

Does the Offer of Free Prescriptions Increase Generic Prescribing?

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An increasingly popular strategy in value-based insurance design (VBID) is a preferred generic co-pay tier in which certain medications are available free of charge on the presumption this will shift demand away from expensive brand name drugs and produce savings for insurers and customers alike. Behavioral economists find that the demand for free goods tends to be much higher than for the same goods offered at very low prices. According to Anderson: “Free has the effect of bending the demand curve—demand shoots up in a very nonlinear fashion.”¹ Shampner and Ariely argue that this occurs because moving to free not only reduces cost, but also confers special benefits to consumers.² But does this phenomenon hold for prescription drugs? The answer to this question has obvious relevance to private payers using VBID precepts to set drug co-payment levels, and it is also important for public payers including Medicare, as evidenced by Medicare Payment Advisory Commission’s recommendation that co-payments for beneficiaries receiving low-income subsidies (LIS) be raised for brands but reduced to zero for generics.³

Recent articles by Hoadley et al⁴ and Tang et al⁵ would appear to support the wisdom of that policy based on analyses of Medicare beneficiaries’ use of statins, antidepressants, and antidiabetic drugs in Part D plans with and without zero co-pay tiers. However, neither study could account for formulary exclusions and both used cross-sectional designs that are potentially sensitive to selection bias (ie, if beneficiaries with a preference for generic drugs are drawn to plans offering them at no cost, this unobserved behavior will confound the true impact of zero co-pays on generic utilization). We designed the current study to be free of both sources of bias.

In brief, our approach exploited a natural experiment in which Part D enrollees receiving the LIS were randomized to benchmark plans in their region. Some of these plans offered zero generic co-pays and others did not. Randomization ensures equivalent beneficiary characteristics among all plans within a given region and eliminates selection bias. Any observed differences in generic utilization across plans must thus be due to plan policies, including free generics and differences in formulary restrictions. We

ABSTRACT

OBJECTIVES: To test if offering zero generic co-pays for oral antidiabetic drugs (OADs) and statins increases generic dispensing for low-income subsidy (LIS) recipients with diabetes enrolled in Medicare Part D.

STUDY DESIGN: We analyzed a natural experiment in which LIS recipients were randomized to Part D plans in 2008. Some plans placed selected generic OADs and statins on zero co-pay tiers whereas others did not. Randomization eliminated selection effects which could bias the study findings.

METHODS: We analyzed a 5% random sample of Medicare beneficiaries with diabetes from the Chronic Condition Data Warehouse using Part D claims, formulary provisions, and co-pay tiers together with a special file prepared by CMS that identified all randomly assigned LIS recipients in 2008. We calculated proportions using generic drugs in the 2 classes and annual days’ supply among users in plans with and without zero co-pay tiers for the country as a whole and California (where zero co-pay plans were particularly popular).

RESULTS: We found that the demand for generic OADs was not significantly different in plans with and without zero co-pay tiers. By contrast, a large difference was observed in the percent of LIS recipients using generic statins in plans with zero co-pay tiers (61.4% vs 54.6%; $P < .01$). However, the difference disappeared once we controlled for formulary restrictions on the most popular brand statin at the time (Lipitor).

CONCLUSIONS: This cautionary tale suggests that policy makers should give greater consideration to formulary provisions when evaluating the effects of free generics in value-based insurance designs.

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TAKEAWAY POINTS

An increasingly popular strategy in value-based health insurance designs, including some Part D plans, is to have a preferred generic tier with no co-pays for selected medications offered on the presumption this will shift demand away from expensive brand name drugs and produce savings for insurers and customers alike.

- ▶ We tested whether low versus zero generic co-pays in Part D plans had any significant impact on generic dispensing of antidiabetic drugs and statins and found none.
- ▶ Plans used both the pull of free drugs and the push of formulary restrictions to achieve higher rates of generic use, and it was the push rather than the pull that proved effective in the case of statins.
- ▶ This cautionary tale suggests that policy makers should give greater consideration to formulary provisions when evaluating the effects of free generics in value-based insurance designs.

focused the analyses on Medicare beneficiaries with diabetes who used oral hypoglycemic agents (ie, OADs) and/or statins in 2008.

METHODS

Data Source and Study Population

The study used 2008 data from a 5% random sample of the Medicare population from the CMS Chronic Condition Data Warehouse (CCW). The files included basic enrollment information by service type (Parts A, B, C, and D); Part D LIS status, including plan assignment method (beneficiary selection or CMS random assignment); paid claims records for all Medicare-covered services; and a special file provided us by CMS that contained complete formulary information on covered drugs and restrictions (prior authorization [PA], step therapy, and quantity limits) for every Part D plan.

We selected the study population as a subset of a sample of Medicare beneficiaries with diabetes drawn from a previously published study.⁶ The inclusion criteria for the original study cohorts were: 1) Medicare beneficiaries enrolled throughout 2008 with continuous Part A, B, and D coverage; 2) dual-eligible LIS recipients with incomes less than or equal to the federal poverty level and continuously enrolled in CMS-assigned benchmark prescription drug plans (PDPs); 3) diagnosed with diabetes based on *International Classification of Diseases, Ninth Revision, Clinical Modification* codes 250.xx, 357.2, 362.01, 362.02, or 366.41 on hospital inpatient and medical claims prior to 2008; and 4) filled at least 1 OAD and/or statin prescription in 2008.

Beneficiaries enrolled in Medicare Advantage prescription drug plans (MAPDs) were excluded because CMS does not randomly assign LIS recipients to MAPDs. LIS enrollees in long-term care nursing facilities were excluded because medications are centrally managed and available with no cost sharing. Finally, beneficiaries residing in American territories and Puerto Rico were excluded as we did not have information regarding generic substitution laws in these areas, which might affect generic utilization rates.

For the current study, we created 2 overlapping cohorts of

randomized LIS recipients who used OADs and/or statins in 2008. Each cohort was subdivided into 2 groups based on whether their assigned Part D plan offered any generic OADs or statins free of charge. Plans with zero generic co-pay tiers were identified using the following criteria. First, we limited the analysis to plans with at least 30 drug users in each cohort to assure there were multiple beneficiaries taking the most common generic drugs in each class. Next, we identified plans in which non-LIS enrollees had zero co-pays for all prescriptions filled for at least 1 generic

OAD or statin over the year. We then checked to determine whether all LIS recipients enrolled in these same plans also paid zero co-pays for the same generic medications. Plans meeting both criteria were considered zero co-pay plans. Nonzero co-pay tier plans were identified based on evidence that no generic OAD or statin was filled at zero co-pay tiers except for prescriptions filled by dual-eligible LIS recipients during the catastrophic phase of the Part D benefit. Individuals assigned to plans that did not offer free generics paid statutory co-pays of \$1.05 for generics and \$3.10 for brands.

