How Low-Income Subsidy Recipients Respond to Medicare Part D Cost Sharing

Bruce Stuart, Franklin B. Hendrick, Jing Xu, and J. Samantha Dougherty

Objectives. To determine the magnitude and mechanisms of response to Medicare Part D cost sharing by low-income subsidy (LIS) recipients using oral hypoglycemic agents (OHAs) and statins.

Data Sources. Medicare data for a 5 percent random sample of beneficiaries with diabetes enrolled in fee-for-service Part D drug plans in 2008.

Study Design. We evaluated the impact of differences between generic and brand cost sharing rates among cohorts of LIS and non-LIS recipients to determine if wider price spreads increased the generic dispensing rate (GDR) and reduced total drug use and cost.

Principal Findings. We found little association between cost sharing and aggregate OHA and statin use. In adjusted analyses, non-LIS beneficiaries who paid 46 percent of total OHA costs had 2.5 percent fewer OHA days supply than full benefit dual eligibles who paid just 5 percent of their therapy costs. For statins, the difference in days supply between those facing the lowest and highest cost sharing was 4.6 percent. Higher cost sharing was associated with filling fewer but larger prescriptions for both generics and brands.

Conclusions. Higher generic and brand copays had little association with OHA and statin use among LIS recipients. This implies that modest changes in required cost sharing for these medicines would have very little substantive impact on generic dispensing or utilization patterns among LIS recipients and thus would have little effect on total program spending. At the same time, any increases in out-of-pocket costs would be expected to shift costs and place greater financial burden on low-income beneficiaries, particularly those in poor health.

Key Words. Medicare Part D, LIS, oral hypoglycemic agents, statins, cost sharing

Setting prescription drug cost sharing rates for poor recipients in public programs has always posed a challenge for health policy makers. If the rates are “too high,” it can impede access to essential medications and may have

the unintended consequence of actually increasing medical and hospital costs (Salas et al. 2009; Roebuck et al. 2011; U.S. Congressional Budget Office, 2012). But if the rates are “too low,” poor recipients have little incentive to choose cost-effective medications. This issue recently came to the fore in policy recommendations to reduce generic copays and increase brand copays for LIS recipients from the Medicare Payment Advisory Commission (2012), the Bipartisan Policy Center (2013), and the President’s FY 2014 budget (U.S. Congressional Budget Office 2012). Although these proposals were not enacted into law, the question remains whether such a policy would have the intended consequence of encouraging LIS beneficiaries to shift from brand to generic medications without creating a serious economic burden for them.

The literature on prescription cost sharing in poor populations is surprisingly sparse (Baicker and Goldman 2011). Older studies by Coulson and Stuart (1995), Stuart and Zacker (1999), and others (see Lexchin and Grootendorst 2004) indicated that demand elasticity for pharmaceuticals ranged between -0.3 and -0.4 for low-income individuals. More recent research by Bishop et al. (2009) and Chandra, Gruber, and McKnight (2013) suggests lower elasticity estimates (between -0.12 and -0.16) for this population. However, these estimates are drawn from relatively small observational studies with limited generalizability.

Correctly estimating price responsiveness in pharmaceutical markets is difficult due to the complexity of cost sharing schemes used by insurers (Carrera, Goldman, and Joyce 2013). The typical Part D plan today has five tiers (preferred and nonpreferred generics, preferred and nonpreferred brands, and specialty drug), and three distribution channels (preferred and nonpreferred retail pharmacies and mail order) (Medicare Payment Advisory Commission 2014). Moreover, all payers impose restrictions on access to certain drugs through formulary exclusions, prior authorization, and step therapy. Finally, state laws influence the level of generic dispensing through mandatory substitution statutes. Extracting pure demand-side price effects under these circumstances is difficult, to say the least.

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In this study we exploited a natural experiment in the design of the Part D benefit to identify financial incentives and beneficiary responses to differences in cost sharing for covered medications for LIS recipients. Cost sharing for these enrollees differs substantially depending on a narrow range of income and asset eligibility tests. We focused the main study on utilization of oral hypoglycemic agents (OHAs) used to maintain glycemic control in the treatment of type 2 diabetes. OHAs represent an attractive drug class for conducting this type of analysis as the class comprises many generic and brand products that either have direct or potential therapeutic substitutes. To assess the generalizability of our findings, we replicated all study procedures for a subsample of statin users.

METHODS

Data Source and Study Population

The study used data from a 2008 5 percent random sample of the Medicare population from the Chronic Condition Data Warehouse (CCW). The files included enrollment information and Part D subsidy status together with paid claims records for Part A, B, and D services.

Inclusion criteria were (1) Medicare enrolled throughout 2007–2008 with continuous Part A, B, and D coverage, (2) continuously enrolled in stand-alone prescription drug plans (PDPs), (3) diagnosed with diabetes based on ICD-9 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 one OHA and/or statin prescription in 2008. We excluded beneficiaries enrolled in Medicare Advantage prescription plans because they lacked Medicare claims necessary for sample identification. We excluded LIS enrollees in long-term nursing facilities because medications are centrally managed and available with no cost sharing. Finally, we excluded beneficiaries residing in American territories.

