

Value-Based Insurance Design and Antidiabetic Medication Adherence

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Among the commercially insured, pharmacy benefits define the availability, accessibility, and cost of prescription drugs. Routinely, total drug costs are paid by both the insurance provider and the plan participant, with the plan participant's share of the drug price often determined by tiered (or escalating) copayments for generic, preferred brand, and non-preferred brand drugs.¹ To address growth in pharmacy expenditures, insurance providers have steadily increased copayments and adopted other utilization management strategies, including prior authorization, step-therapy requirements, and limits on the quantity of medication dispensed.^{2,3}

Although effective at controlling pharmacy trend (year-over-year increases in pharmacy expenditures), prescription drug benefits that shift greater costs to consumers or increase barriers to access can result in lower rates of drug treatment, poorer adherence, and increased rates of treatment discontinuation.⁴⁻⁷ Unfortunately, when pharmacy benefit designs reduce the use of essential therapies (eg, antidiabetics), reduced adherence may have deleterious effects on health status.⁸⁻¹⁰

To counteract this effect, some insurers have implemented value-based insurance designs (VBIDs).¹¹ Value-based insurance designs selectively lower or even eliminate copayments for highly effective preventive medications prescribed for the management of chronic health conditions in an effort to improve medication adherence, improve health outcomes, and lower healthcare costs.^{11,12} Hence, insurers are increasingly drawn to VBID for medications indicated for prevalent health conditions for which empirical evidence suggests that treatment adherence will improve outcomes.

To date, few studies have investigated the effect of changing from a tiered formulary to a VBID with a corresponding drop in copayments for all drugs in key therapeutic classes. Moreover, none of the existing studies have been large enough to evaluate initiation of therapy and persistency of therapy. We examined the impact of implementing a VBID on adherence to and utilization of insulin and oral antidiabetic pharmacotherapy in a large cohort of patients.

ABSTRACT

Objective: To evaluate the impact on adherence to antidiabetic pharmacotherapy of implementing a value-based insurance design (VBID).

Study Design: Retrospective pre-post controlled study.

Methods: We compared adherence to insulin and oral antidiabetic therapy among 20,173 continuously eligible plan participants 1 year before and after their pharmacy benefit transitioned from a 3-tiered formulary to a VBID, and 190,889 controls selected at random from plan participants whose pharmacy benefit remained tiered. With the VBID benefit, the generic and insulin copayment dropped from \$15 to \$0, the preferred brand copayment dropped from \$30 to between \$10 and \$15, and the non-preferred brand copayment stayed at \$35. Adherence was measured as treatment initiation rates, discontinuation rates, and medication possession ratio (MPR) among plan participants with (continuers) and without (initiators) recent history of antidiabetic therapy use.

Results: Compared with controls, the VBID plan participants cohort had higher overall treatment initiation rates (2.3% vs 1.6%) and lower discontinuation rates (initiators 16.0% vs 24.3%; continuers 26.0% vs 29.8%) in the year after benefit design change. The VBID initiators (26.4% vs 40.2%) and continuers (33.1% vs 45.8%) of insulin therapy were significantly less likely to discontinue therapy, although discontinuation rates for oral antidiabetic medications remained similar between the groups. The VBID cohort had significant increases in mean MPR (4.9%) after benefit design change compared with controls (-2.3%).

Conclusions: Changes in pharmacy benefit design improved therapy adherence to diabetes treatment. Particularly important may be the increased treatment initiation rates, which likely represent the cohort of patients avoiding treatment because of cost.

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PRACTICAL IMPLICATIONS

In this retrospective study, adherence to insulin and oral antidiabetic therapy was measured 1 year before and after patients' pharmacy benefit transitioned from a 3-tiered formulary to value-based insurance design (VBID), with patients whose pharmacy benefit remained tiered serving as controls.

- Compared to controls, VBID plan participants had higher overall treatment initiation rates and medication possession ratios, and lower discontinuation rates in the year after the benefit design change.
- Particularly important may be the increased treatment initiation rates, which likely represent the cohort of patients who avoided treatment because of cost.

METHODS

Study Design

We conducted a retrospective pre–post controlled study, comparing commercially insured plan participants whose pharmacy benefit design changed from a traditional, 3-tiered formulary to a VBID with a random sample of participants drawn from plans that experienced no change in the traditional pharmacy benefit design.

