

Did Medicare Part D Reduce Disparities?

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The primary objective of the Medicare Prescription Drug, Improvement, and Modernization Act was to provide seniors with affordable coverage for their prescription medications through the new Medicare Part D prescription drug benefit. This aim has largely been achieved as more than 35 million Medicare beneficiaries are now enrolled in Part D plans, and approximately 9 out of 10 report being satisfied with their plan.¹ While Part D has reduced the financial burden of prescription drug spending for beneficiaries—particularly those with low incomes or extraordinarily high out-of-pocket drug expenses—whether the gap in coverage induced beneficiaries to change their use of medications or discontinue use of an effective therapy, and for whom the gap induced this behavior, is an empirical question.

The Part D benefit has a well-known gap in coverage commonly referred to as the “donut hole.” Under the standard benefit, beneficiaries who do not qualify to receive a Low-Income Subsidy (LIS) face a deductible, followed by a 25% coinsurance rate; but once they have spent up to a designated level on medications in a year (\$2960 in 2015), they must start paying full price for their drugs. Only after a beneficiary reaches the “catastrophic” limit in out-of-pocket spending (\$4700 in 2015) does coverage resume with minimal cost sharing thereafter. This nonlinear design is more complicated than a simple increase in patient cost sharing, as it alters both the current and future price of a drug. Once a non-LIS beneficiary reaches the coverage gap, each prescription he fills is likely to cost more. Yet, at the same time, each fill increases the likelihood of reaching the catastrophic threshold, which lowers the expected price of future prescriptions that year. Further, any price change in the gap is temporary since benefits reset at the beginning of the next calendar year. How beneficiaries—particularly those with low levels of education and resources—respond to changes in coverage over the course of the year is largely unknown.

Recent work finds that the Part D coverage gap reduces beneficiaries’ use of essential medications,² but does not examine the differential responses of minorities and the near-poor who do not qualify for federal subsidies. Racial and ethnic minorities have higher rates of chronic illness than nonminorities, and members of lower socioeconomic status (SES) groups are frequently less able to manage the complex treatment regimens often required in managing a disease.³ In-

ABSTRACT

Objectives

We assessed whether Medicare Part D reduced disparities in access to medication.

Study Design

Secondary data analysis of a 20% sample of Medicare beneficiaries, using Parts A and B medical claims from 2002 to 2008 and Part D drug claims from 2006 to 2008.

Methods

We analyzed the medication use of Hispanic, black, and white beneficiaries with diabetes before and after reaching the Part D coverage gap, and compared their use with that of race-specific reference groups not exposed to the loss in coverage. Unadjusted difference-in-difference results were validated with multivariate regression models adjusted for demographics, comorbidities, and zip code-level household income used as a proxy for socioeconomic status.

Results

The rate at which Hispanics reduced use of diabetes-related medications in the coverage gap was twice as high as whites, while blacks decreased their use of diabetes-related medications by 33% more than whites. The reduction in medication use was correlated with drug price. Hispanics and blacks were more likely than whites to discontinue a therapy after reaching the coverage gap but more likely to resume once coverage restarted. Hispanics without subsidies and living in low-income areas reduced medication use more than similar blacks and whites in the coverage gap.

Conclusions

We found that the Part D coverage gap is particularly disruptive to minorities and those living in low-income areas. The implications of this work suggest that protecting the health of vulnerable groups requires more than premium subsidies. Patient education may be a first step, but more substantive improvements in adherence may require changes in healthcare delivery.

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Take-Away Points

We examined the impact of the Medicare Part D coverage gap on medication use by Hispanics, blacks, and whites with diabetes. These findings suggest that the Part D coverage gap was particularly disruptive to medication use for minorities and those of low socioeconomic status.

