Value-Based Design and Prescription Drug Utilization Patterns Among Diabetes Patients

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Faced with increasing costs and a challenging economic climate, many US firms continue to increase the health insurance contribution required of their employees. Since 2001, worker contributions to employer-sponsored health insurance have increased 131%, outpacing the 113% increase in premiums over the same period.[1] Specific changes have included alterations in the structure and amounts of prescription drug cost sharing. In the past decade, the average cost-sharing amount for generic medications has grown 25% from $8 to $10 between 2001 and 2011; there have been larger changes in cost sharing for preferred and nonpreferred brand medications, with increases of 93% and 69%, respectively.[1]

One strategy to address specific healthcare costs that has gained traction in recent years is the use of value-based benefit design (VBID). This approach utilizes incentives within the employee benefit structure to encourage the use of high-value health services.[2] Lowering out-of-pocket exposure for particular classes of drugs is a popular mechanism of value-based plans, and has been an especially prevalent method to address diabetes, a condition whose annual economic toll in the United States is approaching $200 billion.[3] Reducing medication out-of-pocket costs for patients with diabetes has had several positive effects across multiple studies, including improvements in medication initiation and adherence, lower treatment discontinuation rates, and decreased disease-related costs.[4-9]

Recently, Gibson and colleagues[8] assessed the effects of a value-based pharmacy access program that lowered the out-of-pocket costs of all brand diabetes medications to the lowest (generic) tier for employees, spouses, and dependents of 2 units of a large, multi-industry firm. They observed that the value-based program, when combined with concurrent disease management (DM), was associated with an increase in adherence to diabetes medical guidelines and a positive return on investment for diabetes-related spending.[8]

ABSTRACT

Objectives: To measure the effects of a value-based pharmacy access program on utilization patterns for insulin and to determine how cost sharing impacts use of generic and brand antidiabetic medications.

Study Design: A panel analysis was conducted with enrollees as the cross-sectional unit and calendar quarters from 2005 through 2008 as the unit of time.

Methods: Enrollees were matched 1-to-1 using propensity scores to a comparison group in the same firm (~1800 enrollees per arm) with disease management but without the value-based pharmacy benefit. We measured the medication possession ratio and user rates for each medication class and estimated multivariate models controlling for confounders.

Results: The estimated effects of the program on medication possession ratios for brand oral diabetes medications were 1.99, 3.33, and 4.77 percentage points higher than the effects without the value-based program in the first, second, and third years of program implementation, respectively (all P <.055). For generic medications, the effects rose in a complementary fashion and were 4.33, 4.66, and 5.11 percentage points higher in years 1, 2, and 3, respectively (all P <.01). For insulin, the effects on user rates were no different in the first year, but were higher in the second and third years (both P <.01), suggesting treatment augmentation with insulin occurred at a greater rate. Similar trends were found for user rates.

Conclusions: These results suggest that reduced patient cost sharing may facilitate more appropriate prescribing of diabetes medications, allowing for treatment decisions that are more readily accepted by patients.

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PRACTICAL IMPLICATIONS

Adjustments to prescription drug cost sharing may facilitate more appropriate prescribing decisions and patient adherence.

- Changing out-of-pocket exposure for particular drug classes is a common mechanism of value-based prescription benefit programs.
- Lowering patient prescription cost sharing led to improvements in the use of and adherence to brand and generic oral antidiabetic medication and insulin.
- Reduced out-of-pocket costs for diabetes medications can improve the extent to which some recommended diabetes treatment guidelines are followed.

Additionally, an increase in adherence to diabetes medication was observed over time; however, these results were reported for the entire antidiabetic medication drug class.

The purpose of this investigation was to estimate the effects of the pharmacy program on utilization of generic and brand antidiabetic oral medications and insulin. Results of this study will provide needed information regarding the differential effects of cost-sharing changes on adherence to generic and brand medications, which will aid in the design of future programs.