Identification and Selection of the Study Population

The VBID cohort was comprised of age-eligible plan participants from 3 CVS Caremark clients that implemented a VBID on January 1, 2007. Plans with concurrent educational intervention or disease management programs provided by CVS Caremark were excluded to avoid potential confounding intervention effects. A contemporaneous control group was selected at random from plan participants with extant tiered prescription drug plans. We developed an external control group selection procedure that matched the control group to the VBID group on different characteristics such as adjudication platform, client type (ie, employer, health plan, Medicare, Medicaid), maximum allowable benefit, deductible, mail or retail coverage, and mean out-of-pocket costs at the group level. After the groups were selected and matched, plan participants in the VBID group were individually matched to participants in the control groups by sex (male, female), age group (<40, 40–64, 65+ years), and geographic region (Northeast, South, Midwest, West, other).

Eligible study participants were continuously eligible for pharmacy benefits for the 12 months before and after January 1, 2007 (the VBID implementation date). The control group comprised plan participants who were

continuously enrolled in traditional, 3-tiered formulary plans during the study baseline and who remained in such plans in the follow-up period.

As of January 1, 2007, participants in the VBID group had the cost of tier 1, generic antidiabetic medications lowered from \$15 to \$0 per 30-day prescription. For tier 2, preferred brand drugs, patient cost-sharing levels were lowered from \$30 in 2006 to amounts from \$10 to \$15 (depending on the drug/client) in 2007. Users of tier 1 and tier 2 medications in the control group, however, had no changes in their copayment of \$10 during the study period. The copayment for non–preferred branded agents (tier 3) was between \$30 and \$35 in both groups throughout the baseline and follow-up periods. The average copayment for insulin decreased from \$28 to \$0 for VBID participants in the postchange period, whereas traditional participants faced an increase from \$23 to \$28 in the same time period. The average out-of-pocket cost for oral antidiabetic drugs did not change for the control group at \$18, but for the VBID group the cost for oral agents decreased from \$21 to \$10.

Antidiabetic medication use was categorized by therapeutic classes identified by either 4- or 6-digit Medispan Generic Product Identifier (GPI) codes for oral antidiabetic agents (antidiabetic combinations [GPI 2799], biguanides [GPI 2725], the thiazolidinedione [TZD] class of insulin-sensitizing agents [2766xx], and sulfonylureas [GPI 2720]) or insulin (GPI 2710). Both groups were further categorized into (1) initiators—participants with no pharmacy claims in the therapeutic class between July 1 and December 31, 2006, and with an index prescription for an antidiabetic medication between January 1 and June 30, 2007; and (2) continuers/discontinuers—plan participants who had at least 2 paid claims in the therapeutic class of interest during the baseline period and available days supply within the final 45 days to December 31, 2006. Note that initiators included those using 1 antidiabetic agent who added another.

To assess changes in medication use, we examined administrative pharmacy claims from January 1 through December 31, 2006, the baseline period, and utilization in the first year in which the VBID was implemented (January 1 through December 31, 2007), the follow-up period.

Measures

We assessed medication adherence by determining treatment initiation and discontinuation rates and compliance. We defined the initiation rate as the number of plan participants who started therapy in the follow-up period divided by the total number of plan participants with no history of antidiabetic medication use during the baseline period. We defined the discontinuation rate

Table 1. Percent Distribution of Selected Characteristics, Overall and by Medication Use Status