- Hispanics, especially those residing in poorer areas, reduced medication use more than whites and blacks when they were required to bear the full costs of their medications.
- Hispanics and blacks were more likely than whites to discontinue a therapy after reaching the coverage gap, but more likely to resume once coverage restarted.
- Improving medication adherence and the health of vulnerable groups requires more than premium subsidies.

deed, black and Hispanic enrollees report greater difficulty obtaining information and purchasing needed medications in Part D.⁴

In this paper, we examined the effects of cycling in and out of coverage on the prescription drug use of racial and ethnic minorities and other vulnerable subgroups of Medicare beneficiaries. We compared changes in prescription drug use of white, black, and Hispanic beneficiaries before and after reaching the coverage gap for 2 different beneficiary groups: 1) those eligible for the full LIS who face minimal cost sharing and thus are unaffected by the coverage gap; and 2) nonsubsidized beneficiaries who pay the full cost of medications in the coverage gap (non-LIS). We estimated changes in medication use after reaching the gap separately by race, and we focused on beneficiaries with diabetes because it disproportionately affects ethnic minorities and is a major risk factor for a wide range of other health conditions. If the gap is prompting beneficiaries to use pharmaceuticals differently—especially if it leads them to discontinue an effective therapy—it should have been evident in this sample.

STUDY DESIGN AND METHODS

Data

We used a 20% random sample of Medicare beneficiaries enrolled in Part D. This data set links enrollment and Parts A and B claims for traditional fee-for-service Medicare enrollees (2002 to 2008) to Part D claims (2006 to 2008). The Part A data includes information about inpatient hospital stays, including length of stay, diagnosis-related group, department-specific charges, and up to 10 individual procedure codes and diagnostic codes. Part B information includes claims submitted by physicians and claims from other healthcare providers and facilities for services reimbursed by Part B. Each claim contains diagnostic *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* and Current Procedure Terminol-

ogy-4 codes, dates of service, demographic information on beneficiaries, and a physician identification number.

The pharmacy data include all of the key elements related to prescription drug events (eg, drug name; National Drug Code, dosage, supply, date of service). Each pharmacy claim includes the amount of the LIS; the true out-of-pocket amount; and a field that indicates in which benefit phase a claim was made: deductible, pre-coverage gap, coverage gap, or catastrophic phase (or whether the claim straddles 2 of these phases). The Part D data identify the exact date that non-LIS beneficiaries entered and exited the coverage gap, as well as when LIS beneficiaries—not subject to the gap—reached the same levels of prescription drug spending associated with entrance into and exit from the gap.

The denominator file contains demographic information about each beneficiary including date of birth, gender, beneficiary type (eg, recipient, or not, of the LIS), and zip code of residence. We linked 5-digit zip codes to the American Community Survey to measure neighborhood socioeconomic status, including education (ie, level of schooling attained) and median household income. The Medicare data also include externally validated measures of race/ethnicity. Self-reported measures on race/ethnicity were refined using Research Triangle Institute estimates based on geography and first and last names.

Sample

The study sample consisted of Medicare beneficiaries 65 years and older with diabetes. Persons with diabetes commonly take medications for glycemic control, hypertension, and dyslipidemia, and proper medication adherence is associated with large reductions in both macro- and microvascular complications. Clinical trials consistently show that complications from this disease can be avoided or deferred with tight glycemic control.^{3,5} We identified beneficiaries with diabetes based on at least 1 inpatient or skilled nursing facility diagnosis, or 2 or more outpatient diagnoses of diabetes. We also assumed that a beneficiary with a Part D claim for insulin has diabetes. Once identified, beneficiaries were assumed to have diabetes in subsequent years.

We restricted our analysis to those enrolled in traditional fee-for-service Medicare and a stand-alone Part D drug plan. Individuals were required to have the same Part D contract/plan for the entire year. Our sample included 2 groups of beneficiaries: those receiving the full LIS and those not receiving any type of subsidy (non-LIS) and who

thus had no gap coverage. LIS beneficiaries do not pay Part D premiums and face minimal cost sharing throughout the year. As a result, they are not subject to the coverage gap even when their level of drug spending reached the coverage gap threshold (eg, \$2250 in 2006) and should not have reason to change their medication use before and after reaching the various (hypothetical) coverage thresholds. We used the LIS as controls and compared their medication use before and after reaching the gap to that of non-LIS beneficiaries, who face vastly different prices over the course of the year and spending distribution.

Given that 2006 was the initial year of the program and that beneficiaries could enroll up until May 15, we restricted our analyses to 2007 and 2008. Nonetheless, we used the 2006 data for risk adjustment, categorization of beneficiaries, and to compute medication use in 2007 for medications initiated in 2006 or earlier. In 2007, the study sample included 557,756 beneficiaries: 416,495 whites, 69,947 blacks, and 71,314 Hispanics.