Exploratory analyses showed that among all PDP regions, 49% of LIS enrollees in plans offering zero co-pays for some generic OADs and 59% of enrollees in plans offering zero co-pays for generic statins were California residents. Given the high popularity of zero co-pay tiers in California PDPs, we decided to estimate models both at the national level and for the state.

The **Figure** presents a flowchart showing how the study samples were selected, beginning with the entire CCW 5% sample of about 2.6 million beneficiaries and ending with the subsamples of LIS recipients randomized to California PDPs with and without zero co-pay provisions for OADs and statins.

Other Measures

Although random plan assignment would ensure the balance of enrollee characteristics within each Part D region, it would not ensure balance across regions. To address that issue, we identified a large number of personal factors that could plausibly influence rates of generic prescribing, including demographic characteristics, diabetes duration and severity, diabetes management activities, comorbidities, and utilization of Medicare services other than drugs. Individual variables in each of these domains are shown in the left-hand column of **Table 1**.

Randomization also does not control for plan policies, other than zero co-pay tiers, that might influence utilization of generic OADs and statins. The most obvious candidate here is plan formulary design given that Part D sponsors have been shown to use these drug lists to drive market demand.⁷ We used the First DataBank drug dictionary to identify all drugs within our 2 classes

of interest and then matched that against the CMS formulary file.⁸ This allowed us to identify all OADs and statins that were included and excluded from each plan formulary by name and brand/generic status. The formulary file also permitted us to identify all products with significant access restrictions requiring either PA or step therapy.

The 2 most common operational measures of formulary restrictions in the literature are the percentage of individuals subject to specific types of restrictions⁴ and a dummy variable indicating whether at least 1 drug in the class is subject to restriction.⁵ Neither approach captures the full impact of formulary designs on individual behavior because restrictions on popular drugs can have a much bigger effect than those placed on seldomly used products. Although our study was not focused primarily on the impact of formulary design, we were interested in whether formulary restrictiveness was correlated with plan policies for zero co-pays. We tested this association for all individual OADs and statins and discovered a strong positive correlation coefficient ($r = 0.5$) between restrictions on Lipitor (primarily formulary exclusions) and the offer of zero co-pays for generic statins. No other restrictions on commonly used drugs had correlation coefficients greater than 0.25. Based on these findings, we added a Lipitor restriction variable to our multivariate model together with count variables indicating the total number of OAD and statin drugs subject to formulary exclusion, PA, or step therapy.

Finally, because some Part D regions include several states, we controlled for state-level differences in generic substitution laws. There were 3 broad types of laws: 1) allows for generic substitution by pharmacists if “brand only” not indicated by physician, allows for brand if requested by patient, and mandates brand only if indicated by physician; 2) mandates generic substitution by pharmacists if “brand only” not indicated by physician, allows for brand if requested by patient, and mandates brand only if indicated by physician; and 3) mandates generic substitution if “brand only” not indicated by physician, and mandates brand if indicated by physician.

Statistical Analysis

We tested the relationship between zero co-pay tiers and generic utilization rates using a standard 2-part model design. The first equation in each set of models estimated the relationship between the availability of zero generic co-pays and the proportion of all

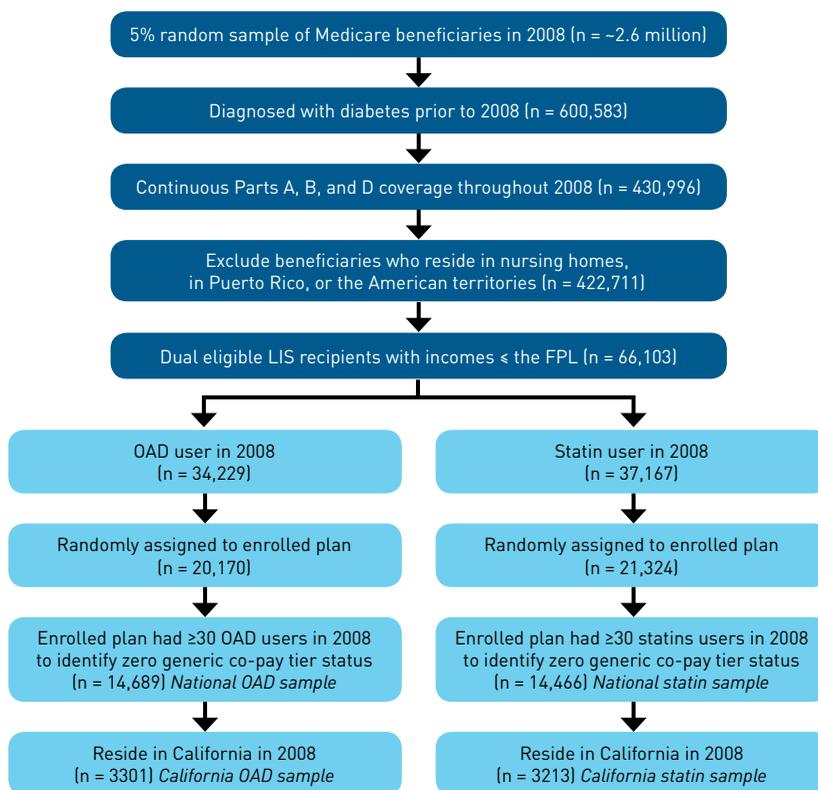
drug users filling any generic prescription. The second equation estimated the impact of zero co-pays on annual days' supply of generics filled by generic users. All models were estimated using ordinary least squares (OLS) regression, with the full set of covariates listed in Table 1. In the national models, we controlled for regional differences with 33 region dummies, with 1 region (32 for California) as the reference.

The study was approved by the University of Maryland Institutional Review Board.

RESULTS

Table 1 profiles the characteristics of our study cohorts of LIS recipients using OADs. At the national level, we identified 43 plans offering zero co-pays for generic OADs with a combined 3682 LIS enrollees meeting study inclusion/exclusion criteria. The most common free OADs in these plans were glipizide, glipizide XL, glyburide, and glyburide-metformin (Table 2). The comparison cohort included 11,007 LIS recipients enrolled in 242 plans that offered no free OADs. The 2 national cohorts exhibited somewhat different demographic characteristics, but had similar rates for

FIGURE. Sample Selection Flowchart



FPL, federal poverty level; LIS, low-income subsidy; OAD, oral antidiabetic drugs.