Characteristic	Total Study Population, %		Initiators, %		Continuers, %		Discontinuers, %	
	VBID (n = 20,173)	Control (n = 190,889)	VBID (n = 466)	Control (n = 2954)	VBID (n = 1363)	Control (n = 4003)	VBID (n = 709)	Control (n = 1955)
Female	66.7	66.7	71.5	67.9	66.5	63.4	63.9	64.2
Age, y								
<18	0.5	0.5	0.6	0.6	0.5	0.6	0.3	1.0
18-39	13.3	13.3	21.0	18.5	11.0	11.7	9.7	13.8
40-55	42.6	42.6	50.6	50.1	41.8	39.2	45.0	42.2
56-64	38.3	38.3	25.5	24.9	41.4 ^a	31.6 ^a	38.9 ^a	31.3 ^a
65+	5.2	5.2	2.15 ^b	5.9 ^b	5.4 ^b	16.9 ^b	6.1 ^b	11.8 ^b
Baseline medication use								
Insulin	3.2 ^a	1.8 ^a			19.1 ^b	11.5 ^b	24.0 ^a	21.6 ^a
Antidiabetic combinations	0.4 ^a	1.1 ^a			1.2	1.5	2.4 ^a	1.8 ^a
Sulfonylurea	4.6 ^b	2.7 ^b			29.5 ^b	18.1 ^b	31.7 ^b	20.1 ^b
Metformin	8.6 ^b	5.0 ^b			47.8 ^b	35.7 ^b	49.6 ^b	35.9 ^b
TZD	3.7 ^a	2.9 ^a			22.2 ^a	18.0 ^a	34.3 ^b	20.8 ^b
Any oral antidiabetic	9.5 ^b	7.2 ^b			80.9 ^a	88.5 ^a	76.0 ^a	78.4 ^a
Baseline MPR (>80%)								
Insulin	52.8 ^b	63.5 ^b			59.6 ^b	80.4 ^b	45.9 ^b	54.4 ^b
Antidiabetic combinations	52.1 ^b	64.3 ^b			60.1 ^b	74.6 ^b	47.5 ^b	57.4 ^b
Sulfonylurea	57.7 ^b	70.6 ^b			64.7 ^b	81.8 ^b	51.3 ^b	59.1 ^b
Metformin	51.7 ^b	66.9 ^b			60.8 ^b	78.6 ^b	45.9 ^b	57.2 ^b
TZD	53.5 ^b	67.4 ^b			67.1 ^b	78.5 ^b	44.9 ^b	57.7 ^b
Any oral antidiabetic	53.8 ^b	67.6 ^b			62.6 ^b	78.9 ^b	47.0 ^b	57.9 ^b

MPR indicates medication possession ratio; TZD, thiazolidinedione; VBID, value-based insurance design.

^a $P < .01$.

^b $P < .001$.

as the proportion of all antidiabetic users with a lapse of at least 60 days following the exhaustion of days supply, including those users with 2 antidiabetic agents who discontinued 1 agent. Plan participants who changed from one antidiabetic therapeutic class to another during the follow-up period were excluded from this calculation.

We defined compliance using the medication possession ratio (MPR), calculated as the sum of the days supply of medication divided by the number of days between the first fill and the last refill, excluding the days supply of the last refill. The MPR scores were calculated among continuers only, were truncated at 100% for plan participants who consistently refilled early, and were calculated annually for calendar years 2006 and 2007 to determine changes in compliance (MPR difference). For plan participants on multiple antidiabetic classes (eg, metformin and insulin), MPR scores were a weighted average of class-level MPRs, weighted by days of therapy (in the drug class) in the follow-up period.

Analysis

The impact of implementing a VBID on medication adherence was analyzed by comparing the MPR, changes in MPR, and initiation and discontinuation rates between the 2 study populations. Analyses of variance and t tests were used for analyzing continuous data; the Pearson χ^2 test was used for categorical data. To adjust for population differences in age and sex, logistic regression models were constructed to assess the probability of discontinuing therapy, and linear regression models were constructed to predict follow-up MPR among initiators and difference in MPR (follow-up minus baseline) among continuers. When multivariable methods did not influence the relationship between benefit design and adherence (eg, linear regression models), only unadjusted results were reported. Data were analyzed using SAS version 9.1 (SAS Institute Inc, Cary, NC). All statistical tests were conducted at the $P < .05$ significance level.

Table 2. Comparisons of Initiation and Discontinuation Rates, Adherence, and Mean Change in Adherence Between VBID and Control Groups

Therapy	Initiators		Continuers	
	VBID	Control	VBID	Control
Insulin				
Initiation rate, %	0.8 ^a	0.4 ^a		
Discontinuation rate, %	26.4 ^a	40.2 ^a	33.1 ^a	45.8 ^a
Adherence of initiators, MPR	0.851	0.825		
Changes in compliance, MPR difference			0.082 ^a	-0.017 ^a
Oral antidiabetic drugs				
Initiation rate, %	2.3 ^a	1.4 ^a		
Discontinuation rate, %	13.2	16.2	19.5	18.2
Adherence of initiators, MPR	0.831	0.840		
Changes in compliance, MPR difference			0.022 ^a	-0.028 ^a
Any antidiabetic agents				
Initiation rate, %	2.3 ^a	1.6 ^a		
Discontinuation rate, %	16.0 ^a	24.3 ^a	26.0 ^b	29.8 ^b
Adherence of initiators, MPR	0.857	0.858		
Changes in compliance, MPR difference			0.049 ^a	-0.023 ^a

MPR indicates medication possession ratio; VBID, value-based insurance design.
^a*P* < .001.
^b*P* < .01.