Statistical Analysis

Our strategy was to estimate the difference in medication use before and after the coverage gap for a treatment (non-LIS) and control group (LIS), by drug class and race/ethnicity. We estimated race-specific changes in medication use before and after reaching the coverage gap for the non-LIS, and benchmarked these changes to race-specific changes in the medication use of LIS beneficiaries at similar levels of drug spending (ie, before and after reaching the “hypothetical” threshold of the coverage gap). We used multivariate regression to control for the variation in demographic and socioeconomic characteristics, and interacted binary indicators for each beneficiary group (LIS/non-LIS) with race/ethnicity. Standard errors were clustered at the individual level and computed using bootstrapping.

Our key outcome measure was medication adherence. We measured adherence using the Medication Possession Ratio (MPR), which is the fraction of days that a patient “possesses” or has access to medication, as measured by prescription fills. For example, a patient who filled a 30-day script on April 1 and refilled the prescription on May 10 would have an MPR of 75% for that period since they possessed 30 pills over a 40-day span. For each drug class, we computed the total days’ supply of medications before and after reaching the coverage gap to compute the percentage of compliant days for each individual in the sample. The remaining days’ supply at the end of 1 year was carried over to the subsequent year. We estimated changes in the rate of MPR, overall and by therapeutic class, as well as the proportion of all prescriptions dispensed as generic.

We also examined the fraction of white, black, and Hispanic beneficiaries who stopped using a class of medication after reaching the gap, and the fraction that resumed use in the first 90 days of the next year. Discontinuation was measured by comparing medication use within a therapeutic class in the 90 days prior to a beneficiary’s gap entry date and after reaching the gap. For example, a beneficiary observed taking an oral hypoglycemic, an antihypertensive, and a statin before reaching the gap, but only an oral hypoglycemic and an antihypertensive after entering the gap (for the remainder of the year) would be categorized as having discontinued 1 medication within the relevant classes. We also examined the extent to which beneficiaries switched medications after reaching the gap (from brand to generic), for classes that were neither brand- nor generic-dominated.

We measured changes in medication use for the 9 most prevalent drug classes used to treat diabetes and its comorbidities (diabetes-related medications) and the 9 most common classes used by these beneficiaries for other conditions (non-diabetes-related). Diabetes-related classes include: oral hypoglycemic agents, angiotensin-converting-enzyme (ACE) inhibitors, calcium channel blockers, diuretics, beta-blockers, angiotensin II receptor blockers (ARBs), statins, loop diuretics, digitalis glycosides, and combination antihypertensives. ACE inhibitors and ARBs are combined into a single class because they are commonly considered therapeutically interchangeable. The set of other drugs consists of the 9 most prevalent non-diabetes-related classes used by this set of beneficiaries: antidepressants, antipsychotics, central nervous system medications (the majority of which are Alzheimer’s disease medications like Aricept, Namenda, and Razadyne, as well as Lyrica, which treats nerve and muscle pain), antiasthmatics, platelet aggregation inhibitors (eg, Plavix), antiulcerants, anticonvulsants, opioid analgesics, and hormones/synthetics/modifiers. Using both diabetes-related and non-diabetes-related medications allowed us to examine whether beneficiaries with diabetes are more or less price sensitive for their disease-specific medications. In some analyses, we report the average price of a 30-day supply of the drugs in each class; these prices were derived empirically from the data.

We used estimates from multivariate regression models to predict the change in medication use by race/ethnicity, for diabetes-related and non-diabetes-related classes. The models controlled for health status using binary indicators for the most common comorbid conditions based on ICD-9-CM diagnostic codes in the medical claims. These included 20 conditions defined in the Chronic Conditions Warehouse, as well as hypertension, hyperlipidemia, asthma, and gastrointestinal disorders. We also adjusted