TABLE 1. Characteristics of Low-Income Subsidy Recipients Randomized to Part D Plans Nationally and in California With and Without Zero Co-Pay for Generic Oral Hypoglycemic Agents in 2008

	National		California	
	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier
Number of plans	43	242	3	8
Number of LIS recipients	3682	11,007	1790	1511
Characteristics				
Age, years: %				
<65	32.0	37.5 ^a	22.9	22.8
65-74	35.5	32.3	40.7	39.6
75-80	17.8	16.2	20.7	20.7
>80	14.7	14.0	15.8	16.9
Sex, %				
Male	36.0	32.0 ^a	40.4	38.9
Female	64.0	68.0	59.6	61.2
Race/ethnicity, %				
White	51.8	54.4 ^a	45.5	45.3
Black	18.5	25.5	8.7	8.4
Hispanic	14.4	10.1	22.3	21.8
Asian	11.6	6.2	18.7	18.2
Native American	0.6	1.3	0.7	0.5
Other	3.2	2.5	4.1	5.9
Diabetes duration/severity				
Months since first diagnosis, mean (SD)	57.6 (34.8)	57.1 (35.4)	56.5 (35.0)	55.7 (35.2)
Uncontrolled diabetes, ^b %	38.4	38.3	39.3	39.3
Long-term complications, ^c %	32.9	32.0	33.7	35.6
Short-term complications, ^d %	2.9	2.1 ^a	3.1	2.7
Comorbidities				
RxHCC counts, mean (SD)	7.3 (3.4)	7.4 (3.4)	7.2 (3.3)	7.4 (3.3) ^a
Chronic kidney disease, %	21.8	20.8	23.7	25.8
Cancer, %	6.8	6.0	7.4	7.5
Chronic heart failure, %	21.2	22.1	21.1	23.3
COPD, %	22.1	25.5 ^a	18.3	22.2 ^a
Cognitive impairment, %	10.3	9.5	9.6	9.1
Mental illness, %	25.2	30.2 ^a	17.7	17.5
Healthcare utilization				
Hospital days, mean (SD)	3.3 (20.2)	3.8 (17.4)	2.3 (8.0)	2.7 (7.9)
SNF days, mean (SD)	0.8 (5.5)	0.8 (6.2)	0.7 (5.5)	0.7 (5.8)
Physician visits, mean (SD)	11.6 (9.2)	11.6 (9.6)	11.9 (9.1)	12.7 (9.3) ^a
Number of chronic medications, mean (SD)	8.9 (3.8)	9.0 (3.8)	8.73(3.64)	8.8 (3.7)
Part A payments, mean (SD)	5341 (15,650)	5373 (14,953)	5297 (17,464)	5687 (15,863)
Part B payments, mean (SD)	6405 (10,329)	7045 (11,337) ^a	6155 (9838)	6610 (10,189)

(continued)

TABLE 1. Characteristics of Low-Income Subsidy Recipients Randomized to Part D Plans Nationally and in California With and Without Zero Co-Pay for Generic Oral Hypoglycemic Agents in 2008 (continued)

	National		California	
	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier
Diabetes management, %				
A1C test	85.2	87.1 ^a	83.9	86.5 ^a
Eye exam	44.0	42.9	47.3	45.5
LDL-C test	79.9	78.3 ^a	82.0	79.6
Influenza vaccination	44.5	45.3	45.5	44.7
Plan formulary restrictions				
Number of OAD drugs subject to major formulary restriction, mean (SD)	12.0 (6.3)	9.0 (6.57) ^a	9.5 (7.5)	12.4 (2.3) ^a
State substitution law category, %				
Category I ^e	76.7	72.7 ^a	–	–
Category II ^f	14.4	18.0	–	–
Category III ^g	8.9	9.3	–	–

A1C indicates glycated hemoglobin; COPD, chronic obstructive pulmonary disease; LDL-C, low-density lipoprotein cholesterol; LIS, low-income subsidy; OAD, oral antidiabetic drug; RxHCC, Prescription Drug Hierarchical Condition Categories; SD, standard deviation; SNF, skilled nursing facility.

^aDifference between enrollees by zero co-pay tier status significant at $P < .05$.

^bPresence of 1 of the following *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes in the primary diagnosis field of any Part A or Part B claim type: 25002, 25003.

^cPresence of 1 of the following *ICD-9-CM* codes in the primary diagnosis field of any Part A or Part B claim type: 25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093.

^dPresence of 1 of the following *ICD-9-CM* codes in the primary diagnosis field of any Part A or Part B claim type: 25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033.

^eState law: allows for generic substitution by pharmacists if "brand only" not indicated by physician, allows for brand if requested by patient, and mandates "brand only" if indicated by physician. States include AL, AK, AZ, AR, CA, CO, CT, DE, DE,GA, ID, IL, IN, IA, KS, LA, MD, MI, MS, MO, MT, NE, NH, NM, NC, ND, OH, OK, OR, PA, SC, SD, TX, UT, VA, WI, and WY.

^fState law: mandates generic substitution by pharmacists if "brand only" not indicated by physician, allows for brand if requested by patient, and mandates "brand only" if indicated by physician. States include FL, HI, KY, MN, NV, NJ, RI, TN, VR, WA, and WV.

^gState law: mandates generic substitution by pharmacists if "brand only" not indicated by physician, and mandates "brand only" if indicated by physician. States include ME, MA, and NY.

TABLE 2. Oral Hypoglycemic Agents and Statins Placed on Zero Co-Pay Tiers by Benchmark Part D Plans in 2008

Product	Percent of Plans
Oral hypoglycemic agents on zero co-pay tiers	
Glipizide XL	41.9
Glipizide	37.2
Glyburide-metformin	32.6
Glyburide	25.6
Glimepride	20.9
Glipizide ER	20.9
Metformin HCL	20.9
Glyburide micronized	16.3
Acarbose	16.3
Glipizide-metformin	9.3
Chlorpropamide	4.7
Statins on zero co-pay tiers	
Pravastatin sodium	56.7
Lovastatin	53.3
Simvastatin	23.3

diabetes severity, comorbidities, and Medicare utilization. The biggest difference between the 2 plan types was in the number of OADs subject to formulary exclusion or major restriction (12 in zero co-pay plans vs 9 in nonzero co-pay plans).

By contrast, the 2 California cohorts had virtually identical characteristics, as would be expected given random assignment (California is a single PDP region). We identified 3 California PDPs that offered free OADs ($n = 1790$) and 8 that did not ($n = 1511$). Unlike plans in other regions, the California PDPs offering free OADs actually placed major formulary restrictions on fewer individual products compared with other plans (9.5 vs 12.4).