This research was conducted in compliance with applicable laws governing the use and disclosure of protected health information, including the privacy regulation issued pursuant to the Health Insurance Portability and Accountability Act of 1996.

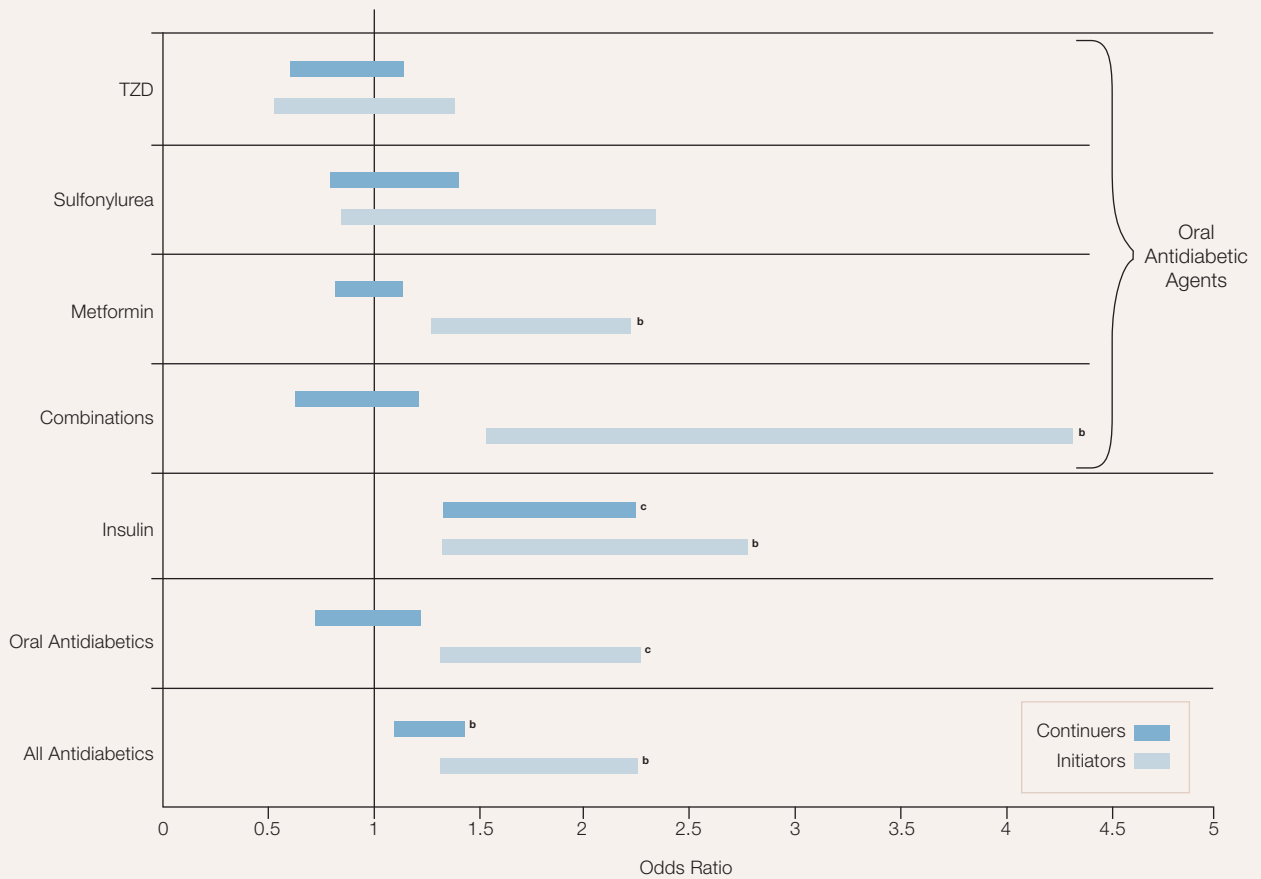
RESULTS

There were a total of 20,173 and 190,889 plan participants in the VBID and control groups, respectively (Table 1). The groups were similar with regard to age and sex. Nearly 10.3% of the VBID group and 8.1% of the control group used antidiabetic therapy during the baseline year, with higher rates of both insulin use (3.2% vs 1.8%; *P* < .01) and oral antidiabetic use (9.5% vs 7.2%; *P* < .001) among VBID participants. These treatment levels were appropriate and within the estimated 10.7% prevalence of diagnosed and undiagnosed diabetes among people age 20 years or older in the United States.¹³ However, the VBID population had substantially lower baseline MPR scores for insulin (MPR >80% for 52.8% vs 63.5%; *P* < .001) and for oral antidiabetic agents (MPR >80% for 53.8% vs 67.6%; *P* < .001).

During the follow-up period, therapy initiation rates among VBID plan participants were significantly higher than those among controls (insulin, 0.8% vs 0.4%; any oral antidiabetic drug, 2.3% vs 1.4%) (Table 2), but were within the national average, based on the annual age-adjusted incidence (or new cases) of diabetes of 5.0 to 12.8 per 1000 persons.¹⁴ The higher rates of initiation in the VBID group were noted in each therapeutic class, overall, and among each age and sex group. Furthermore, among VBID initiators, the subsequent rate of discontinuation was significantly lower in each therapeutic category compared with controls (Table 2). After adjusting for differences in age and sex, there were no differences in the likelihood of discontinuation in either TZDs or sulfonylureas. However, initiators in the control group had significantly higher odds of discontinuing metformin (odds ratio [OR] = 1.7; 95% confidence interval [CI] = 1.2, 2.2), oral antidiabetic combinations (OR = 2.5; 95% CI = 1.5, 4.3), and insulin (OR = 1.9; 95% CI = 1.3, 2.8), which translated to significantly higher odds of discontinuing any oral antidiabetic therapy and all antidiabetic therapy overall (Figure). In other words, an OR greater than 1, if statistically significant, indicated that therapy discontinuation was more likely in the control group, and an OR less than 1 indicated that discontinuation was less likely in the control group. Furthermore, there were no significant differences in average MPR scores for