The sample meeting these criteria was then stratified into four groups according to level of LIS support: (1) full subsidy/full benefit dual eligible (FBDE), (2) full subsidy/nonfull benefit (non-FB), (3) partial subsidy, and (4) non-LIS. FBDE recipients included all dual eligibles with incomes at or below 100 percent of the federal poverty line (FPL). Non-FB recipients had incomes between 100 percent and 135 percent and received Medicaid, Supplemental Security Income, or a Medicare Savings Plan, together with other low-income

applicants who met the law's asset test. Partial subsidy enrollees were ineligible for the full subsidy with limited assets and incomes up to 150 percent of FPL.

Measures of OHA Use and Cost

Oral and injectable noninsulin hypoglycemic drugs available in 2008 included metformin, sulfonylureas, alpha-glucosidase inhibitors, amylinomimetics, thiazolidinediones (TZDs), dipeptidyl peptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 agonists (GLP-1), and meglitinides. During the study period, all TZDs, DPP-4s, GLP-1s, and meglitinides were single-source, brand-only preparations.

Our primary outcomes of interest were annual days supply of generic and brand OHAs, the GDR, and total annual per-beneficiary cost of OHA therapy. Secondary outcomes were annual number of OHA fills, days supply per fill, and cost per standardized 30-day fill.

Cost Sharing for Part D Enrollees

Part D plans have heterogeneous cost sharing provisions applicable to non-LIS enrollees. Less appreciated are the complex cost sharing features faced by LIS recipients. Drug copays for FBDE recipients in 2008 were \$1.05 per generic fill and \$3.10 per brand fill. However, there were several exceptions: (1) institutionalized FBDE beneficiaries paid zero copays, (2) drugs filled after the Part D out-of-pocket (OOP) threshold were also subject to zero copays, and (3) if the Part D plan offered certain drugs on a tier with prices below the LIS nominal rate, then LIS recipients were charged that rate. Most important, fills were not delimited by size—the copay for 30 days was the same as for 90 days.

The statutory copays for non-FB LIS recipients in 2008 were \$2.25 per generic fill and \$5.60 per brand fill regardless of size with the same exceptions as for full benefit duals. Partial subsidy recipients were subject to an annual deductible (\$56 in 2008) and a flat 15 percent coinsurance rate up to the OOP threshold after which they paid the same copay rates as non-FB beneficiaries.

Cost sharing for non-LIS beneficiaries in 2008 depended on plan type and formulary features. Defined standard benefit plans charged an annual deductible of \$275 and 25 percent coinsurance up to the initial coverage limit. Thereafter, cost sharing was 100 percent to the catastrophic

coverage phase when copays dropped to about 5 percent. However, most Part D plans had no deductible and used copays with variable rates depending on prescription type (generic or brand), size, and distribution channel.

Hypotheses and Tests for Price Responsiveness

The combination of heterogeneous price schedules together with beneficiaries' ability to influence how much they pay per unit of medications in certain support categories creates a unique opportunity to understand how Part D financial incentives drive utilization decisions for chronic care medications like OHAs. We based our assessment of these incentives on four hypotheses: (1) annual days supply of OHAs will fall as the burden of cost sharing rises; (2) GDR will increase as the spread between generic and brand cost sharing rates widens; (3) mean number of fills will fall and days supply per fill will rise as cost sharing rises; and (4) partial subsidy and non-LIS beneficiaries will use lower cost OHAs compared to full support LIS recipients.

The rationale for hypothesis #1 is the standard economic theory of demand—as the effective rate of cost sharing rises, quantity demanded should fall. Hypothesis #2 derives from the fact that brand OHAs become progressively more expensive relative to generics as the level of aggregate cost sharing rises. This is expected to result in higher GDRs among beneficiaries in the higher cost sharing groups.

Hypothesis #3 is driven by two factors. Both FBDE and non-FB recipients face fixed generic and brand copayments regardless of fill size. Members of both groups could minimize OOP by filling the largest possible prescriptions (normally 90 days supply). There are noneconomic reasons why this does not routinely occur, but as the cost burden becomes increasingly heavy, we expected to find that individuals would have progressively fewer fills and larger prescriptions.

The fourth hypothesis reflects another manifestation of fixed copays for full subsidy LIS recipients. Members of these two groups have no incentive to shop for lower cost versus higher cost brand OHAs as the cost per fill is the same. This is also true for generics except in rare cases where Part D plans offer a very low or zero copay tier. By contrast, members of the partial subsidy and non-LIS groups can lower their total OOP obligations by selecting relatively cheaper generics and brands.

Statistical Analysis

We tested these hypotheses in three steps. First, we computed descriptive statistics for effective cost sharing rates and OHA quantity and cost measures for each cohort for generic and brand products separately and combined using bivariate tests to identify significant differences in outcome values across the four study cohorts.