Table 3 presents similar data for our statin user cohorts. Nationally, 30 PDPs with 3334 LIS enrollees offered enrollees free generic statins in 2008 compared with 223 ($n = 11,132$) that did not. Over half of the zero co-pay plans offered either pravastatin and/or lovastatin free and just under a quarter offered free simvastatin (Table 2). Both types of plans placed formulary restrictions on many statin products. Lipitor was subject to major formulary restrictions for two-thirds of LIS recipients enrolled in zero co-pay plans nationally compared with just 21% in nonzero co-pay plans. In California, about half of the LIS recipients in zero co-pay plans

TABLE 3. Characteristics of Low-Income Subsidy Recipients Randomized to Part D Plans Nationally and in California With and Without Zero Co-Pay for Generic Statins in 2008

	National		California	
	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier
Number of plans	30	223	3	6
Number of LIS recipients	3334	11,132	1970	1243
Characteristics				
Age, years: %				
<65	27.0	35.8 ^a	20.0	20.0
65-74	36.2	31.8	39.9	39.1
75-80	19.7	17.4	22.0	22.0
>80	17.0	15.0	18.2	18.1
Sex, %				
Male	36.5	31.7 ^a	39.6	38.1
Female	63.5	68.3	60.4	61.9
Race/ethnicity, %				
White	51.6	56.1 ^a	47.3	46.5
Black	15.8	25.6	8.8	8.1
Hispanic	15.6	8.4	20.2	18.9
Asian	13.0	6.4	19.0	21.1
Native American	0.5	1.2	0.7	0.4
Other	3.4	2.3	4.1	5.1
Diabetes duration/severity				
Months since first diagnosis, mean (SD)	54.2 (34.6)	55.0 (34.9)	52.8 (34.4)	52.7 (34.4)
Uncontrolled diabetes, ^b %	31.9	32.3	31.4	31.1
Long-term complications, ^c %	28.8	28.6	27.8	28.6
Short-term complications, ^d %	2.1	2.2	2.3	2.2
Comorbidities				
RxHCC counts, mean (SD)	7.8 (3.5)	7.8 (3.4)	7.6 (3.3)	7.7 (3.4)
Chronic kidney disease, %	25.9	24.4	26.2	26.5
Cancer, %	6.8	6.4	7.4	7.6
Chronic heart failure, %	24.7	25.5	24.9	27.8
COPD, %	23.3	27.9 ^a	21.2	23.3
Cognitive impairment, %	11.1	10.3	10.7	9.2
Mental illness, %	24.4	30.7 ^a	18.9	19.0
Healthcare utilization				
Hospital days, mean (SD)	3.1 (8.9)	4.0 (15.2) ^a	2.4 (7.3)	2.9 (8.5)
SNF days, mean (SD)	0.9 (6.5)	0.9 (6.5)	0.8 (6.5)	0.7 (5.5)
Physician visits, mean (SD)	12.4 (9.3)	12.2 (9.8)	12.7 (9.3)	13.0 (9.7)
Number of chronic medications, mean (SD)	8.9 (3.7)	9.3 (3.7) ^a	8.7 (3.6)	8.9 (3.7)
Part A payments, mean (SD)	6117 (17,137)	6201 (16,503)	5677 (17,296)	5808 (15,543)
Part B payments, mean (SD)	7332 (11,495)	8002 (12,296) ^a	6989 (10,579)	7005 (10,922)

(continued)

TABLE 3. Characteristics of Low-Income Subsidy Recipients Randomized to Part D Plans Nationally and in California With and Without Zero Co-Pay for Generic Statins in 2008 (Continued)

	National		California	
	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier	Zero Generic Co-Pay Tier	No Zero Generic Co-Pay Tier
Diabetes management, %				
A1C test	76.2	78.1 ^a	75.6	76.2
Eye exam	46.3	43.5 ^a	48.2	46.8
LDL-C test	85.2	82.3 ^a	86.4	82.9 ^a
Influenza vaccination	48.7	49.4	48.7	47.6
Plan formulary restrictions				
Number of STN drugs subject to major formulary restriction, mean (SD)	7.8 (1.9)	6.5 (3.5) ^a	7.0 (2.0)	8.5 (1.6) ^a
Lipitor restriction	67.8	21.3 ^a	48.7	1.8 ^a
State substitution law category, %				
Category I ^e	77.0	69.5 ^a	–	–
Category II ^f	14.2	20.1	–	–
Category III ^g	8.8	10.5	–	–

A1C indicates glycated hemoglobin; COPD, chronic obstructive pulmonary disease; LDL-C, low-density lipoprotein cholesterol; LIS, low-income subsidy; RxHCC, Prescription Drug Hierarchical Condition Categories; SD, standard deviation; SNF, skilled nursing facility; STN, statin.

^aDifference between enrollees by zero co-pay tier status significant at $P < .05$.

^bPresence of 1 of the following *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes in the primary diagnosis field of any Part A or Part B claim type: 25002, 25003.

^cPresence of 1 of the following *ICD-9-CM* codes in the primary diagnosis field of any Part A or Part B claim type: 25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093.

^dPresence of 1 of the following *ICD-9-CM* codes in the primary diagnosis field of any Part A or Part B claim type: 25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033.

^eState law: allows for generic substitution by pharmacists if “brand only” not indicated by physician, allows for brand if requested by patient, and mandates “brand only” if indicated by physician. States include AL, AK, AZ, AR, CA, CO, CT, DE, DE.GA, ID, IL, IN, IA, KS, LA, MD, MI, MS, MO, MT, NE, NH, NM, NC, ND, OH, OK, OR, PA, SC, SD, TX, UT, VA, WI, and WY.

^fState law: mandates generic substitution by pharmacists if “brand only” not indicated by physician, allows for brand if requested by patient, and mandates “brand only” if indicated by physician. States include FL, HI, KY, MN, NV, NJ, RI, TN, VR, WA, and WV.

^gState law: mandates generic substitution by pharmacists if “brand only” not indicated by physician, and mandates “brand only” if indicated by physician. States include ME, MA, and NY.

faced restrictions on Lipitor, whereas only 1.8% of enrollees in nonzero co-pay plans did so.

We found that very high percentages of LIS recipients used generic OADs (>86%) in the national-level analyses (Table 4). There was a small, nonsignificant 1.2% difference in the percentage of OAD users who filled any prescription for a generic OAD between plans with and without zero co-pay tiers. Zero co-pay status also had a small 1.7-day nonsignificant effect on the annual days' supply of OADs among generic users. Adjustment for all covariates, including counts of OADs subject to major formulary restrictions, had no effect on these results (complete results from all regressions are available in the eAppendix [eAppendices available at ajmc.com]). Findings were similar in the OAD analyses restricted to California PDPs.

Our statin analyses produced very different results. Much smaller percentages of the study population used generic statins compared with generic OADs, and there was a marked difference in unadjusted generic statin user rates between plans with and without zero co-pay tiers (61.4% vs 54.6% in the national-level analysis and 53.4% vs 41.1% in the California analyses, respectively;

both significant at $P < .01$). In the unadjusted comparisons, annual days' supply of statins was 8.4 days lower in zero co-pay PDPs ($P < .01$) nationally and 3.4 days (nonsignificant) lower in California.

After adjustment, all significant differences in generic statin use disappeared. To see if Lipitor restrictions were responsible for the dramatic difference in the proportions of generic statin users in zero versus nonzero co-pay plans, we estimated other-wise identical regressions excluding that variable. Without Lipitor restrictions in the models, the adjusted effects associated with zero co-pays were almost as high as in the unadjusted models (results not shown). Formulary restrictions—and Lipitor restrictions in particular—explain why generic statin use was much higher in PDPs with zero co-pays.