FRAMEWORK

Typically, brand and generic medications have been viewed as substitutes for each other; however, the body of literature comparing these medications suggests there may be a more complex relationship. There is some concern that value-based programs that lower only brand name out-of-pocket exposure will prove to be costly, as they may give patients an incentive to replace lower-cost generic medications with higher-cost brand name medications, running contrary to cost-sharing trends that place brand medications at the highest cost-sharing levels. Such a pattern was observed by Nair and colleagues,[9] who examined the effects of a value-based program that lowered all brand medications to the first (generic) tier. They found higher utilization of brand name diabetes medications in each of the 2 years following the copayment reduction, but no difference in diabetes generic medication utilization in the first year and a drop in the second year, although a comparison group was not used to control for important contemporaneous trends such as generic introductions or new brand name medications.[9]

Conversely, several studies have examined the effects of higher brand name copayments on generic use in several medication classes, holding copayments for generic medications constant. In these studies, for the most part, use of brand name medications went in the expected downward direction due to the out-of-pocket increase in price.[10-17] However, utilization of generic medications has been seen to increase,[10] decrease,[11,12,16] or stay the same[12,14,15,16] following an increase in brand name copayments (not generic copayments), varying by medication class and the cost-sharing structure. Importantly, the size of the difference between brand and generic cost-sharing amounts (ie, the brand-generic "differential") is important in the relative use of brand and generic medications.[17]

METHODS

Data Source

The Truven Health Advantage Suite data warehouse for the firm implementing the pharmacy access program was used for this investigation. This data warehouse contains the inpatient and outpatient medical claims, outpatient prescription drug claims, and enrollment information along with patient characteristics such as age, sex, health plan, and length of enrollment. In addition to the internal comparison groups, firms were selected from the Truven Health MarketScan Commercial Claims and Encounters Database to serve as a comparison group for the enrollee cohort who participated in the pharmacy access program.

Pharmacy Access Program

Beginning January 1, 2006, the firm implemented a voluntary DM program for all individuals covered under their medical plan. Similar to programs offered by other major firms, this program included targeted mailings, condition-specific workbooks, telephone nurse outreach services, educational mailings, coaching, and periodic monitoring. A letter describing the program components was provided to employees in the affected business units; further communication regarding the program continued throughout the follow-up period.

Concurrently, the firm offered a diabetes value-based pharmacy program to employees and dependents of 2 US-based business units. Through this program, cost sharing was lowered to 10% for all diabetes medications (see **eAppendix A**) from original levels of 10% for generic, 20% for preferred brand, and 35% for nonpreferred brand medications. Both the value-based and DM programs were implemented separately, and the DM vendor was unaware of the specific groups receiving the value-based benefit.

The baseline year for the study was 2005—before the intervention began—and the 3 subsequent years (2006, 2007, and 2008) were included in the postintervention

period. All enrollees under the age of 65 years who had at least 4 contiguous quarters of enrollment in 2005 through 2008 were selected.

Our analysis focused on the effects of the value-based pharmacy program on enrollees with DM. Variations in program implementation allowed for the analysis of a natural, internal comparison group: plan enrollees with DM who worked in business units where the value-based program was not offered. Subsequently, enrollees in both the value-based and DM programs were matched to enrollees with DM only. As a secondary analysis, a comparison group was constructed from firms in the MarketScan Database without a value-based program. We ensured that the overall characteristics of the firms, their spending trends before the study period, and their adherence trends (2005) were similar to those of the intervention firm.

Matching was performed using propensity score estimation based on the probability of being in a specific program. This was done using a collection of variables: age, sex, area of residence, employment classification and status, relationship to employee, median income and college graduates in the zip code of residence, plan type, health status, and length of plan enrollment. Applying the resulting propensity score, program enrollees were then matched to enrollees in each of the comparison groups.

A panel data file was constructed with enrollee as the cross-sectional unit and calendar quarter as the unit of time. Enrollee experience was captured in quarterly increments throughout the benefit enrollment time frame or through the end of December 2008, whichever was later. We used an intent-to-treat framework, assigning enrollees to their initial plan or program; therefore, any rare instances of crossover would likely bias our results downward. This approach also retains nonusers of medications in each quarter.