Next we estimated OLS regression models using SAS version 9.2 to test whether varying levels of cost sharing influenced annual days supply and cost for generic, brand, and total OHAs, plus GDR. These models were estimated with dummy variables for LIS support categories and covariates described below.

As a final step, we computed price spread elasticities using an approach similar to Gilman and Kautter (2008). It is impossible to directly measure brand or generic price elasticities using conventional methods because cost sharing rates for brands and generics rise together as the level of LIS support declines. Instead, we estimated changes in study outcomes in response to the widening spread between generic and brand cost sharing rates as LIS support falls. We then used these spread measures in a variant on the standard arc elasticity formula ($\% \Delta Q / \% \Delta P$). For example, we calculated the differential in brand-generic price spreads shown in Table 2 for FBDE (\$1.47) and non-FB (\$2.54) recipients to estimate $\% \Delta P = 53.3$ percent between the two groups. Combined with an estimated $\% \Delta Q = -4.2$ percent for the same two groups from our regression analysis, we calculate a generic-brand price spread elasticity of $\epsilon = -0.08$ for brand OHAs. We replicated this process comparing differences in price spreads between FBDE recipients and partial subsidy and non-LIS recipients to create a total of three elasticity estimates for brand OHAs. Using the same procedures, we estimated elasticities for quantity and cost for generic OHAs, generic and brand OHAs combined, and GDR.

Controlling for Confounding

Our regression models statistically controlled for a wide variety of variables that could plausibly confound the relationship between LIS support group and our outcomes of interest. These included basics demographic characteristics that are typically correlated with income and thus LIS support; diabetes severity, comorbidity, and health care utilization measures that may affect diabetes medication regimens; and diabetes tests and preventive services that may help control for health adherer bias. In addition, we identified whether

individuals entered the Part D coverage gap to account for the dramatic increase in out-of-pocket cost for non-LIS recipients with high drug spending. The individual variables in each of these domains are shown in Table 1 together with source notes and variable definitions. All explanatory variables were measured in 2007 to avoid the possibility of reverse causality with respect to outcomes measured in 2008.

Of particular note are our controls for disease severity and comorbidities. Diabetes ICD-9 codes reflect a wide range of severity levels that could affect prescribing patterns. For example, uncontrolled hyperglycemia and long-term cardiovascular complications typically require more complex treatment regimens (e.g., multiple vs. single OHAs, thus increasing days supply). Cardiovascular complications also warrant statin therapy. We used three diabetes severity measures recommended by the Agency for Healthcare Research and Quality (AHRQ) to identify uncontrolled diabetes (AHRQ 2013), short-term diabetes complications (AHRQ 2012a,b), and long-term diabetes complications (AHRQ 2012a,b). On the other hand, the competing demands of comorbidity may reduce adherence with OHA and statins. Together with indicators for selected diseases frequently associated with diabetes, we used the Prescription Drug Hierarchical Condition Category (RxHCC) risk adjustment model developed by CMS as a comorbidity index. The model takes more than 14,000 disease (ICD-9) codes and aggregates them into 167 condition categories. We counted the number of unique condition categories represented by diagnoses in Medicare claims for 2007 as our measure of comorbidity.

In addition to individual-level covariates, we assessed differences in plan-level formulary restrictions (number of OHAs off-formulary or subject to prior authorization or step therapy) and captured differences in pharmacist generic substitution laws across the country (mandates generic prescribing unless prescriber indicates brand only, permits generic substitution unless prescriber indicates brand only, permits brand if requested by patient, and mandates brand if brand prescribed).

Study Replication for Statin Users

To assess the generalizability of our findings to other drug classes, we replicated all of the analyses described above for a sample of 126,490 statin users selected from our main sample of diabetics enrolled in Part D plans in 2008.

Table 1: Characteristics of Community-Dwelling Part D Enrollees with Diabetes Using Oral Hypoglycemic Agents by Low-Income Subsidy (LIS) Support Category

Beneficiary Characteristics	LIS Subsidy Support Category			
	Full Subsidy—Full Benefit Dual Eligible (FBDL) (N = 34,229)	Nonfull Benefit (Non-FB) (N = 17,856)	Partial Subsidy (N = 2,454)	No LIS (N = 61,505)
Age (%)				
<65	34.5	32.8	17.0	5.8
65–74	33.3	34.3	34.4	43.9
75–80	17.3	17.0	22.9	24.7
80+	14.9	15.9	25.7	25.7
Sex (%)				
Male	32.3	33.2	31.9	41.8
Female	67.7	66.8	68.1	58.2
Race/ethnicity (%)				
White	55.4	70.1	81.8	90.7
Black	22.0	23.1	13.9	6.2
Hispanic	10.6	3.7	1.7	0.7
Asian	8.0	0.9	1.0	0.8
Native American	1.1	1.0	0.6	0.3
Other	2.8	1.2	1.1	1.3
Diabetes duration/severity				
Months since 1st diagnosis (SD)	58.3 (34.9)	56.7 (34.2)	59.5 (33.9)	57.1 (34)
Uncontrolled diabetes (%)*	37.4	35.0	31.5	29.4
Long-term complications (%)†	30.7	26.4	26.0	23.4
Short-term complications (%)‡	2.1	1.7	1.8	1.2
Number OHA fills subject to utilization management (SD)	2.6 (5.1)	2.6 (4.8)	2.3 (4.4)	2.2 (4.1)

