use than did lower-risk individuals.

Statistical analysis and simulation

We used bivariate analyses and multivariate regressions to examine the relationship between the OOP price and the cumulative number of statin fills in the demand model, and in the cost offset model, we estimated the effect of the cumulative number of statins fills on cumulative Medicare Part A and Part B spending. The statin demand model was estimated by using ordinary least squares regression, and the cost offset model was a generalized linear model with a gamma distribution and log link to approximate the right skewed distribution of Medicare costs. Because vir-

Table 1 – Mean values for dependent variables and OOP price, for full sample and by CVD risk.

	Full cohort (N = 899)		By CVD risk			
			High risk (n = 350)		Low risk (n = 549)	
	Mean	SE	Mean	SE	Mean	SE
Medicare Part A and Part B spending, cumulative 3 y (2005$)	36,690	1653	40,041	2840	34,553	2010
Statin fills, cumulative 3 y, 30 d	24.4	0.4	25.5	0.7	23.7	0.5
First-year OOP spending per statin fill ($)	28.8	1.0	26.8	1.6	30.0	1.4

Source. Medicare Current Beneficiary Survey 1997–2005.
CVD, cardiovascular disease; high risk, high risk for cardiovascular event; low risk, low risk for cardiovascular event; SE, standard error of the mean; OOP, out-of-pocket.

Table 2 – Characteristics of sample cohort: Medicare beneficiaries with diabetes and baseline statin use.

	Full cohort (N = 899)		By CVD risk			
			High risk (n = 350)		Low risk (n = 549)	
	Mean or %	SE	Mean or %	SE	Mean or %	SE
Count of other drugs used (mean)	8.6	0.2	9.1	0.3	8.2	0.2
Supplemental medical insurance only (%)	19.8	1.3	18.0	2.1	20.9	1.7
Supplemental medical and prescription insurance (%) (not mutually exclusive)						
Employer plan	51.6	1.7	51.4	2.7	51.7	2.1
Other private	2.0	0.5	2.3	0.8	1.8	0.6
Other public	8.6	0.9	10.0	1.6	7.7	1.1
Self-purchased	15.7	1.2	15.1	1.9	16.0	1.6
No supplemental medical or prescription insurance (%)	7.9	0.9	9.1	1.5	7.1	1.1
Age (y) (%)						
<65 (SSDI)	9.0	1.0	12.9	1.8	6.6	1.1
65–69	27.8	1.5	31.1	2.5	25.7	1.9
70–74	22.1	1.4	26.6	2.4	19.3	1.7
75–79	20.8	1.4	18.0	2.1	22.6	1.8
80+	20.2	1.3	11.4	1.7	25.9	1.9
≥65 (former SSDI)	18.8	1.3	25.4	2.3	14.6	1.5
Females (%)	47.8	1.7	46.9	2.7	48.5	2.1
Race						
Non-Hispanic white	84.1	1.2	80.3	2.1	86.5	1.5
Non-Hispanic black	9.0	1.0	12.9	1.8	6.6	1.1
Hispanic	4.1	0.7	2.9	0.9	4.9	0.9
Other	2.8	0.5	4.0	1.0	2.0	0.6
Marital status (%)						
Married	64.3	1.6	63.1	2.6	65.0	2.0
Widowed	9.6	1.0	12.0	1.7	8.0	1.2
Single	26.1	1.5	24.9	2.3	27.0	1.9
Education (%)						
No high school	12.9	1.1	13.7	1.8	12.4	1.4
Some high school	16.5	1.2	15.4	1.9	17.1	1.6
High school graduate	32.9	1.6	34.3	2.5	32.1	2.0
Some higher education	37.5	1.6	36.3	2.6	38.3	2.1
Annual income (%)						
≤100% FPL	7.5	0.9	8.0	1.5	7.1	1.1
101%–199% FPL	32.6	1.6	34.9	2.6	31.1	2.0
200%–299% FPL	26.4	1.5	26.0	2.3	26.6	1.9
≥300% FPL	33.4	1.6	30.9	2.5	35.0	2.0
Census region (%)						
East	20.9	1.4	20.3	2.2	21.3	1.7
Midwest	26.7	1.5	29.1	2.4	25.1	1.9
South	39.5	1.6	40.3	2.6	39.0	2.1
West	12.9	1.1	10.3	1.6	14.6	1.5
Diabetes type (%)						
Type 1	10.5	1.0	12.6	1.8	9.1	1.2
Type 2	83.0	1.4	81.5	2.3	83.9	1.8
Self-report health status (%)						
Excellent/very good	25.8	1.5	18.0	2.1	30.8	2.0
Good	34.3	1.6	37.1	2.6	32.4	2.0
Fair	27.8	1.5	31.1	2.5	25.7	1.9
Poor	12.0	1.1	13.7	1.8	10.9	1.3
Body mass index (%)						
<18.5 (underweight)	0.2	0.2	0.3	0.3	0.2	0.2
18.5–24.9 (normal)	20.1	1.3	5.1	1.2	29.7	2.0
25.0–29.9 (overweight)	40.3	1.6	10.3	1.6	59.4	2.1
30.0–34.9 (obese 1)	24.4	1.4	56.0	2.7	4.2	0.9
35.0–39.9 (obese 2)	9.6	1.0	20.9	2.2	2.4	0.6
40.0+ (obese 3)	2.8	0.5	6.6	1.3	0.4	0.3
Comorbidities (%)						
Diabetes complications	23.6	1.4	26.0	2.3	22.0	1.8
Chronic kidney disease	5.2	0.7	6.9	1.4	4.2	0.9