DISCUSSION

Using a study design with high internal validity based on random assignment, we found little evidence of any bounce in demand for generic OADs or statins among LIS recipients enrolled in plans

TABLE 4. Enrollment, Use, and Days' Supply With Generics Among LIS Recipients Randomized to Part D Plans With and Without Zero Co-Pays for Generic OADs and Statins in 2008

Characteristic	Zero Generic Co-Pay Plans	Nonzero Generic Co-Pay Plans	Unadjusted Difference in Percentage Use/ Days' Supply	Adjusted Difference in Percentage Use/ Days' Supply
Oral Hypoglycemic Agents (OADs)				
National level				
Percentage using generic OADs	87.9%	86.7%	1.2% (<i>P</i> = .06)	0.2% (<i>P</i> = .83)
Mean days' supply (SD) among OAD users	337.8 (196.1)	336.2 (188.9)	1.7 days (<i>P</i> = .67)	-0.3 days (<i>P</i> = .94)
California				
Percentage using generic OADs	86.7%	87.2%	-0.5% (<i>P</i> = .70)	-0.8% (<i>P</i> = .53)
Mean days' supply (SD) among OAD users	329.5 (195.8)	329.2 (188.2)	0.3 days (<i>P</i> = .97)	-5.1 days (<i>P</i> = .48)
Statins				
National level				
Percentage using generic statins	61.4%	54.6%	6.9% (<i>P</i> < .01)	-1.1% (<i>P</i> = .37)
Mean days' supply (SD) among statin users	237.1 (123.1)	245.5 (123.0)	-8.4 days (<i>P</i> < .01)	0.1 days (<i>P</i> = .98)
California				
Percentage using generic statins	53.4%	41.1%	12.3% (<i>P</i> < .01)	4.1% (<i>P</i> = .27)
Mean days' supply (SD) among statin users	223.1 (125.6)	226.5 (127.1)	-3.4 days (<i>P</i> < .63)	8.2 days (<i>P</i> = .59)

LIS indicates low-income subsidy; OAD, oral antidiabetic drug; SD, standard deviation.

offering zero co-pays for selected generics in these 2 drug classes. This lack of response is consistent with recent study results showing that low-income individuals are generally not sensitive to small changes in prescription drug prices.^{6,9,10} However, it is not what we expected to find based on other experimental studies of demand for free goods, the results of which have shown a marked spike in demand at zero prices.^{1,2} One plausible reason for this null finding is that, unlike other consumer goods, prescription drugs depend on physician orders, and physicians may either be reluctant to change their recommended medications in response to small patient savings or they may be unaware that the drugs are available free.

Our results are also inconsistent with findings published by Hoadley et al⁴ and Tang et al.⁵ For example, Hoadley et al found that in 2008 (the same year as in our study), the probability of using any generic statin was 13% higher in plans with zero co-pays compared with plans in which the mean generic co-pay was \$5.15. Their analysis excluded LIS recipients, so the price differential between those enrolled in plans with and without a zero co-pay tier was somewhat larger than in our study, but the unadjusted effect size was virtually the same (12.5% difference in our national-level analysis). We determined this difference was attributable solely to formulary restrictions on Lipitor, not zero co-pays.

The CMS Part D formulary file was not available to researchers until 2010, but we had access to an earlier beta version of this file for 2008. Researchers using standard CCW files prior to 2010 had access to flags for PA, step therapy, and quantity limits from the CCW plan characteristics file for drugs filled by at least 1 Part D enrollee included

in the researcher's study sample. However, these flags systematically underestimate the true extent of formulary restrictions, because formulary exclusions are not accounted for and other restrictions are undercounted in cases where no enrollee used drugs subject to utilization management. These effects can be quite large: based on the CMS beta version of the 2008 formulary file, we found that 16.2% of all benchmark plans excluded Lipitor as a covered drug, 7.5% placed it on PA, and 7.1% required step therapy. By contrast, Hoadley et al, using the 2008 plan characteristics file flags, determined that no Part D plan required either PA or step therapy for Lipitor.

Limitations

Our focus on LIS recipients with diabetes means that we cannot generalize our results to other segments of the Medicare Part D population. However, it is worth noting that LIS recipients account for 40% of the entire Part D enrollment and about 55% of program costs.¹¹ Diabetes is one of the most prevalent chronic conditions in the Medicare population, affecting 28% of all beneficiaries in 2014.¹²

Examining zero co-pay effects on individuals who are otherwise subject to nominal cost sharing represents perhaps the strongest test of the hypothesis that "free" confers special benefits to users of chronic care medications. Based on the economics literature, we had expected a spike in demand at zero price even though the absolute reduction in out-of-pocket cost was minimal; that turned out not to be the case. Moreover, one might have expected that LIS recipients would be sensitive to even small price differences given their low incomes, but that too was not confirmed.

Second, we examined just 2 drug classes and further research is necessary to determine whether the effects we found for OADs and statins also apply to other classes. Both classes included many different products, which should make generic substitution relatively easy. Zero co-pay tiers could have a different impact in classes with fewer medications.

Third, although we were able to control for confounding associated with formulary exclusion and restrictions, we did not have access to other plan policies that could conceivably bias our results. For example, one common aspect of medication therapy management programs is for pharmacists to provide patients with information about possible generic substitution. Disease management and wellness programs might have a similar effect.

Lastly, our data are for 2008 when VBID pricing precepts applied by Part D plans were less developed than today. The fact that zero generic co-pay tiers are much more commonly used today only increases the relevance of our study findings. Part D plan formularies are also much more restrictive than they were in 2008. How these 2 trends interact is an important unanswered question that warrants future research.

CONCLUSIONS

Some Part D plans use both the pull of free drugs and the push of formulary restrictions to achieve higher rates of generic use. In this study, the push, rather than the pull, proved effective. This cautionary tale suggests that policy makers should give greater consideration to formulary provisions when evaluating the effects of free generics in VBIDs. ■

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eAppendix

eAppendix Table 1. Full Regression Model Results for Probability of Use of Generic Oral Hypoglycemic Agents (OADs) and Annual Days Supply Among Users in 2008 at National Level

Characteristics	Coefficient (Standard Error)		
	Probability of Use (in %) N=14,689	Annual Days Supply N=12,781	
LIS support category			
Nonzero positive copay generic plan	Reference	Reference	
Zero copay generic plan	0.15 (0.69)	-0.31 (4.25)	
Age			
<65	0.58 (0.69)	-17.29 (4.19)	*
65-74	Reference	Reference	
75-80	0.39 (0.87)	-5.25 (5.01)	
80+	-0.54 (0.96)	-12.51 (5.21)	*
Sex			
Male	Reference	Reference	
Female	-1.33 (0.6)	-12.73 (3.63)	*
Race			
White	Reference	Reference	
Black	0.35 (0.73)	-29.47 (4.26)	*
Hispanic	-1.63 (0.98)	-24.86 (5.66)	*
Asian	-1.4 (1.15)	12.77 (6.83)	
Native American	-4.99 (2.92)	-33.85 (16.36)	*
Other	-4.57 (1.95)	6.84 (10.95)	*
Diabetes duration/severity			
Months since 1 st diagnosis (per month)	-0.011 (0.01)	0.48 (0.05)	*