Measures

The medication possession ratio (MPR), a metric representing fill adherence, was calculated as the percentage of days covered by medications within the calendar quarter for generic and brand oral antidiabetic medications and for insulin. The MPR was calculated using the fill dates and days of supply on the prescription drug claims to determine the number of days that medications were on hand. The MPR can range from 0% to 100%, and was calculated separately for oral antidiabetic medications and insulin. Prescription drug fills prior to 2005 were not available. Because the days on hand early in 2005 were likely a result of fills made in 2004, the adherence measure for the first quarter of 2005 was not utilized for analyses as it was likely to be understated.

A user rate was also calculated. It was set to 1 for patients with medication in the class of interest during the quarter and to 0 for patients with no medications in the class. As a dichotomous variable, the user rate can serve as a measure of initiation or discontinuation of a medication class.

Statistical Methods

Program effects were measured as the trends in the intervention group occurring postintervention (net of preimplementation levels) and also were the net of trends in the comparison group at the same time. The program effects were measured using multivariate generalized estimating equations as a function of the quarters when the program was in effect (post 2006 in the intervention group), the number of quarters since program inception (allowing for any time-varying effects of the program), and enrollee comparison group membership, which estimated fixed effects common to both groups or unique to the comparison group.

Additionally, other covariates of this function were measured quarterly and included age, male sex, relationship to employee (employee, spouse, or dependent), census region, median income within the zip code of residence, and type of health plan (indemnity, exclusive provider organization/point of service, health maintenance organization, preferred provider organization). Health status was measured in the preimplementation period (2005) for those with enrollment in 2005 or in the first 4 quarters of enrollment for those enrolling afterward and includes the Charlson Comorbidity Index score, an aggregate measure based on diagnoses associated with 19 conditions,[18] and the number of Psychiatric Diagnostic Groupings, because the Charlson Comorbidity Index does not contain mental health conditions. There are 12 Psychiatric Diagnostic Groupings, which are indicated by *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes, which include mental health conditions such as alcohol use disorders, other substance use disorders, depression, bipolar disorder, and schizophrenia.[19]

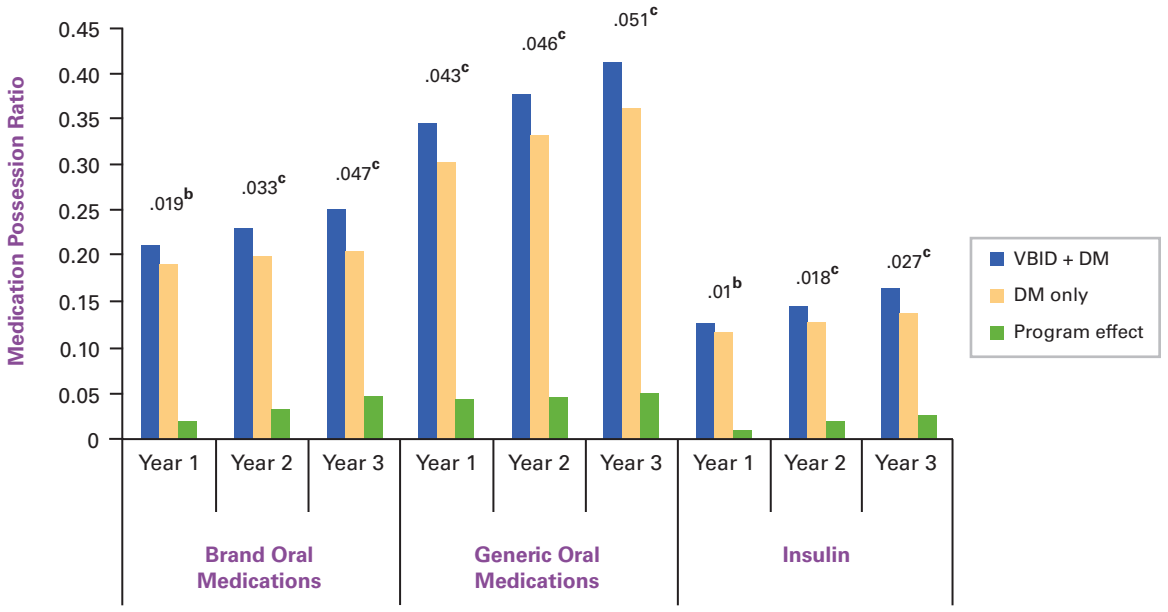
Calendar quarter of enrollment was also incorporated into this function, representing the contemporaneous trend. Sensitivity analysis of the form of the trend variable (eg, linear, linear plus quadratic) was performed with no material change in results. In all models, standard errors were adjusted for clustering within enrollees.