(*continued on next page*)

Table 2 (*continued*)

	Full cohort (N = 899)		By CVD risk			
			High risk (n = 350)		Low risk (n = 549)	
	Mean or %	SE	Mean or %	SE	Mean or %	SE
Hypertension	70.3	1.5	80.0	2.1	64.1	2.0
Ischemic heart disease	53.2	1.7	50.3	2.7	55.0	2.1
Congestive heart failure	24.1	1.4	30.0	2.5	20.4	1.7
Hyperlipidemia	75.1	1.4	71.7	2.4	77.2	1.8
COPD	10.8	1.0	14.3	1.9	8.6	1.2
Osteoarthritis	14.0	1.2	16.3	2.0	12.6	1.4
Cognitive impairment (%)	10.7	1.0	12.6	1.8	9.5	1.3
Psychiatric conditions (%)	7.8	0.9	10.0	1.6	6.4	1.0
ADL limitations (mean)	0.8	0.0	1.0	0.1	0.7	0.1
Current smoker (%)	9.7	1.0	24.9	2.3	0.0	0.0
MCBS induction year (%)						
1997	10.2	1.0	8.0	1.5	11.7	1.4
1998	12.1	1.1	10.3	1.6	13.3	1.5
1999	15.8	1.2	14.6	1.9	16.6	1.6
2000	17.4	1.3	19.1	2.1	16.2	1.6
2001	19.9	1.3	22.3	2.2	18.4	1.7
2002	24.6	1.4	25.7	2.3	23.9	1.8
Community months (mean)	32.3	0.3	32.4	0.5	32.2	0.4
Died during follow-up (%)	10.2	1.0	13.1	1.8	8.4	1.2
Entered LTC facility (%)	3.7	0.6	4.9	1.2	2.9	0.7
Lost to follow-up (%)	10.8	1.0	6.6	1.3	13.5	1.5
Self-reported diabetes only (%)	8.5	0.9	7.4	1.4	9.1	1.2

Source. Medicare Current Beneficiary Survey 1997–2005.

ADL, activities of daily living; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; high risk, high risk for cardiovascular event; FPL, Federal Poverty Level; LTC, long-term care; low risk, low risk for cardiovascular event; MCBS, Medicare Current Beneficiary Survey; SE, standard error of the mean; SSDI, Social Security Disability Insurance.

tually all subjects had some Medicare spending over the 3-year observation period, we estimated one-part models, replacing the small number of zero observations with a value of $1.

To simulate the effects of a VBID, we first generated a deterministic prediction for our dependent variables, based on the observed OOP price and all other variables. Then, we capped the OOP price at various levels, and generated a predicted value for the number of statin fills. We computed total and plan prescription drug spending, assuming that the total spending per standard fill did not change, but that for some users, the number of fills would increase and the spending per fill would shift from the user to the drug plan. The predicted number of fills was then substituted into the cost offset model and a new Medicare Part A and Part B spending value was generated. We computed the change in predicted statin fills from baseline by using the simulated OOP prices. Similarly, we computed the change in plan drug spending and Medicare Part A and Part B spending associated with the simulated OOP prices. The predictions used the observed values for each individual, with the exception of the OOP price. This approach differs from the more common practice of generating predictions by using sample means and permits us to examine heterogeneity in the magnitude of response. Analyses used SAS (9.2) or Stata (version 10). The study protocol was approved by the University of Maryland Baltimore Institutional Review Board.