either insulin or the oral antidiabetics during the year subsequent to initiating therapy (Table 2). Among continuers, VBID plan participants were significantly less likely than controls to discontinue insulin therapy in 2007 (33.1% vs 45.8%; *P* < .001); however, there was no difference in the discontinuation rates of oral antidiabetic therapy (Table 2). These results persisted after adjustment for age and sex (Figure).

Adherence to antidiabetic therapy overall as measured by changes in MPR increased significantly (4.9% points; *P* < .001) in the VBID group (MPR difference 4.9%; SE = 0.007), whereas plan participants in the control group who remained in tiered plans decreased in the same period (MPR difference -2.3%; SE = 0.004). Improvements in MPR also were observed across the 2 therapeutic classes in

Figure. Adjusted Odds of Discontinuing Therapy in Initiators and Continuers: Control Versus Value-Based Insurance Design^a



TZD indicates thiazolidinedione.
^aAdjusted for age and sex. Referent group: value-based insurance design (odds ratio = 1).
^b*P* < .01.
^c*P* < .001.

the VBID group compared with the control group: insulin users (MPR difference 8.2% vs -1.7%) and oral antidiabetic users (MPR difference 2.2% vs -2.8%) (Table 2). These results persisted after adjusting for age, sex, and mail-order utilization.

DISCUSSION

Among patients with diabetes, glycemic control is achieved and maintained with proper diet and regular exercise, and often is supported by long-term use of prescription medications.^{14,15} The American Diabetes Association standards of medical care in diabetes recommend monotherapy as an adjunct to diet to lower blood glucose in patients with type 2 diabetes (non-insulin dependent) or in combination with a sulfonylurea, metformin, or insulin when diet plus monotherapy do not result in adequate glycemic control. However, patients routinely delay or underuse antidiabetic

pharmacotherapy.^{15,16} Although there are numerous reasons for undertreatment, prescription drug costs remain one of the most important barriers.^{9,16}

This study examined changes in prescription drug utilization behavior after implementation of a pharmacy benefit design that substantially lowered out-of-pocket costs for antidiabetic medications. In this study, converting from a traditional tiered formulary benefit to a VBID with substantially lower out-of-pocket costs for generic and brand medications resulted in higher levels of medication adherence (with MPRs increasing an average of 4.9%), an increase in treatment initiation rates, and a decrease in discontinuation rates.