Uncontrolled diabetes ^a	1.37 (0.58)	*	-0.96 (3.51)	
Long-term complications ^b	0.94 (0.63)		2.79 (3.75)	
Short-term complications ^c	1.93 (1.74)		-5.4 (11.09)	
Comorbidities				
RxHCC counts (per RxHCC)	-0.43 (0.14)	*	-7.21 (0.79)	*
Chronic kidney disease	-5.47 (0.8)	*	-30.08 (4.31)	*
Cancer	2.57 (1.15)	*	4.5 (6.6)	
Chronic heart failure	-1.48 (0.8)		-16.33 (4.47)	*
Chronic obstructive pulmonary disorder	-0.4 (0.73)		-13.63 (4.23)	*
Cognitive impairment	1.42 (1.03)		-0.98 (5.88)	
Mental illness	-0.36 (0.69)		1.35 (4.13)	
Health care utilization				
Hospital days (per day)	0.02 (0.01)	*	-0.02 (0.09)	
SNF days (per day)	-0.04 (0.06)		-0.39 (0.27)	
Physician visits (per visit)	-0.03 (0.04)		-0.21 (0.22)	
Number of chronic medications (per medication)	0.65 (0.09)	*	9.38 (0.57)	*
Part A payments (per dollar)	0.00006 (0.00002)	*	-0.001 (0.0001)	*
Part B payments (per dollar)	-0.00021 (0.00004)	*	-0.001 (0.0002)	*
Diabetes management				
HbA1C test	-0.28 (0.92)		36.99 (5.35)	*
Eye exam	0.55 (0.58)		16.3 (3.44)	*
LDL-C test	-0.74 (0.77)		14.18 (4.55)	*
Influenza vaccination	-0.94 (0.58)		20.26 (3.42)	*
Plan formulary restrictions				

Number OAD drugs subject to utilization management (per drug)	0.16 (0.05)	*	0.25 (0.27)	
Lipitor restriction	-		-	
State substitution law category				
Category I ^d	Reference		Reference	
Category II ^e	-0.08 (1.44)		7.69 (8.6)	
Category III ^f	2.78 (3.78)		40.12 (24.14)	
PDP region				
PDP region 1	2.92 (4.1)		-15.44 (25.56)	
PDP region 2	-0.69 (3.35)		1.62 (21.76)	
PDP region 3	-2.54 (3.97)		-20.55 (25.14)	
PDP region 4	-4.49 (2.5)		22.19 (14.72)	
PDP region 5	-3.32 (2.07)		31.86 (12)	*
PDP region 6	-0.83 (1.98)		19.46 (12.13)	
PDP region 7	-0.2 (1.85)		9.88 (10.4)	
PDP region 8	-4.97 (1.56)	*	-10.42 (8.49)	
PDP region 9	-2.96 (1.99)		-6.82 (10.29)	
PDP region 10	-2.61 (2.27)		-4.95 (12.59)	
PDP region 11	1.14 (2.11)		14.29 (12.06)	
PDP region 12	-0.5 (1.63)		-4.06 (9.84)	
PDP region 13	3.15 (1.32)	*	40.56 (9.21)	*
PDP region 14	-0.2 (1.73)		26.9 (10.5)	*
PDP region 15	0.36 (1.85)		-0.97 (10.79)	
PDP region 16	-2.85 (2.88)		42.52 (17.25)	*
PDP region 17	2.94 (1.2)	*	45.99 (8.03)	*
PDP region 18	3.66 (2.45)		19.06 (16.22)	
PDP region 19	2.2 (3.44)		-28.76 (19.52)	

PDP region 20	-7.89 (2.72)	*	-11.79 (12.86)	
PDP region 21	-5.68 (2.79)	*	-6.71 (14.45)	
PDP region 22	-1.07 (1.38)		-14.29 (7.29)	
PDP region 23	2.06 (2.55)		23.53 (15.13)	
PDP region 24	-2.37 (4.14)		-18.06 (19.51)	
PDP region 25	-2.81 (2.21)		10.37 (13.19)	
PDP region 26	6.05 (3.84)		65.06 (24.99)	*
PDP region 27	4.13 (3.44)		-25.93 (26.87)	
PDP region 28	3.02 (2.82)		-10.27 (16.34)	
PDP region 29	14.03 (2.61)	*	-45.06 (54.85)	
PDP region 30	6.34 (1.92)	*	27.29 (13.23)	*
PDP region 31	-0.44 (4.41)		-13.4 (17.31)	
PDP region 32	Reference		Reference	
PDP region 33	1 (5.02)		-61.49 (26.22)	*

^aPresence of one of the following ICD9 codes (25002, 25003) in the primary diagnosis field of any Part A or Part B claim type.

^bPresence of one of the following ICD9 codes (25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093) in the primary diagnosis field of any Part A or Part B claim type .

^cPresence of one of the following ICD9 codes (25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033) in the primary diagnosis field of any Part A or Part B claim type.

^dState law: Allows for generic substitution by pharmacists if "brand only" not indicated by physician; allows for brand if requested by patient; and mandates brand only if indicated by physician. States include AL, AK, AZ, AR, CA, CO, CT, DE, DE,GA, ID, IL, IN, IA, KS, LA, MD, MI, MS, MO, MT, NE, NH, NM, NC, ND, OH, OK, OR, PA, SC, SD, TX, UT, VA, WI, and WY.

^eState law: Mandates generic substitution by pharmacists if "brand only" not Indicated by physician; allows for brand if requested by patient; and mandates brand only if indicated by physician. States include FL, HI, KY, MN, NV, NJ, RI, TN, VR, WA, and WV.