Table. Characteristics of Patients in the Study Groups

Characteristics	VBID + DM (n = 1876)	DM Only (n = 1876)	*P*
Mean follow-up, quarters	12.4	12.5	.706
Mean age, y	48.4	47.9	.203
Age groups, %			
0-17 y	3.4	3.6	.721
18-34 y	7.5	8.2	.431
35-44 y	17.1	16.8	.828
45-54 y	37.4	37.5	.946
55-64 y	34.6	33.8	.630
Sex, %			
Male	59.4	58.5	.550
Female	40.6	41.5	
Plan type, %			
Comprehensive	12.6	13.3	.528
EPO/POS	8.1	7.8	.763
HMO	33.2	32.8	.781
PPO	46.1	46.1	>.99
MSA, %			
Non-MSA	7.5	7.8	.667
MSA	92.5	92.2	.667
Region, %			
Northeast	24.5	21.3	.020
North Central	10.4	11.0	.527
South	55.5	57.4	.249
West	9.6	10.3	.478
Relation to employee, %			
Employee	63.7	63.1	.709
Spouse	32.0	32.2	.889
Dependent	4.3	4.7	.582
Employee classification, %			
Salary	72.2	70.6	.279
Hourly	27.8	29.4	
Employment status, %			
Active, full-time	94.9	95.0	.823
Others (early retiree, Medicare eligible, COBRA, LTC, unknown)	5.1	5.0	
Income in zip code, $	52,437	52,116	.577
College graduates in zip code, %	28.8	28.6	.614
Health status			
Charlson Comorbidity Index score	0.17	0.17	.842
Psychiatric Diagnostic Groupings, n	0.09	0.09	.929

COBRA indicates Consolidated Omnibus Budget Reconciliation Act; DM, disease management; EPO, exclusive provider organization; HMO, health maintenance organization; LTC, long-term care; MSA, metropolitan statistical area; POS, point of service; PPO, preferred provider organization; VBID, value-based insurance design.
Source: Truven Health Advantage Suite 2005 through 2008.

Figure 1. Adherence to Diabetes Medications[a]



DM indicates disease management; VBID, value-based insurance design.
[a]Estimated program effect size values are noted above bars.
[b]P <.05 for program effect.
[c]P <.01 for program effect.

Using predicted values from the model estimates, we calculated each measure in the first, second, and third years after program implementation for the intervention group and the comparison group. The estimated program effect (the difference between the intervention group and the comparison group) was also calculated in each year.

RESULTS

Preintervention Characteristics

We found 1876 enrollees in the value-based program who also participated in the DM program. Those with both the value-based and DM programs were matched to the same number of enrollees without the value-based program (DM only) and to the same number of enrollees within the MarketScan Database.

The **Table** describes the characteristics of each cohort, all of which were used in the matching procedure. When the comparison group was generated within the same firm (without the value-based program), all characteristics were similar except the percentage residing in the Northeast region. When the comparison group was generated from similar firms in the MarketScan Database, most characteristics were similar; however, several statistically significant differences were observed, including sex, residents of the Northeast region, those enrolled in a health maintenance organization or preferred provider organization, and the proportion of spouses and dependents in the cohorts (see **eAppendix B**).