Results

Descriptive findings

The sample included 899 Medicare beneficiaries with diabetes who used statins during their baseline year, with 350 identified as higher-risk patients. Table 1 and Table 2 report sample means and proportions for the dependent and independent measures respectively, overall and stratified by risk status. Overall, patients filled an average of 24.4 out of a maximum 36 fills, with a slightly higher value among higher-risk patients (25.5 compared with 23.7 fills among the lower-risk patients). Mean cumulative medical spending over the 3-year observation period was $36,690, with higher spending among the higher-risk group ($40,041) than among the lower-risk group ($34,553). Table 3 reports results from the ordinary least squares regressions of the OOP price on the number of statin fills, overall and stratified by risk status. For each dollar increase in the OOP price, there is a reduction of 0.086 statin fills ($P < 0.0001$); the estimated elasticity is −0.101. The estimated effects are somewhat larger for the higher-risk than for the lower-risk group, with elasticity estimates of −0.111 and −0.089, respectively. The full set of regression coefficients is provided in Appendix Table 1 in Supplemental Materials found at doi: 10.1016/j.jval.2012.01.008. Although the models overall are highly significant, relatively few individual variables are significant. Increasing education levels are associated with increased fills, while the presence of diabetes complications is associated with lower adherence, suggesting that lower adherence in the past may be associated with the development of diabetes complications.

Table 4 reports results from the multivariate regressions of statin fills on Medicare spending. Overall, the estimated effect of an additional 30-pill fill is a reduction of $159.57 ($P = 0.03$) in Medicare spending. For the higher-risk patients, the estimated effect is almost double, at $279.54 ($P > 0.01$) while the estimated effect for the lower-risk patients is smaller ($97.47, $P = 0.29$) and not significantly different than zero. The full set of regression coefficients is

Table 3 – Estimated effects of the OOP price per fill on cumulative 3-y statin fills.

Cohort	N	Mean OOP price ($)	Mean fills (N)	Coefficient	SE	$P > \|z\|$	Price elasticity	Model R^2
Overall	899	28.77	24.41	−0.086	0.015	0.000	−0.101	0.317
High risk	350	26.81	25.50	−0.106	0.023	0.000	−0.111	0.455
Low risk	549	30.02	23.72	−0.070	0.019	0.000	−0.089	0.298

Source. Medicare Current Beneficiary Survey 1997–2005.
high risk, high risk for cardiovascular event; low risk, low risk for cardiovascular event; SE, standard error of the mean; OOP, out-of-pocket.

reported in Appendix Table 2 in Supplemental Materials found at doi: 10.1016/j.jval.2012.01.008.

The simulated effects of VBID are illustrated in Figure 2. Figure 2A shows the simulated effects of capping the OOP price at various levels on changes in third-party payer spending on statins. For example, relative to the baseline prediction of $1280, third-party spending on statins increased by $340 when the OOP price was capped at $25 and by $794 when the OOP price was capped at $1. Estimates vary slightly by risk status. Figure 2B illustrates the effects of VBID on changes in Medicare Part A and Part B spending. For the overall sample, the implementation of VBID pricing reduced Medicare spending by $262 (price cap at $25) to $531 (price cap at $1). The effect for the higher-risk subgroup was substantially higher, ranging from a reduction of $558 to $1193. The net effect of changes in third-party spending in these two categories is illustrated in Figure 2C. Overall, the reduction in the OOP price associated with VBID generated a net increase in third-party spending, beginning with the $25 cap and increasing as the OOP price cap diminished. The net effect was a savings to third-party payers for the higher-risk group, ranging from $249 to $415 across the various price caps. For the lower-risk groups, the results were inverted, with net increases in third-party spending as price caps were lowered.

Discussion

The results of this study provide the first empirical evidence that a VBID strategy may be effective within the Medicare population, and in particular, demonstrate that its selective application could deliver net savings to the Medicare program [38]. Previous studies have reported on changes in drug use associated with cost-sharing, while others have reported on reduced medical costs associated with medication adherence. In this study, we integrated the two components and simulated the net effects from the perspective of Medicare as a third-party payer. Our simulated cost offsets were substantial for the higher-risk subgroup, with a net savings of $415 per patient associated with a $1 co-payment, but did not yield net offsets for the group of diabetes patients overall. These findings suggest that a VBID strategy may be very attractive within the Medicare program if it is feasible to target the benefit. Further research, however, including intervention studies, to confirm the response and net costs of a VBID strategy of this type is warranted.