Continued

Table 1. Continued

Beneficiary Characteristics	LIS Subsidy Support Category			
	Full Subsidy—Full Benefit Dual Eligible (FBDE) (N = 34,229)	Nonfull Benefit (Non-FB) (N = 17,856)	Partial Subsidy (N = 2,454)	No LIS (N = 67,505)
Comorbidities				
RxHCC counts (SD)	7.3 (3.3)	6.8 (3.1)	6.8 (3)	6.8 (3)
Chronic kidney disease (%)	18.1	16.2	17.0	15.3
Cancer (%)	6.0	6.4	7.3	9.9
Chronic heart failure (%)	20.7	18.9	18.9	15.4
Chronic obstructive pulmonary disorder (%)	23.1	21.5	19.7	14.5
Cognitive impairment (%)	8.1	5.8	4.9	6.1
Mental illness (%)	29.4	23.9	19.3	13.8
Health care utilization				
Hospital days (SD)	3.1 (13.4)	2.6 (11.9)	2.3 (6.6)	2 (6.9)
SNF days (SD)	0.6 (5.2)	0.8 (5.8)	0.8 (5.2)	1.1 (7.6)
Physician visits (SD)	11.7 (9.8)	10.2 (8.8)	10.1 (8)	10.4 (8.1)
Number of chronic medications (SD)	8.8 (3.9)	8.1 (3.7)	7.7 (3.4)	6.9 (3.4)
Part A payments (SD)	4,598.66 (12,855)	3,865.67 (11,139)	3,631.91 (10,090)	3,732.88 (11,331)
Part B payments (SD)	6,558.33 (10,386)	5,390.65 (9,152)	4,735.54 (7,324)	4,480.8 (6,578)
Entry in Part D donut hole (%)	71.8	65.2	56.2	43.4
Diabetes management (%)				
HbA1C test	84.3	85.5	88.5	89.8
Eye exam	44.2	39.4	43.7	53.4
LDL-C test	77.6	78.6	80.6	83.4
Influenza vaccination	46.1	47.6	56.2	62.6
Plan formulary restrictions				
Number OHAs subject to utilization management (SD)	8.7 (6.4)	7 (6.9)	5.8 (7.1)	3.9 (6.8)

*Presence of one of the following ICD9 codes (25002, 25003) in the primary diagnosis field of any Part A or Part B claim type (AHRQ, 2013).

[†]Presence 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 (AHRQ, 2012a,b).

[‡]Presence 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 (AHRQ, 2012a,b).

RESULTS

Main Study Results for OHA Users

A total of 116,044 OHA users met the main study inclusion criteria (Table 1). Just under half (47 percent) received some LIS support with FBDE being the largest group (29 percent) and recipients of partial support being the smallest (2 percent). Demographic characteristics varied widely. Over a third (34.5 percent) of FBDE recipients were under age 65 compared to just 5.8 percent for non-LIS beneficiaries. Beneficiaries aged 75 and older predominated in the partial subsidy and non-LIS groups. The FBDE group was the most racially mixed with slightly under half (44.6 percent) being minorities compared to less than 10 percent among non-LIS beneficiaries.

The four groups were similar in diabetes duration. Diabetes severity measures were consistently highest for FBDE LIS recipients and lowest for non-LIS beneficiaries. Significant fractions of each group experienced uncontrolled diabetes (29.4–37.4 percent). Between 23.4 percent and 30.7 percent of beneficiaries had evidence of long-term diabetes complications.

FBDE recipients had the highest rates of comorbidity (7.3 RxHCC counts) and were more likely than members of any other group to have cognitive impairment (8.1 percent) and mental illness (29.4 percent). They incurred the highest utilization of Medicare services (except SNF days), had the highest mean Part A and B expenditures, and filled more chronic care medications (9.3) than any other group. FBDE recipients were much less likely than non-LIS beneficiaries to have had HbA1C tests, eye exams, cholesterol tests, and flu shots.

Table 2 reports unadjusted measures of cost sharing, quantity, and cost of OHAs used by members of each cohort. Effective copay rates for standardized 30-day fills for generic OHAs ranged from \$0.65 to \$5.12, representing nearly an eightfold difference in cost sharing faced by FBDE and non-LIS beneficiaries. For brands, effective copays for standardized 30-day fills ranged between \$2.12 and \$50.60 for the same two groups—a 24-fold difference. The spread in cost sharing between generics and brands ranged from \$1.47 for FBDE recipients to \$45.48 for beneficiaries receiving no LIS support—a 31-fold differential.