■ **Table 1.** Beneficiary Characteristics, by Coverage Group and Race

	White		Black		Hispanic	
	LIS (n = 123,033)	Non-LIS (n = 293,462)	LIS (n = 50,440)	Non-LIS (n = 19,507)	LIS (n = 57,283)	Non-LIS (n = 14,031)
Demographics						
Age in years (mean)	75.0 ^a	75.8	74.6 ^a	73.9	74.5 ^a	74.2
Male (%)	28.8 ^a	42.4	22.9 ^a	38.0	34.2 ^a	44.4
Socioeconomic status^b						
Median income (\$)	48,697 ^a	57,926	40,984 ^a	46,660	45,561 ^a	48,256
Years of education (mean)	13.3 ^a	13.7	12.9 ^a	13.2	12.5 ^a	13.2
Rx utilization measures (mean)^c						
Pre-gap MPR	0.80 ^a	0.80	0.76 ^a	0.75	0.74 ^a	0.73
Post gap MPR	0.78 ^a	0.73	0.74 ^a	0.67	0.72 ^a	0.63
Pre-gap GDR	0.49 ^a	0.48	0.50 ^a	0.48	0.43	0.43
Post gap GDR	0.54 ^a	0.55	0.56 ^a	0.57	0.48 ^a	0.52
Median month of coverage gap entry	7.10 ^a	8.70	7.80 ^a	9.00	7.60 ^a	8.90

	White		Black		Hispanic	
	LIS (n = 109,143)	Non-LIS (n = 268,680)	LIS (n = 43,930)	Non-LIS (n = 17,151)	LIS (n = 44,455)	Non-LIS (n = 12,492)
Parts A and B utilization (mean) 2005^d						
No. of office visits	9.0 ^a	9.0	7.5 ^a	7.7	9.2 ^a	9.4
No. of emergency department visits	7.7 ^a	6.3	8.7 ^a	6.3	7.5 ^a	4.6
No. of inpatient stays	0.5 ^a	0.3	0.5 ^a	0.3	0.4 ^a	0.3
No. of inpatient days	2.6 ^a	1.7	2.8 ^a	2.0	2.2 ^a	1.5
Parts A and B spending (mean \$) 2005^d						
Total	9698 ^a	7869	10,260 ^a	8160	10,581 ^a	6917
Inpatient	4251 ^a	3152	4265 ^a	3200	3909 ^a	2438
Outpatient	1455 ^a	1196	2227 ^a	1724	1839 ^a	1033
Other	3992 ^a	3521	3768 ^a	3236	4833 ^a	3446

GDR indicates generic dispensing ratio; LIS, low-income subsidy; MPR, medication possession ratio; Rx, prescription.

^aIndicates LIS and non-LIS values are significantly different at 1% ($P < .01$).

^bSocioeconomic status is measured at zip code level.

^cMPR and GDR are measured before spending reaches the coverage gap level ("pre") and after spending reaches coverage gap levels ("post") in 2007.

^dUtilization and spending for beneficiaries covered by fee-for-service Medicare Part A & B for all 12 months of 2005.

Sample is individuals aged 65 years and older with diabetes. Demographics, socioeconomic status, MPR, and GDR are measured in year 2007. Spending and utilization measured in 2005 to demonstrate pre-Part D differences across groups. These factors are correlated with health status and highlight differences across groups.

for age, age-squared, gender, time indicators, and zip code level measures of income.

Finally, we compared changes in medication use for LIS and non-LIS beneficiaries living in low-income areas to understand the relationship between changes in medication use and income effects proxied by the median household income in a beneficiary's zip code. We defined the "near-poor" as white, black, and Hispanic beneficiaries who resided in zip codes with a median household income below \$25,000 (the bottom income quartile of the sample of non-LIS beneficiaries).