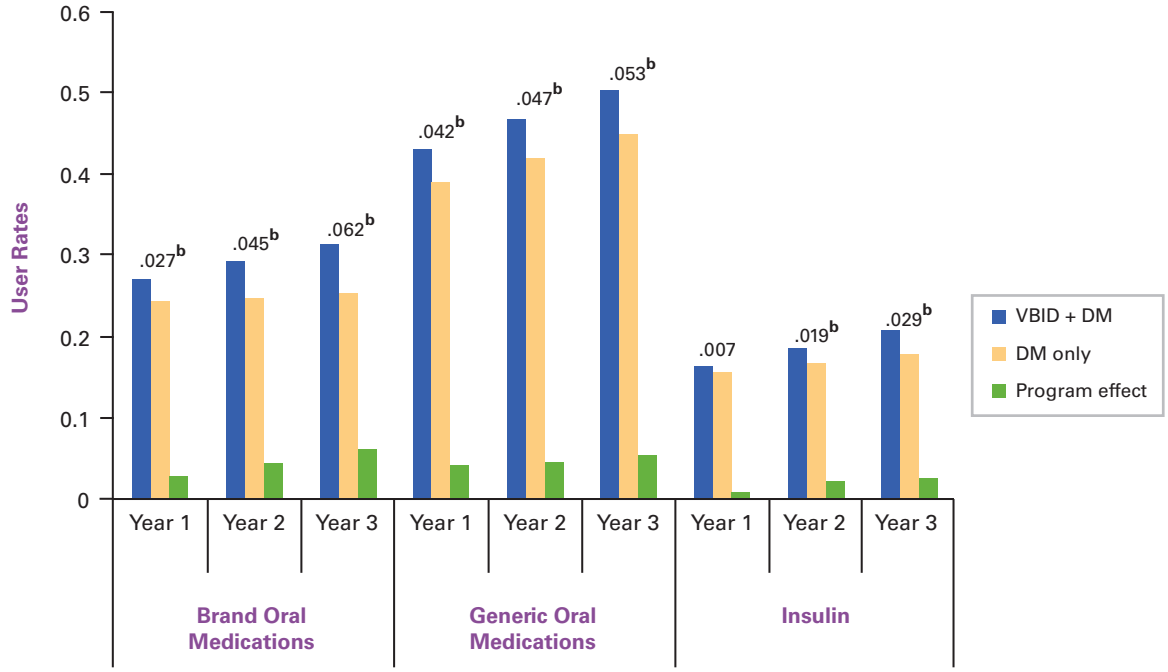
The majority of all enrollees were 45 years and older, and the average age of those in disease management was approximately 48 years. Nearly 60% were male, and most were enrolled in either a health maintenance organization or a preferred provider organization. More than half resided in the southern United States, and nearly two-thirds were employees. Comorbid conditions or psychiatric diagnoses were rare across the entire study population.

Preintervention levels of adherence in the value-based program were insulin, 0.10; brand name oral medication, 0.196; and generic oral medication, 0.282. Preintervention user rates were insulin, 0.135; brand name oral medication, 0.248; and generic oral medication, 0.367. These rates were also similar in the comparison group (all P >.05, not shown).

Program Effects

Figure 1 and **Figure 2** show the estimated program effects. Within the first year of the program, significant changes in medication use were observed between groups; most dramatically, the mean generic medication MPR was 4.3 percentage points higher for patients with both the value-based and DM programs versus patients with the DM only program (P <.01). The program effect in this group of medications grew slightly over time,

Figure 2. User Rates (Percentage of Patients With at Least 1 Fill) for Diabetes Medications



DM indicates disease management; VBID, value-based insurance design.
[a]Estimated program effect size values are noted above bars.
[b]P <.01 for program effect.

the difference between cohorts reaching 5.1 percentage points by year 3 (P <.01). Notable changes in brand name medication MPRs were also observed: a 1.9 percentage point program effect was observed after the first year (P <.05) and this effect increased 1.4 percentage points in the each of the subsequent 2 years, for a final effect difference of 4.7 percentage points (P <.01). Statistically significant differences in adherence to insulin were also observed between enrollees in the value-based plan and patients receiving DM only, but these differences were smaller, increasing by 1 percentage point in the first year (all P <.05) and growing to 2.7 percentage points by the end of year 3 (P <.01).

Program effects on the user rates were also observed throughout the study period. The most dramatic impacts were again realized in the generic oral medication class, where program effects of 4.2, 4.7, and 5.3 percentage points were seen in the first, second, and third years, respectively (all P <.01). Relatively large differences between the user rates in the study groups, year over year, were observed in the brand name oral medication class: user rates were 2.7 percentage points higher in the value-based group after the first year, 4.5 percentage points higher after the second year, and 6.2 percentage points higher by the end of year 3 (all P <.01). Program effect differences in user rates were also observed with insulin; however, statistically significant changes were not realized until the second year of the program: user rates were 1.9 and 2.9 percentage points higher in years 2 and 3, respectively (P <.01), growing by at least 1 percentage point each year.