Within the current structure of the Medicare Part D system, managed care prescription drug plans (MA-PDPs) would have the capacity to benefit from any net savings in medical expenditures, because the medical and prescription drug benefits are integrated. The introduction of VBID for MA-PDPs would clearly present a competitive advantage for these types of plans over their stand-alone Part D plan counterparts. That said, reducing cost-sharing for the sickest enrollees may also lead to adverse risk selection, with the sickest beneficiaries favoring MA-PDPs offering it. In addition, some MA-PDPs may balk at introducing such mechanisms where it is not possible to ensure that targeted beneficiaries will remain in the MA-PDP for sufficient time for the plan to benefit from the downstream offsets.

While the logistics of implementing VBID for MA-PDP enrollees may be relatively straightforward, applying VBID mechanisms to other types of drug coverage may be more complex. Downstream savings in medical care costs reaped by the Medicare fee-for-service program clearly present no incentive for ex-ante increases in coverage by stand-alone PDPs under Part D. Other mechanisms would need to be devised to provide the necessary incentives to reduce co-payments, for example, increased levels of federal subsidy to Part D plans to cover the additional plan costs for targeted beneficiaries. Employer sponsored plans that receive the retiree drug subsidy could be further subsidized for implementing a VBID cost-sharing structure, and the Federal Employee Health Benefits Program could easily adopt these changes as well.

Targeting VBID incentives to higher-risk beneficiaries presents a number of important logistical issues that would need to be addressed, such as how patients are designated as eligible and how the alternative co-payment structure is implemented at the time prescriptions are filled [39]. In addition, targeting VBID co-payment reductions may generate perceptions of inequity because individual patients are charged different co-payments for the same medications. Concerns about inequity may be dispelled if insurers emphasize the role of clinical need in targeting the benefit. Of potentially greater concern is that targeting by clinical status could potentially create perverse incentives. It could, for example, discourage some individuals from attempting to lose weight or quit smoking if they thought it could lead to the loss of their preferred VBID status.

While our example demonstrates the feasibility of a VBID strategy, the study is subject to limitations. The study period for our data

Table 4 – Estimated effects of statin fills on 3-y cumulative Medicare spending.

		Mean fills (N)	Medicare Part A and Part B spending ($)	Marginal effect incremental fill	SE	$P > \|z\|$
Overall	899	24.41	36,690	−159.57	73.24	0.03
High risk	350	25.50	40,041	−279.54	111.66	0.01
Low risk	549	23.72	34,553	−97.47	91.56	0.29

Source. Medicare Current Beneficiary Survey 1997–2005.
high risk, high risk for cardiovascular event; low risk, low risk for cardiovascular event; SE, standard error of the mean.