Consistent with hypothesis #1, beneficiaries facing the lowest cost sharing (FBDE) had the highest mean days supply of all OHAs combined (452 days) and the group facing the highest cost sharing (non-LIS)

Table 2: Out-of-Pocket Cost Sharing, Quantity, and Cost of Oral Hypoglycemic Agents (OHAs) Filled by Part D Enrollees with Diabetes by Low-Income Support Category in 2008

OHA Cost Sharing, Quantity, and Cost Measures	Subsidy Support Category			
	Full Subsidy— Full Benefit Dual Eligible (FBDE)	Nonfull Benefit (Non-FB)	Partial Subsidy	No LIS
OHA out-of-pocket cost sharing				
Effective copay per 30-day supply				
Generic [†]	\$0.65	\$1.39*	\$1.93*	\$5.12*
Brand [‡]	\$2.12	\$3.93*	\$18.64*	\$50.60*
Generic/brand price differential	−\$1.47	−\$2.54	−\$16.71	−\$45.48
OHA quantity measures				
Mean annual days supply				
Generic (SD)	295.88 (211)	300.03 (210)*	319.83 (204)*	318.82 (210)*
Brand (SD)	156.52 (216)	141.54 (204)*	117.90 (188)*	113.56 (184)*
Total (SD)	452.40 (280)	441.57 (264)*	437.73 (251)*	432.38 (248)*
Mean generic dispensing rate for all OHAs [§]	0.70	0.72*	0.77*	0.77*
Mean generic dispensing rate for multisource OHAs [¶]	0.99	0.99	0.99	0.99
Mean annual number of fills				
Generic (SD)	8.7 (6.8)	8.5 (6.6)*	8.7 (6.3)	7.7 (6.1)*
Brands (SD)	4.6 (6.8)	4.0 (6.1)*	3.3 (5.4)*	2.9 (5.0)*
Total (SD)	13.3 (9.1)	12.5 (8.4)*	12.0 (7.8)*	10.6 (7.4)*
Mean days supply per fill				
Generic (SD) [†]	38.0 (18.1)	40.2 (20.3)*	42.9 (22.4)*	50.3 (25.8)*
Brand (SD) [‡]	37.6 (17.8)	39.7 (20.1)*	40.0 (20.9)*	46.0 (24.6)*
Total (SD)	37.7 (17.4)	39.9 (19.7)*	42.0 (21.6)*	49.1 (25.1)*
OHA cost measures				
Mean cost per 30-day fill (\$)				
Generics (SD) [†]	13.97 (9)	13.90 (10)	13.55 (10)*	12.88 (10)*
Brands (SD) [‡]	147.14 (68)	146.61 (67)	139.15 (65)*	139.50 (60)*
Annual OHA cost (\$)				
Generic (SD) [†]	161.62 (143)	161.82 (144)	159.75 (142)	156.09 (140)*
Brand (SD) [‡]	1,605.12 (1,211)	1,559.06 (1,160)*	1,390.92 (1,131)*	1,335.99 (1,041)*
Total (SD)	909.30 (1,172)	830.38 (1,101)*	687.93 (992)*	656.29 (928)*

[†]Restricted to generic drug users.

[‡]Restricted to brand name drug users.

[§]Generic dispensing rate (GDR) defined as the proportion of total OHA days supply filled with generics.

[¶]Generic dispensing rate for metformin, sulfonylureas, and alpha-glucosidase OHAs.

*Significantly different from FBDE at $p < .05$.

had the fewest days supply (432), but the difference was a mere 4.6 percent. Non-LIS beneficiaries filled 37.7 percent fewer days supply of brand OHAs compared to FBDE recipients (114 vs. 157), but only 7.2 percent more days supply of generics (319 vs. 296). As a result, FBDE recipients had the lowest GDR (70 percent), while non-LIS beneficiaries had the highest GDR (77 percent) as predicted by hypothesis #2. However, in the three pharmacologic classes with both generic and brand products (metformin, sulfonylureas, and alpha-glycosidase inhibitors), the GDR was 99 percent across the board.

Underlying these differences in days supply were differential patterns in fill rates and fill sizes. The number of generic fills was 11 percent higher among FBDE recipients compared to non-LIS beneficiaries (8.7 vs. 7.7), but the fill rate for brands was 37 percent higher for FBDE recipients (4.6 vs. 2.9). Consistent with hypothesis #3, average days supply for generic OHA fills by non-LIS beneficiaries was 32 percent higher than for FBDE recipients (50.3 vs. 38.0). The mean fill size for brands was 22 percent higher (46.0 vs. 37.6).

The next panel in Table 2 presents data on OHA costs. As expected (hypothesis #4), the two full support LIS groups showed little difference in average cost per 30-day fill (\$13.97 vs. \$13.90 for generics by FBDE and non-FB recipients, respectively, and \$147.14 vs. \$146.61 for brands by the two groups). On the other hand, the average cost per 30-day supply for non-LIS beneficiaries was below that of FBDE recipients for generics (\$12.88 vs. \$13.97) and brands (\$139.50 vs. \$147.14).

The overall cost of OHA therapy for non-LIS beneficiaries was 28 percent below that of FBDE recipients (\$656.29 vs. \$909.30) driven primarily by 17 percent lower spending on brands (\$1,335.99 vs. \$1,605.12).