When compared with patients from the MarketScan matched sample, insulin and generic medication user rates and adherence rates were typically higher in the group both enrolled in a value-based plan and receiving DM. User rates for brand oral medications were higher in the intervention group in each year, reaching marginal levels of significance (approximately 0.10). Adherence rates for brand name oral medications were not significantly different from those in the comparison group in each year (**eAppendix C**).

DISCUSSION

Value-based approaches have been implemented by a variety of employers, using cost-sharing price signals to better meet the health needs of their beneficiaries. Such strategies have often involved the reduction or elimination of prescription drug copayments, leading to improvements in adherence to many prescription medications.[4,6,20] Although most studies have examined the

effects on medication use in aggregate, the design of the value-based program we examined allowed us to determine whether effects were consistent across brand and generic medications and insulin.

Results suggested that combined enrollment in a value-based plan and DM led to increased use of and adherence to oral antidiabetic medications and insulin. Significant effects were observed for generic medication user rates and MPRs after only 1 year, and the effects remained relatively stable over the 3 years of the program. A more dramatic year-over-year improvement was observed with brand medications: user rates nearly doubled and MPRs increased by more than 1 percentage point in each year. Smaller differences in the use of and adherence to insulin were also realized.

These results suggest once disparities in out-of-pocket costs were reduced due to the pharmacy access program, prescribing decisions that were more patient-centric might have been made. Because of coinsurance features for patients in this particular pharmacy access program, the postimplementation medication costs averaged $14.12 and $5.35 for brand and generic medications, respectively, retaining a brand-generic differential in price. In this case, there could have been a greater focus on choosing the most appropriate medication—whether generic or brand—for a particular patient. It is reasonable to suggest that, in this population with a smaller brand/generic differential, medication decisions were made on the basis of what was more medically relevant to each patient. If our findings are a true reflection of how prescribing behavior and subsequent medication use responded to changes in cost sharing, then that is evidence of the influence value-based plans may have on both patients and providers.

The change in insulin uptake realized over the course of the study was another notable finding. In the first year of reduced cost sharing, significant program effects were not realized for insulin, whereas significant initial differences between the study groups were seen for both types of oral medications. However, in years 2 and 3, significant differences in the use of insulin were observed. Such a delayed uptake may signal patterns in the treatment process due to the changes in out-of-pocket exposure. When cost sharing was initially lowered, it is likely that adding additional oral medications to the treatment regimen was preferable to adding insulin—opting for maximum effect from less expensive oral medications rather than switching to an injectable in the first year. Once the maximum effect was realized with oral medications, patients in need of additional therapy, as recommended by guidelines,[21] were then switched to insulin (a suggestion supported by the user rates for this class of medication in years 2 and 3). Such a pattern would suggest that lower out-of-pocket costs for diabetes medications can improve the extent to which some recommended diabetes treatment guidelines are followed.

The study was limited by a lack of information about how prescribing decisions were made subsequent to the implementation of the value-based insurance design and whether this had an impact on clinical outcomes such as glycemic control. As the data set used does not include clinical measures, it was not possible to examine this question.

However, it is also likely that the effects realized for insulin may have been underestimated because the majority of enrollees had type 2 diabetes, and this population tends to underuse insulin. Because there are no generic forms of insulin, changes in cost sharing for this class of medication may substantially impact its use. Although the observed effect reinforces this contention, its magnitude is likely to reflect the makeup of our study population and the specific blend of patients with type 1 and type 2 diabetes.

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eAppendix A. Medications to Treat Diabetes