^fState law: Mandates generic substitution by pharmacists if "brand only" not Indicated by physician; and mandates brand only if indicated by physician. States include ME, MA, and NY.

eAppendix Table 2. Full Regression Model Results for Probability of Use of Generic Oral Hypoglycemic Agents (OADs) and Annual Days Supply Among Users who Reside in California in 2008

Characteristics	Coefficient (Standard Error)	
	Probability of Use (in %) N=3,301	Annual Days Supply N=2,869
LIS support category		
Nonzero positive copay generic plan	Reference	Reference
Zero copay generic plan	-0.77 (1.23)	-5.05 (7.2)
Age		
<65	1.83 (1.46)	0.55 (9.54)
65-74	Reference	Reference
75-80	-1.84 (1.73)	-5.83 (9.75)
80+	-1.59 (1.92)	-28.4 (10.62) *
Sex		
Male	Reference	Reference
Female	-1.84 (1.21)	-12.09 (7.43)
Race		
White	Reference	Reference
Black	-0.89 (2.07)	-35.83 (12.39) *
Hispanic	-2.04 (1.53)	-13.99 (9.14)
Asian	-2.16 (1.72)	8.93 (9.93)
Native American	-8.91 (8.87)	-95.42 (44.91) *
Other	-5.43 (3.16)	4.7 (18.3)
Diabetes duration/severity		
Months since 1 st diagnosis (per month)	0.001 (0.02)	0.49 (0.11) *
Uncontrolled diabetes ^a	1.53 (1.23)	4.87 (7.3)

Long-term complications ^b	2.9 (1.28)	*	6.05 (7.85)	
Short-term complications ^c	0.59 (3.43)		-13.58 (20.52)	
Comorbidities				
RxHCC counts (per RxHCC)	-0.87 (0.3)	*	-6.73 (1.7)	*
Chronic kidney disease	-4.78 (1.62)	*	-40.1 (8.93)	*
Cancer	2.38 (2.32)		13.21 (13.55)	
Chronic heart failure	-1.03 (1.71)		-12.07 (9.66)	
Chronic obstructive pulmonary disorder	1.02 (1.64)		-10.81 (9.65)	
Cognitive impairment	-1.18 (2.33)		4.45 (14.09)	
Mental illness	0.15 (1.67)		1.99 (10.32)	
Health care utilization				
Hospital days (per day)	0.15 (0.13)		-1.39 (0.74)	
SNF days (per day)	-0.04 (0.14)		-0.34 (0.66)	
Physician visits (per visit)	0 (0.09)		-0.05 (0.49)	
Number of chronic medications (per medication)	0.53 (0.21)	*	9.94 (1.2)	*
Part A payments (per dollar)	0.00004 (0.00008)		0 (0.0004)	
Part B payments (per dollar)	-0.00015 (0.00008)		-0.001 (0.0004)	
Diabetes management				
HbA1C test	1.24 (1.93)		35.12 (11.04)	*
Eye exam	0.76 (1.23)		11.99 (7.36)	
LDL-C test	0.47 (1.71)		-1.9 (10.33)	
Influenza vaccination	-1.94 (1.24)		20.55 (7.45)	*
Plan formulary restrictions				
Number OAD drugs subject to utilization management (per drug)	-0.02 (0.1)		-0.52 (0.62)	
Lipitor restriction	-		-	

^aPresence of one of the following ICD9 codes (25002, 25003) in the primary diagnosis field of any Part A or Part B claim type.

^bPresence of one of the following ICD9 codes (25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093) in the primary diagnosis field of any Part A or Part B claim type .

^cPresence of one of the following ICD9 codes (25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033) in the primary diagnosis field of any Part A or Part B claim type.

eAppendix Table 3. Full Regression Model Results for Probability of Use of Generic Statins (STNs) and Annual Days Supply Among Users in 2008 at National Level

Characteristics	Coefficient (standard error)			
	Probability of Use (in %) N=14,466	Annual Days Supply N=8,126		
LIS support category				
Nonzero positive copay generic plan	Reference	Reference		
Zero copay generic plan	-1.11 (1.24)	0.09 (4.05)		
Age				
<65	-1.47 (1.02)	-13.71 (3.42)	*	
65-74	Reference	Reference		
75-80	-1.29 (1.19)	2.44 (4.03)		
80+	0.73 (1.27)	14.63 (4.13)	*	
Sex				
Male	Reference	Reference		
Female	-1.2 (0.87)	-5.11 (2.91)		
Race				
White	Reference	Reference		
Black	3.25 (1.05)	-28.15 (3.51)	*	*
Hispanic	2.18 (1.42)	-30.8 (4.64)		*
Asian	-3.51 (1.64)	-13.9 (5.7)	*	*
Native American	12.95 (4.13)	-29.71 (13.82)	*	*
Other	-2.64 (2.57)	-11.91 (8.92)		
Diabetes duration/severity				
Months since 1 st diagnosis (per month)	-0.04 (0.01)	0.17 (0.04)	*	*
Uncontrolled diabetes ^a	-0.12 (0.9)	-9.18 (3.03)		*

Long-term complications ^b	-0.36 (0.96)		1.82 (3.2)	
Short-term complications ^c	2.04 (2.68)		-13.19 (9.03)	
Comorbidities				
RxHCC counts (per RxHCC)	0.077 (0.19)		-3.94 (0.64)	*
Chronic kidney disease	-2.21 (1.04)	*	7.19 (3.5)	*
Cancer	1.21 (1.62)		10.17 (5.43)	
Chronic heart failure	0.34 (1.06)		3.84 (3.5)	
Chronic obstructive pulmonary disorder	-0.98 (0.99)		-0.9 (3.29)	
Cognitive impairment	-0.95 (1.38)		9.15 (4.56)	*
Mental illness	0.65 (0.98)		1.92 (3.33)	
Health care utilization				
Hospital days (per day)	0.11 (0.03)	*	-0.32 (0.11)	*
SNF days (per day)	0.25 (0.06)	*	-0.39 (0.18)	*
Physician visits (per visit)	-0.08 (0.05)		-0.01 (0.18)	
Number of chronic medications (per medication)	-0.19 (0.14)		3.01 (0.47)	*
Part A payments (per dollar)	0.00009 (0.00004)	*	-0.0004 (0.0001)	*
Part B payments (per dollar)	0.00005 (0.00004)		0.0001 (0.0001)	
Diabetes management				
HbA1C test	1.6 (1.06)		9.68 (3.61)	*
Eye exam	-0.25 (0.83)		11.95 (2.79)	*
LDL-C test	0.12 (1.14)		0.56 (3.84)	
Influenza vaccination	0.15 (0.82)		21.18 (2.72)	*
Plan formulary restrictions				
Number STN drugs subject to utilization management (per drug)	0.91 (0.14)	*	-0.29 (0.48)	
Lipitor restriction	23.74 (1.06)	*	4.06 (3.41)	
State substitution law category				