Table 3 summarizes key regression results expressed as marginal effects (full results in supporting information). As expected, adjusted differences attributable to support categories were consistently smaller than unadjusted differences, reflecting the impact that diversity of characteristics across the groups had on OHA utilization and cost patterns. For example, the unadjusted difference in annual brand days supply between FBDE and non-FB recipients of 15 days (already a small difference) was reduced to 7 days after adjustment. Likewise, the difference in GDR between FBDE recipients and the other two LIS groups was cut by half (from 2 to 1 percentage point difference between FBDE and non-FB recipients and from 7 to 3.5 percentage point difference between FBDE and partial subsidy

Table 3: Adjusted Differences in Outcome Measures for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support Category in 2008

Outcome Measures	Subsidy Support Category			
	Full Subsidy- Full Benefit Dual Eligible (FBDE)	Nonfull Benefit Dual Eligible (Non-FBDE)	Partial Subsidy	No LIS
Mean annual days supply				
Generic	Reference	4.57 (1.94)*	18.07 (4.22)*	13.21 (1.74)*
Brand	Reference	-7.75 (1.54)*	-19.05 (3.12)*	-16.35 (1.36)*
Total	Reference	-3.18 (2.23)	-0.99 (4.79)	-3.13 (1.99)
Mean overall generic dispensing rate (%)	Reference	1.02 (0.3)*	3.53 (0.62)*	1.78 (0.27)*
Mean generic dispensing rate for multisource OHAs (%) [†]	Reference	-0.01 (0.1)	0.25 (0.2)	0.08 (0.09)
Mean annual number of fills				
Generic	Reference	-0.19 (0.06)*	0.01 (0.13)	-0.9 (0.05)*
Brand	Reference	-0.43 (0.04)*	-0.72 (0.09)*	-0.87 (0.04)*
Total	Reference	-0.62 (0.07)*	-0.71 (0.15)*	-1.77 (0.06)*
Mean days supply per fill				
Generic [‡]	Reference	2.16 (0.2)*	3.52 (0.49)*	9.23 (0.19)*
Brand [§]	Reference	2.63 (0.27)*	1.64 (0.67)*	5.81 (0.26)*
Total	Reference	2.21 (0.18)*	2.84 (0.44)*	8.21 (0.17)*
Mean cost per 30-day fill (\$)				
Generic [‡]	Reference	0.19 (0.1)*	0.31 (0.22)	0.02 (0.08)
Brand [§]	Reference	-1.75 (0.96)	-4.36 (2.05)*	1.07 (0.91)
Mean annual OHA cost (\$)				
Generic [‡]	Reference	3.23 (1.41)*	4.63 (3.07)	4.02 (1.23)*
Brand [§]	Reference	-62.85 (13.74)*	-179.74 (30.95)*	-157.03 (12.22)*
Total	Reference	-43.79 (7.91)*	-106.57 (15.88)*	-89.45 (6.83)*

Notes. Regression models included all variables shown in Table 1. Full model results available in Appendix Tables 3–8.

[†]Restricted to metformin, sulfonylureas, or alpha-glycosidase OHAs users.

[‡]Restricted to generic drug users.

[§]Restricted to brand name drug users.

*Significantly different from FBDE at $p < .05$.

recipients). The difference in annual OHA costs between these two groups fell by more than half from \$79 to \$35.

Table 4 presents our elasticity estimates. In four instances, the numerator in the elasticity equation was statistically insignificant and thus no elasticity was generated. All of the remaining values were in the hypothesized direction. As expected, rising generic/brand price differentials was associated with lower

Table 4: Price Spread Elasticity Estimates

<i>Elasticity Measure</i>	<i>Comparisons</i>		
	<i>Non-FB to FBDE LIS Recipients</i>	<i>Partial Subsidy to FDBE LIS Recipients</i>	<i>Non-LIS to FBDE LIS Recipients</i>
OHA days supply			
Generic/brand price spread elasticity			
Generic impact	0.03	0.03	0.02
Brand impact	−0.08	−0.08	−0.06
Combined generic/brand impact	Nil	Nil	Nil
Generic dispensing rate	0.03	0.09	0.01
OHA cost			
Generic/brand price spread elasticity			
Generic impact	0.04	Nil	0.01
Brand impact	−0.07	−0.07	−0.05
Combined generic/brand impact	−0.09	−0.07	−0.06

Note. Nil = instances where the outcome was not statistically significantly different across the comparison groups in adjusted analyses.

brand utilization and increased generic use, but the differences were small, $e = -0.06$ to -0.08 for brands and $e = 0.02$ to 0.03 for generics. The elasticity for generics and brands combined was essentially zero. Consistent with these results, the GDR elasticity was positive, but again, the magnitude of the effect ($e = 0.03$ to 0.09) was very small. The impact of the generic/brand spread on generic cost ranged between zero and 0.04 . Higher spreads between generic and brand costs had a negative impact on both brand and combined costs ($e = -0.05$ to -0.09).