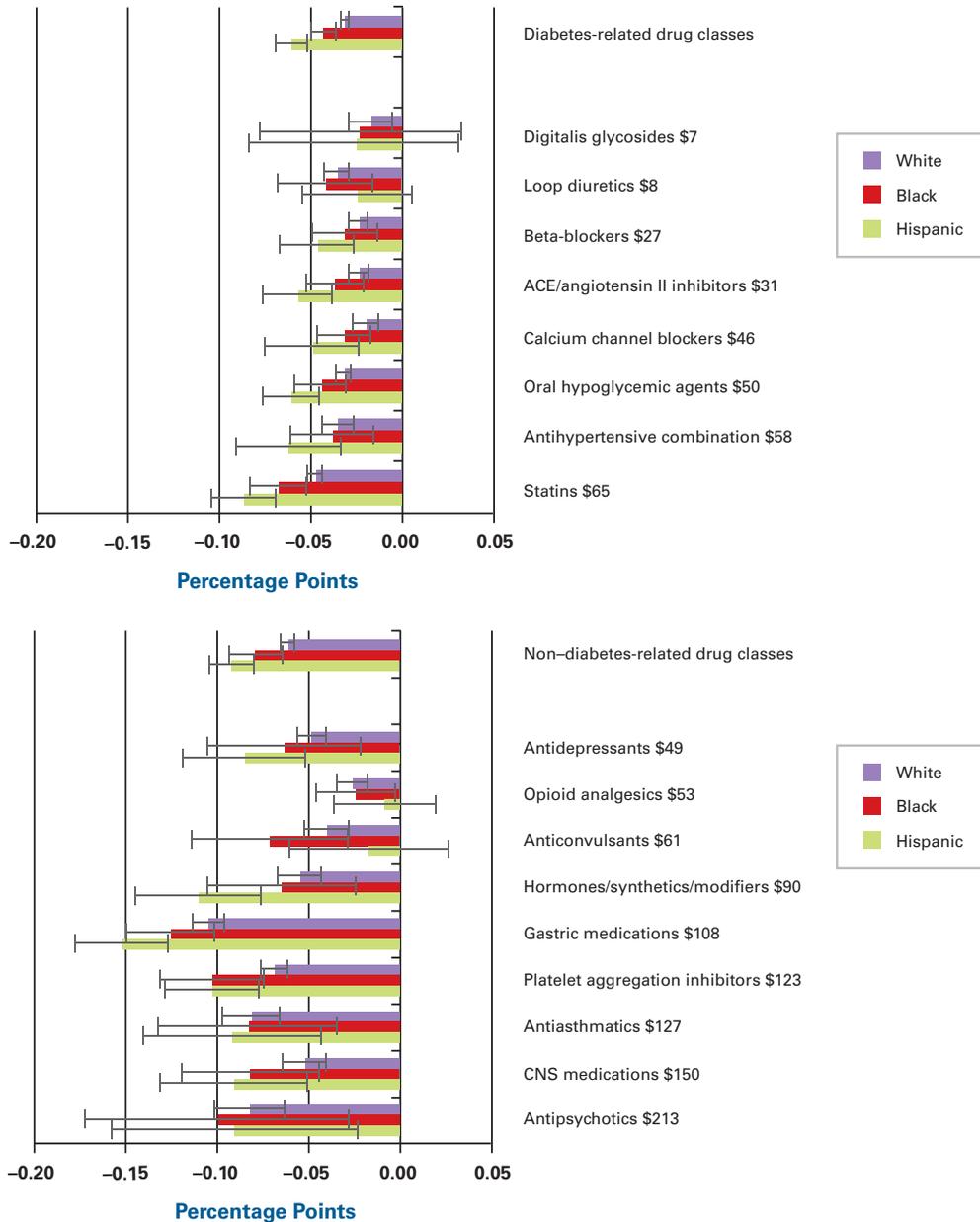
RESULTS

Table 1 shows the characteristics of the study sample by race/ethnicity and beneficiary group. White beneficiaries

were least likely, and Hispanics were most likely to receive the full LIS: more than 80% of Hispanics and less than 30% of whites were categorized as LIS. White beneficiaries had more years of schooling and higher incomes than Hispanics and blacks, but regardless of race/ethnicity, the LIS recipients were more likely to be female and have low SES compared with non-LIS.

Although prescription drug use differed widely by race/ethnicity, it did not differ by beneficiary group (Table 1) before the gap. For example, both LIS and non-LIS whites took their medications about 80% of the time before the coverage gap level of spending. More generally, pre-gap adherence was lowest among Hispanics and changed more dramatically after reaching the coverage gap. Adherence among non-LIS Hispanics declined by 10 percentage points (pp) (from 73% to 63%) after reaching

Figure 1. Regression-Adjusted Difference-in-Difference in Medication Use (MPR), by Therapeutic Class and Race



ACE indicates angiotensin-converting-enzyme; CNS, central nervous system; MPR, medication possession ratio. MPR is the fraction of days that a patient “possesses,” or has access to, medication, as measured by prescription fills. Changes in medication use (ie, regression-adjusted difference-in-difference estimates of changes in medication use after entering the coverage gap [vs before entering the gap] are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status. Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class. Diabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 74,452; whites who did not receive the Low-Income Subsidy (non-LIS): n = 115,333; LIS blacks: n = 26,140; non-LIS blacks: n = 6131; LIS Hispanics: n = 29,113; non-LIS Hispanics: n = 4311. Non-diabetes-related drug classes: LIS whites: n = 65,062; non-LIS whites: n = 89,927; LIS blacks: n = 21,337; non-LIS blacks: n = 4373; LIS Hispanics: n = 25,083; non-LIS Hispanics: n = 3464. Black lines indicate 95% confidence intervals.

the coverage gap compared with just 2pp for whites (76% to 74%).