Insulin	Oral hypoglycemic agents	Glucose-elevating agents
Apidra	Acetohexamide	Diazoxide
Humalog	Actoplus Met	GlucaGen
Humalog Mix 50/50	Actos	Glucagon Emergency Kit
Humalog Mix 75/25	Amaryl	Proglycem
Humulin 50/50	Avandamet	
Humulin 70/30	Avandaryl	
Humulin L	Avandia	
Humulin N	Byetta	
Humulin R	Chlorpropamide	
Humulin U	DiaBeta	
Iletin I NPH	Diabinese	
Iletin II Lente (Pork)	Fortamet	
Iletin II NPH (Pork)	Glimepiride	
Iletin II Regular (Pork)	Glipizide	
Lantus	Glipizide ER	
Novolin 70/30 Innolet	Glipizide-Metformin	
Novolin L	Glucophage	
Novolin N	Glucophage XR	
Novolin N Innolet	Glucotrol	
Novolin R	Glucotrol XL	
Novolin R Innolet	Glucovance	
Novolog	Glyburide	
Novolog Mix 70/30	Glyburide Micronized	
ReliOn N	Glyburide-Metformin HCL	
ReliOn N Innolet	Glycron	
ReliOn R	Glyset	
Velosulin Human BR	Janumet	
	Januvia	
	Metaglip	
	Metformin HCL	
	Metformin HCL ER	
	Micronase	
	Orinase	
	Prandin	
	Precose	
	Riomet	
	Starlix	
	Symlin	
	Tolazamide	
	Tolbutamide	
	Tolinase	

eAppendix B. MarketScan Comparison

Characteristics	VBID + DM (n = 1876)	MarketScan (n = 1876)	*P*
Mean follow-up, quarters	12.4		
Mean age, y	48.4	48.4	.959
Age groups, %			
0-17 y	3.4	2.8	.298
18-34 y	7.5	8.5	.254
35-44 y	17.1	17.9	.519
45-54 y	37.4	34.9	.103
55-64 y	34.6	35.9	.393
Sex, %			
Male	59.4	56.0	.034
Female	40.6	44.0	
Plan type, %			
Comprehensive	12.6	14.2	.165
EPO/POS	8.1	7.1	.262
HMO	33.2	28.7	.003
PPO	46.1	50.0	.016
MSA, %			
Non-MSA	7.5	7.4	.851
MSA	92.5	92.6	
Region, %			
Northeast	24.5	21.2	.018
North Central	10.4	11.5	.272
South	55.5	57.5	.236
West	9.6	9.8	.825
Relation to employee,%			
Employee	63.7	61.1	.099
Spouse	32.0	35.7	.017
Dependent	4.3	8.7	.033
Employee classification, %			
Salary	72.2	74.7	.076
Hourly	27.8	25.3	
Employment status, %			
Active, full-time	94.9	94.5	.610
Others (early retiree, Medicare eligible, COBRA, LTC, unknown)	5.1	5.5	
Income in zip code, $	52,437	51,918	.353
College graduates in zip code, %	28.8	28.4	.401
Health status			
Charlson Comorbidity Index score	0.17	0.16	.622
Psychiatric Diagnostic Groupings, n	0.09	0.11	.224

COBRA indicates Consolidated Omnibus Budget Reconciliation Act; DM, disease management; EPO, exclusive provider organization; HMO, health maintenance organization; LTC, long-term care; MSA, metropolitan statistical area; POS, point of service; PPO, preferred provider organization; VBID, value-based insurance design.

eAppendix C. Marketscan Comparison Effect Estimates

	Year 1			Year 2			Year 3		
Outcome	**VBID + DM**	**MarketScan**	**Effect**	**VBID + DM**	**MarketScan**	**Effect**	**VBID + DM**	**MarketScan**	**Effect**
Medication possession ratio									
Generic oral medications	0.344	0.307	0.037[a]	0.377	0.34	0.037[a]	0.411	0.372	0.039[b]
Brand name oral medications	0.211	0.203	0.008	0.231	0.217	0.014	0.251	0.232	0.019
Insulin	0.127	0.113	0.014[b]	0.145	0.122	0.023[a]	0.164	0.131	0.033[a]
Medication user rates									
Generic oral medications	0.432	0.403	0.029[a]	0.468	0.441	0.027[b]	0.504	0.479	0.025
Brand name oral medications	0.271	0.257	0.014[c]	0.293	0.273	0.02[c]	0.315	0.288	0.027[c]
Insulin	0.165	0.156	0.009	0.187	0.166	0.021[b]	0.208	0.177	0.031[a]

DM indicates disease management; VBID, value-based insurance design.
[a] $P < .01$.
[b] $P < .05$.
[c] P values for years 1, 2, and 3 were 0.103, 0.094, and 0.118, respectively.