Results for Statin Users

Findings from our replication study of statin users are presented in online supporting materials. The characteristics of the two samples were quite similar as would be expected given significant overlap among diabetes patients taking OHAs and statins. Compared to OHAs, mean days supply with statins was lower as was the GDR; generic costs were higher, but brand costs were lower. Regression results for the statin outcome measures were broadly similar to the adjusted results for OHAs. The generic/brand price spread elasticities were all in the expected direction, but highly inelastic, with no measure exceeding 0.08 .

DISCUSSION

We found little price sensitivity in the demand for oral hypoglycemic agents and statins among Part D beneficiaries with diabetes regardless of LIS support category. Higher spreads in cost sharing between generics and brands resulted in fewer days supply, higher GDR, and lower total costs for both drug groups. However, the magnitude of these effects was small. We estimate that it would take a 100 percent increase in the generic/brand copay spread to move the generic dispensing rate in either class by 3 to 9 percent. Such a change in cost sharing would reduce total drug costs by between 6 percent and 9 percent.

There are several plausible explanations for these findings. First, the combination of state generic substitution laws and Part D formulary restrictions has virtually eliminated filling of brands in most multisource drug classes. We found that the GDR for multisource OHAs was 99 percent in every LIS support group as well as for non-LIS enrollees. That leaves beneficiaries with three options for economizing behavior—cut back on overall supply, switch to cheaper—but not identical—products in the same therapeutic class, or fill fewer but larger prescriptions. We found that beneficiaries did not significantly cut back on OHAs even when they paid almost half the total cost. In adjusted analyses, mean annual OHA days supply differed by less than 2.5 percent between FBDE and non-LIS beneficiaries. Judging from the GDR elasticity range of 0.03 to 0.09, we conclude that there was little switching from sole-source brands to generics. We also found little evidence that higher differentials between generics and brand cost sharing drove beneficiaries to switch to relatively cheaper products within generic or brand categories. Rather, the primary behavioral response to higher cost sharing was filling fewer but larger prescriptions for generics and brands alike. It is worth noting that this behavior could have saved beneficiaries money even without the added pressure of higher cost sharing.

Our analyses of statin usage produced similar overall results. In 2008, brand coverage for multisource statins was comparable to OHAs (i.e., brands in such classes were excluded on virtually all formularies), resulting in very low usage of these brands. However, the mean generic dispensing rate for statins was much lower (approximately 50 percent) compared to OHAs (approximately 75 percent), primarily reflecting large demand for Lipitor and lesser demand for Crestor and Vytorin (results not shown). Beneficiaries were somewhat more responsive to differences in prices for generic and brand statins compared to OHAs, but the absolute value of such differences was small.

Our finding little association between varying levels of cost sharing and drug use is consistent with recent studies of other low-income populations (Bishop et al. 2009; Chandra, Gruber, and McKnight 2013). Our findings are also consistent with published estimates from value-based insurance design experiments showing that large reductions in copayment rates for drugs used in treating chronic illness including diabetes are associated with very modest changes in drug use of between 3 and 5 percent (Chernew et al. 2008; Zeng et al. 2010; Choudhry et al. 2011; Gibson et al. 2011; Farley et al. 2012). Two recent studies have examined the effects of low and zero generic cost sharing on use of statins among non-LIS beneficiaries in Part D plans (Hoadley et al. 2012; Tang et al. 2013). Both found that beneficiaries enrolled in zero copay plans were significantly more likely to use generic statins compared to those in plans with higher generic copays. However, these studies did not capture days supply, so their findings are not directly comparable to ours.

The main policy implication from our research is that if our findings also apply to other drug classes, then even doubling brand copays would likely have little impact on either overall generic prescribing rates or Part D costs, but would place a heavier cost burden on low-income beneficiaries, particularly those with multiple chronic conditions taking many different drugs. Our findings showed that the LIS population tends to have greater disease severity and burden relative to the non-LIS population as evident in higher rates of uncontrolled diabetes, diabetes complications, RxHCCs, and select comorbidities. As such, raising LIS copays would create multiplicative increases in out-of-pocket drug expenses that would fall directly on these vulnerable individuals.

Comparing differences in OHA annual costs and generic prescribing rates between full and nonfull benefit dual eligible LIS recipients provides some sense of what might happen if LIS brand copays were doubled. During our study year, the effective 30-day copay for non-FB recipients (\$3.93) was almost twice that of FBDE recipients (\$2.12), but the adjusted differences in GDR and annual OHA cost were just 1 percentage point and \$35, respectively. While this does not consider what would happen if generic copays were reduced to zero as some proposals have recommended, our findings suggest that the effect on both utilizations and savings would be small (as the effective 30-day generic copay for FBDE recipients was only \$0.65). Additionally, our findings show that there is little room for improvement in the 99 percent GDR for multisource OHAs.