Because LIS beneficiaries are in worse health than the non-LIS and face minimal cost-sharing for their medications, they are much more likely to reach the coverage gap

threshold and reach it earlier in the year than non-LIS beneficiaries. However, within beneficiary groups, whites, blacks, and Hispanics reached the coverage gap level of spending at about the same time (late August to early September). Thus, the average duration in the gap was about

■ **Table 2.** Differential Stopping and Conditional Resumption Rates of Non-LIS Group Relative to LIS Group

Stops Drug (% difference non-LIS and LIS) ^a	White (n = 196,178) ^b	Black (n = 33,061)	Hispanic (n = 34,472)
Diabetes drug classes	2.4	4.1	6.7
Non-diabetes drug classes	2.6	3.2	4.2
Resumes Drug (conditional on stopping) (% difference non-LIS and LIS) ^c	White (n = 97,589) ^d	Black (n = 18,257)	Hispanic (n = 20,291)
Diabetes drug classes	6.7	5.9	12.5
Non-diabetes drug classes	4.7	4.1	11.4

LIS indicates Low-Income Subsidy.

^aPercent of non-LIS stoppers minus percent of LIS stoppers, in the coverage gap in 2007.

^bThe number of "stoppers" is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007.

^cAmong stoppers, the difference in percent of non-LIS who resumed and percent of LIS who resumed in the first quarter of 2008.

^dThe number of "resumers" is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007 and stopped medications in at least 1 drug class. For both stoppers and resumers, the sample (relevant sample for this table) is individuals 65 years and older with diabetes who reached the coverage gap in 2007 and remained in the coverage gap for at least 40 days. (Fewer than 40 days in the coverage gap would be too brief a period to observe cessation or resumption behavior.)

The sample for "resumes drug" is further restricted to individuals who stopped a drug in the coverage gap in 2007 and resumed the drug in the first quarter of 2008. The difference between non-LIS and LIS rates is significantly different at 1% for all calculations.

"Observations" refers to the total population that was considered—the denominator for the stopping or resuming ratio.

4 months for those who did not reach the catastrophic threshold by the end of the calendar year.

Multivariate Findings

Figure 1 displays the percentage point change in medication use of non-LIS relative to LIS before and after the coverage gap. We present results by race/ethnicity, adjusting for demographic, health, and socioeconomic characteristics. The top panel displays changes in medication use across 9 diabetes-related classes, and the bottom panel for non-diabetes-related classes. Drug classes are ordered by cost—from lowest to highest average price—to highlight the correlation between adherence and out-of-pocket costs during the coverage gap. For example, use of statins (\$65/mo) declined by 9pp during the coverage gap among non-LIS Hispanics (relative to LIS Hispanics). In practical terms, these changes imply that non-LIS Hispanics took their statins as prescribed 63% of the time after reaching the gap, compared with 72% prior to reaching the gap (tables available upon request). Corresponding figures for blacks and whites are 7pp and 5pp, respectively.

For the 9 diabetes-related drug classes combined, medication use in the gap declined by 6pp for Hispanics, 4pp for blacks, and 3pp for whites. We found a similar pattern in the use of non-diabetes-related medications. Over these 9 classes, use in the coverage gap declined by 9pp for Hispanics, 8pp for blacks, and 6pp for whites. The differential changes in medication use were even larger in percentage terms (as opposed to percentage points) due to racial/ethnic differences in baseline levels of adherence (see eAppendix Figures).