Category I ^d	Reference	Reference	
Category II ^e	0.94 (2.1)	-7.13 (6.81)	
Category III ^f	5.3 (6.83)	5.26 (20.95)	
PDP region			
PDP region 1	5.46 (7.92)	66.53 (20.81)	*
PDP region 2	3.99 (6.21)	20.64 (20.14)	
PDP region 3	0.35 (7.06)	20.76 (21.78)	
PDP region 4	1.6 (3.19)	22.6 (10.8)	*
PDP region 5	1.78 (2.99)	44.53 (10.02)	*
PDP region 6	6.34 (2.81)	30.29 (9.48)	*
PDP region 7	21.79 (2.94)	42.82 (9.25)	*
PDP region 8	1.51 (2.04)	24.16 (7.1)	*
PDP region 9	1.18 (2.88)	8.47 (10.18)	
PDP region 10	20.9 (3.46)	22.95 (11.06)	*
PDP region 11	12.44 (2.93)	11.23 (9.68)	
PDP region 12	23.34 (2.4)	27.76 (7.86)	*
PDP region 13	8.03 (2.05)	21.62 (7.1)	*
PDP region 14	7.51 (2.6)	39.41 (8.1)	*
PDP region 15	-5.51 (2.96)	25.06 (10.56)	*
PDP region 16	7.94 (3.77)	56.39 (10.25)	*
PDP region 17	13.68 (2.02)	38.77 (6.69)	*
PDP region 18	5.92 (3.95)	41.56 (12.39)	*
PDP region 19	6.81 (6.44)	33.01 (22.1)	
PDP region 20	8.46 (3.75)	32.2 (12.55)	*
PDP region 21	-0.09 (4.15)	10.32 (14.89)	
PDP region 22	8.23 (2.26)	6.53 (7.42)	*
PDP region 23	4.2 (3.95)	10.33 (13.72)	
PDP region 24	9 (6.13)	29.1 (19.64)	

PDP region 25	10.88 (2.7)	*	39.35 (9.08)	*
PDP region 26	17.42 (6.87)	*	-0.99 (21.81)	
PDP region 27	6.03 (11.56)		22.34 (26.58)	
PDP region 28	7.25 (5.24)		1.88 (16.79)	
PDP region 29	8.95 (11)		61.78 (33.38)	
PDP region 30	3.92 (3.26)		37.69 (10.77)	*
PDP region 31	10.07 (8.95)		44.75 (20.53)	*
PDP region 32	Reference		Reference	
PDP region 33	18.19 (6.88)	*	28.14 (20.45)	

^aPresence of one of the following ICD9 codes (25002, 25003) in the primary diagnosis field of any Part A or Part B claim type.

^bPresence of one of the following ICD9 codes (25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093) in the primary diagnosis field of any Part A or Part B claim type .

^cPresence of one of the following ICD9 codes (25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033) in the primary diagnosis field of any Part A or Part B claim type.

^dState law: Allows for generic substitution by pharmacists if "brand only" not indicated by physician; allows for brand if requested by patient; and mandates brand only if indicated by physician. States include AL, AK, AZ, AR, CA, CO, CT, DE, DE,GA, ID, IL, IN, IA, KS, LA, MD, MI, MS, MO, MT, NE, NH, NM, NC, ND, OH, OK, OR, PA, SC, SD, TX, UT, VA, WI, and WY.

^eState law: Mandates generic substitution by pharmacists if "brand only" not Indicated by physician; allows for brand if requested by patient; and mandates brand only if indicated by physician. States include FL, HI, KY, MN, NV, NJ, RI, TN, VR, WA, and WV.

^fState law: Mandates generic substitution by pharmacists if "brand only" not Indicated by physician; and mandates brand only if indicated by physician. States include ME, MA, and NY.

eAppendix Table 4. Full Regression Model Results for Probability of Use of Generic Statins (STNs) and Annual Days Supply Among Users who Reside in California in 2008

Characteristics	Coefficient (standard error)	
	Probability of Use (in %) N=3,213	Annual Days Supply N=1,563
LIS support category		
Nonzero positive copay generic plan	Reference	Reference
Zero copay generic plan	4.1 (3.74)	8.17 (15.02)
Age		
<65	1.32 (2.37)	-11.34 (8.49)
65-74	Reference	Reference
75-80	-0.03 (2.36)	5.05 (8.8)
80+	0.52 (2.6)	-1.32 (9.67)
Sex		
Male	Reference	Reference
Female	1.92 (1.78)	-2.62 (6.5)
Race		
White	Reference	Reference
Black	1.54 (3.13)	-11.65 (11.01)
Hispanic	5.39 (2.3) *	-18 (8.03) *
Asian	-5.86 (2.34) *	-3.4 (9.11)
Native American	-17.38 (11.12)	-55.25 (60.57)
Other	-6.13 (4.31)	3.67 (16.78)
Diabetes duration/severity		
Months since 1 st diagnosis (per month)	-0.06 (0.03) *	0.17 (0.1)
Uncontrolled diabetes ^a	0.96 (1.91)	-12.24 (7.06)
Long-term complications ^b	-0.64 (2.09)	-3.23 (7.61)
Short-term complications ^c	4.39 (5.85)	-3.67 (17.8)
Comorbidities		
RxHCC counts (per RxHCC)	0.249 (0.41)	-2.85 (1.48)
Chronic kidney disease	-5.87 (2.18) *	22.42 (8.27) *
Cancer	2.97 (3.36)	26.03 (11.62) *
Chronic heart failure	1.12 (2.25)	-6.49 (8.02)
Chronic obstructive pulmonary disorder	0.34 (2.25)	16.62 (7.99) *
Cognitive impairment	1.1 (2.99)	31.72 (10.62) *
Mental illness	-5.01 (2.37) *	7.26 (9)
Health care utilization		
Hospital days (per day)	0.14 (0.22)	-1.14 (0.52) *
SNF days (per day)	0.16 (0.15)	-0.74 (0.37) *
Physician visits (per visit)	-0.05 (0.11)	-0.06 (0.41)

Number of chronic medications (per medication)	0.31 (0.3)		2.57 (1.09)	*
Part A payments (per dollar)			-0.0001	
	0.00012 (0.0001)		(0.0003)	
Part B payments (per dollar)			0 (0.0004)	
Diabetes management				
HbA1C test	4.25 (2.24)		18.83 (8.37)	*
Eye exam	-3.95 (1.78)	*	22.06 (6.55)	*
LDL-C test	-3.1 (2.57)		-24.12 (8.95)	*
Influenza vaccination	-1.01 (1.77)		21.87 (6.44)	*
Plan formulary restrictions				
Number STN drugs subject to utilization management (per drug)				
	1.21 (0.93)		0.52 (3.66)	
Lipitor restriction	21.8 (4.24)	*	-16.39 (16.28)	

^aPresence of one of the following ICD9 codes (25002, 25003) in the primary diagnosis field of any Part A or Part B claim type.

^bPresence of one of the following ICD9 codes (25040, 25041, 25042, 25043, 25050, 25051, 25052, 25053, 25060, 25061, 25062, 25063, 25070, 25071, 25072, 25073, 25080, 25081, 25082, 25083, 25090, 25091, 25092, 25093) in the primary diagnosis field of any Part A or Part B claim type .

^cPresence of one of the following ICD9 codes (25010, 25011, 25012, 25013, 25020, 25021, 25022, 25023, 25030, 25031, 25032, 25033) in the primary diagnosis field of any Part A or Part B claim type.