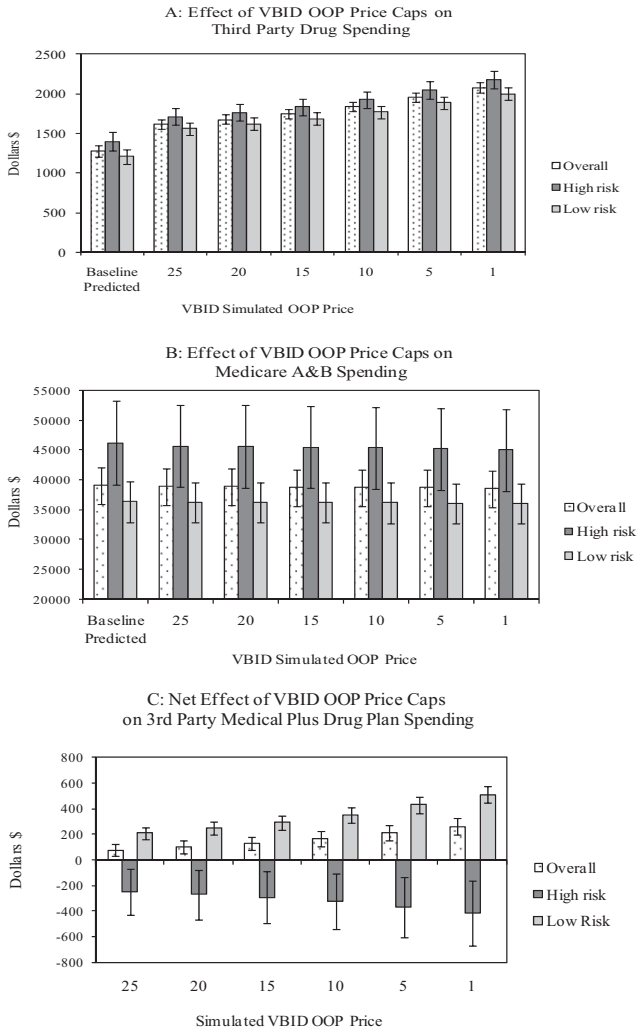

Fig. 2 – Simulated effects of VBID OOP price of standardized statin fill caps on Medicare beneficiaries. High risk, high risk for cardiovascular event; low risk, low risk for cardiovascular event; OOP, out-of-pocket; VBID, value-based insurance design.

ended in 2005. While behavioral responses to price changes are unlikely to vary, and the clinical impacts and medical cost-savings may not have changed dramatically, the costs of statin therapies for Medicare beneficiaries have changed as a result of patent expirations, and perhaps more importantly, following the introduction of Medicare Part D in 2006. Hence, it is important to consider how changes in market price—both total and OOP—affect the VBID calculus. In our analysis, we used observed OOP payments and applied successively generous caps. The observed payments reflected the range of prices over the study period and should have captured reductions in the price of statins associated with generic competition starting in 2002. As generic drugs tend to be subject to even lower co-payments in more recent years—either through tiered formularies or through the pricing policies of big-box stores such as Walmart—a VBID strategy would have to reduce OOP prices even further to elicit increased use. On the other hand, the third-party payer would then be at risk for only a smaller increase in its share of the total drug costs while the downstream savings in medical spending should remain unaffected. Hence, our results may overstate the increased cost to insurers to participate in a VBID strategy and understate the net savings in medical care costs.

The study is observational, and the estimates of price response and medical care offsets are based on cross-sectional and temporal variation. Despite extensive controls for confounding in the multivariate models, there is the potential for bias associated with unobserved health or behavioral factors. In addition, we note that our measures of drug use and spending are not based on insurance claims, and hence may be subject to reporting error. The estimated elasticity is a key element of the simulation. Our elasticity estimates, in the range of about −0.1, are even lower than those reported in the literature. To the extent that they are biased downward, then our simulation provides a conservative measure of the net cost savings associated with a VBID strategy. Finally, we did not attempt to model any costs associated with the implementation, monitoring, and evaluation of the VBID strategy in this simulation; identifying low-cost methods to meet these program requirements is important to the feasibility of a VBID program.

The prevalence of diabetes in the Medicare population was approximately 8.2 million in 2009, while forecasts suggest an increase to almost 15 million by 2034, and an almost fourfold increase in annual diabetes-related expenditure [40]. Nevertheless, while statin therapy is recommended for most diabetic patients, additional examples likely would be needed to justify the expense of implementing a VBID approach. In a related study [16] examining medical care spending offsets associated with the use of oral antidiabetics and angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in the same sample of diabetic patients, we failed to find parallel savings [41–43].

Of course, VBID focuses only on the net costs of increased medication use—whether it is from the third-party or societal perspective. There is no attempt to value and incorporate any survival or quality-of-life benefit from the patient perspective. In addition, there may be benefits to employers related to reduced illness and absenteeism that our estimates cannot capture because they are focused on the insurer [44]. If these were to be included in the calculus, many additional treatments might be identified as appropriate for VBID.

Finally, VBID can be used to increase the use of selected therapies that are demonstrated to be both clinically effective and likely to lead to reduced medical care spending. It is important, however, to recognize that VBID applies a higher standard for the designated services than is currently applied in the Medicare program. Medicare currently covers some therapies for which there is only limited empirical evidence, or evidence of relatively modest clinical benefit, and Congress has been reluctant to mandate that new evidence generated through comparative effectiveness research be used to make coverage decisions [45]. Instead of setting a uniquely high bar for VBID, a better strategy might be to reduce cost-sharing for effective services, even without evidence of a medical cost offset. The increased cost associated with higher use of those services could be offset by limiting coverage or introducing a higher level of cost-sharing for services that have evidence of limited benefit or value [46,47]. Services with a limited evidence base could be covered only through an evidence development strategy, and ultimately this would help to identify additional candidates for VBID. The adoption of VBID may be the needed catalyst to rationalize the use of evidence in coverage decisions.

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Supplemental Materials

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