Study Limitations

Our methods are subject to several limitations. The greatest threat to drawing causal inferences from observational designs is the possibility of unobserved confounding. We observed noteworthy differences in beneficiary characteristics across the four study cohorts. Diabetes severity and comorbidity measures were highest for FBDE recipients and lowest for non-LIS beneficiaries. Similarly, FBDE beneficiaries filled more chronic care medications and incurred substantially higher spending for Part A and B services than any other group. We carefully selected measures to capture differences in diabetes severity, complications, and comorbidities that could reasonably be expected to differentially influence need for OHAs and statins across the four study cohorts. Taken together, the full set of variables explained between a third and 60 percent of the unadjusted differences in days supply, GDR, and annual costs for both drug classes. Nonetheless, we cannot rule other potential confounds.

Four specific concerns warrant mention. First is the issue of potentially endogenous prices. Medicare beneficiaries across the spectrum of LIS support exert some control over the effective rates of cost sharing they face in the Part D marketplace. Full-subsidy LIS recipients can manipulate effective generic and brand copays by filling larger prescriptions. Partial subsidy LIS and non-LIS beneficiaries can influence their effective out-of-pocket obligations by filling larger prescriptions, choosing cheaper drug products, and pacing prescription fills to influence if and when they enter the Part D coverage gap and catastrophic phases. The real question is how endogenous prices affect the magnitude of measured price responsiveness. To give just one example, the statutory brand copay for FBDE recipients in 2008 was \$3.10, whereas the effective copay per 30-day supply was just \$2.12, due to larger fill sizes. This is precisely the behavior one would expect from economizing beneficiaries. Had we used statutory copays in our calculations rather than effective copay rates, the elasticity values would have been lower than reported, given that price is in the denominator of the elasticity ratio. In other words, while we acknowledge the potential for bias, we believe that our estimates represent conservative estimates of the true price responsiveness of LIS recipients.

The second issue regards the relationships between beneficiary income, assets, and LIS support category. This is a concern because the support category determines level of cost sharing. As long as beneficiary income and assets are positively associated with OHA and statin demand, then any between-category comparison will underestimate the true degree of price responsiveness. The magnitude of the bias depends on the relative elasticities of demand,

which we cannot independently measure. There have been few studies of income elasticity of prescription demand and none that we are aware of have focused on the impact of assets on prescription drug demand. The most systematic investigation of the impact of income on prescription drug use to date is by Wasem et al. (2014), who found no association between socio-economic status and use of antihypertensives. Our view is that the income elasticity of demand for OHAs and statins is likely to be low for the same reasons that price elasticity is low; namely, these drugs confer no direct utility to consumers other than control of blood glucose and lipid levels regardless of income. Another reason we believe that any bias from this source is small is the consistency of our estimated price elasticity measures across groups with widely varying income levels. While variation in average incomes across the three LIS support categories is modest, the differences between LIS and non-LIS beneficiaries are much larger. Based on data from the 2008 Medicare Current Beneficiary Survey, we estimate that the median household income of non-LIS Part D enrollees (\$27,500) was roughly three times that (\$9,912) of LIS recipients (data not shown). But this differential pales in comparison to the 8- to 24-fold differences in copays between FBDE and non-LIS beneficiaries. Thus, from a purely empirical perspective, the net effect of between-category comparisons will primarily reflect the impact of cost sharing rather than income.

A third issue relates to the question of whose behavior is reflected in our estimates—patients or their prescribers. In fact, it is both and unraveling the independent causal factors is impossible in cross-sectional observational studies. Prescription drug use is conditional on patients finding a prescriber, communicating symptoms, receiving the prescription, and then filling it. None of the steps in this causal pathway save the last were actually observed, thus leading to significant unexplained variance in our estimates.

A final question regards the generalizability of our findings. Our study was restricted to Medicare beneficiaries, but the findings have potential implications for the commercial market, especially low-income individuals receiving subsidized cost sharing under the Affordable Care Act. Future research is needed to assess demand responsiveness for other medications used by low-income individuals in both the Medicare and commercial markets. Research is also needed to better understand the clinical as well as economic implications of substitution among drugs in mixed brand-generic classes that may occur as a result of cost sharing.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Table A1: Regression Models for Adjusted Differences in Mean Annual Days Supply for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table A2: Regression Models for Adjusted Differences in Mean Generic Dispensing Rate (GDR) for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table A3: Regression Models for Adjusted Differences in Mean Annual Number of Fills for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table A4: Regression Models for Adjusted Differences in Mean Days Supply per Fill for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table A5: Regression Models for Adjusted Differences in Mean Cost per 30-Day Fill for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table A6: Regression Models for Adjusted Differences in Mean Annual Cost for Oral Hypoglycemic Agents (OHAs) Filled by Low-Income Support (LIS) Category in 2008.

Table B1: Characteristics of Community-Dwelling Part D Enrollees with Diabetes Using Statins by Low-Income Subsidy (LIS) Support Category.

Table B2: Out-of-Pocket Cost Sharing, Quantity, and Cost of Statins Filled by Part D Enrollees with Diabetes by Low-Income Support Category in 2008.

Table B3: Adjusted differences in Outcome Measures for Statins Filled by Low-Income Support Category in 2008[†].

Table B4: Price and Spread Elasticity Estimates for Statins.