The significantly higher treatment initiation rates in the VBID cohort, and the correspondingly low discontinuation rate in this population, suggest that some commercially insured individuals remain price sensitive and defer

treatment because of cost. The reported level of therapy use was appropriate if the initiator group consisted only of newly diagnosed participants but fairly modest even in the VBID group if existing diabetes patients with unmet treatment needs were included. National statistics reported that among adults with diagnosed diabetes (type 1 or type 2), 14% take insulin only, 13% take both insulin and oral medication, 57% take oral medication only, and 16% do not take either insulin or oral medication.¹⁵ Although patients with less advanced disease may manage their diabetes through diet and exercise alone and delay initiating oral antidiabetic drug therapy until they need more intensive glycemic control, the observed lower rate of treatment initiation among those in need of insulin in the control group suggests that plans with high levels of cost sharing also will reduce the use of essential medications.

Fewer plan participants ceased taking oral antidiabetic drugs than insulin, with no difference in discontinuation of oral agents between the VBID group and the controls (both initiators and continuers). One possible explanation for this similarity is that these plan participants, irrespective of plan design, already experienced a decrease in out-of-pocket spending due to the wide availability and use of generic oral antidiabetic drugs, so they would be less likely to discontinue their medications. Yet the VBID reduced the discontinuation rates among insulin users. We speculate that discontinuation of insulin was influenced directly by the cost share of medications that they would be or were taking—copayments for insulin decreased from \$28 to \$0 for VBID participants in the postchange period, whereas traditional participants faced a 22% increase to \$28 in the same time period. The out-of-pocket costs for oral antidiabetic drugs for the VBID group decreased more than 50% but did not change for the control group, which may have stabilized utilization in the control group. These findings are consistent with those of 2 other recent studies of benefit design changes in commercially insured populations that showed similar associations with utilization for diabetes and other chronic diseases, although neither of these studies reported the same degree of therapy discontinuation that we observed.^{17,18}

Although previous studies found that continuing users of chronic medications were less sensitive to price in responding to copayment increase,^{19,20} in our study the VBID dramatically improved adherence among continuers. It is possible that other plan benefit features (eg, use of generics) could influence adherence independently of copayment level. It also is noteworthy that adherence rates subsequent to initiation were similar for insulin and the oral antidiabetic classes, a result that runs contrary

to previous studies in which adherence to insulin has been shown to be significantly lower than adherence to oral medications.²¹ This benefit change lowered costs for insulin therapy more than it did for oral therapy (out-of-pocket spending for insulin and oral antidiabetic agents decreased 79% and 52%, respectively, in the postchange period); therefore, difference in adherence rates between therapeutic classes might have been equalized.

Several limitations to our study should be noted. First, because administrative pharmacy claims do not include diagnosis, we could not identify the diagnosed cases that were untreated, nor differentiate between type 1 and type 2 diabetes patients. However, in adult populations, type 2 diabetes represents about 90% to 95% of all cases.¹³ Second, despite the matching criteria, baseline utilization patterns were quite different between the VBID and control groups, although participant demographics were homogeneous. The results of this study need to be interpreted in light of these group differences. Finally, our results are limited to the first year after a benefit design change. The effects of sustained benefit changes on overall medication use likely continue beyond the first year and need to be confirmed with follow-up studies. Future research should quantify the impact of adherence to therapy on improved health outcomes and determine the causal factors leading to higher initiation rates for the VBID group. Additionally, studies that include a wider range of therapeutic classes, including acute and chronic medications, are needed.

CONCLUSIONS

Value-based insurance designs may help overcome some of the barriers to oral antidiabetic and insulin use. By reducing cost sharing and out-of-pocket costs, plan participants on diabetes medications receiving value-based plan coverage were more likely to initiate therapy, less likely to discontinue it, and had better medication adherence. These findings suggest that shifting plan participants from a traditional tiered plan design to a VBID is a viable alternative to existing health plan designs.

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