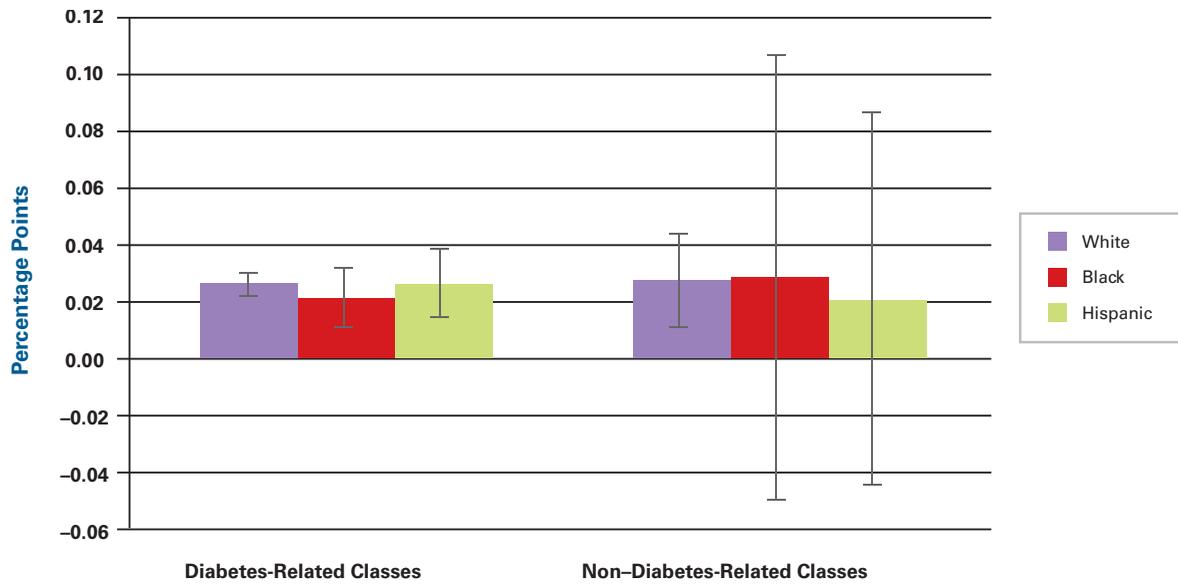
In addition to racial differences, Figure 1 also highlights the correlation between adherence and price. The use of costly, brand-dominant classes such as antipsychot-

ics (\$213), antiplatelets (\$123), and antiulcerants (\$108) declined more sharply than the use of less expensive medications such as beta-blockers (\$27) and diuretics (\$8). For example, the use of antipsychotics dropped by 8pp for whites, 10pp for blacks, and 9pp for Hispanics, while the use of less costly diuretics decreased by 4pp for both whites and blacks, and 2pp for Hispanics.

Reduced medication use can reflect different behavioral responses to the coverage gap, such as stretching a prescription over more days (eg, pill-splitting) or stopping a medication altogether. Table 2 shows differential rates of stopping and later resuming drug therapies, by race/ethnicity. A higher percentage of non-LIS beneficiaries discontinued use of diabetes-related and non-diabetes-related medications after reaching the coverage gap compared with the LIS, and a larger fraction resumed use in the next year once coverage resumed. Discontinuing use was most common among Hispanics, who stopped and resumed at 2 to 3 times the rate of blacks and whites. For example, an additional 6.7% of non-LIS Hispanics discontinued a class of diabetes-related medication after reaching the coverage gap relative to LIS Hispanics (compared with 4.1% of blacks and 2.4% of whites). Among those who stopped, an additional 12.5% of the non-LIS Hispanics (relative to the LIS Hispanics) resumed use in the first quarter of the next year (vs 6.7% of whites and 5.9% of blacks).

While overall medication use declined in the coverage gap, the fraction of drugs dispensed as generic increased modestly. Figure 2 shows race-specific changes in the use of generic drugs after reaching the coverage gap for diabetes-related and non-diabetes-related classes, relative to the LIS. Among the 9 diabetes-related classes, generic use increased 2 to 3pp in the coverage gap for each race/ethnicity. We found similar effects among the non-diabe-

■ **Figure 2.** Regression-Adjusted Difference-in-Difference in Generic Dispensing Rate (GDR), by Race



GDR for the angiotensin-converting-enzyme (ACE) inhibitors/angiotensin II receptor blocker (ARB) class is for ACE inhibitors only since the ARB class is brand-dominated.

Changes in use of generic medications (ie, “changes”) refers to regression-adjusted difference-in-difference estimates of changes in use of generics after entering the coverage gap (vs before entering the gap) were based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

This analysis is limited to therapeutic classes that are neither brand- nor generic-dominated. Diabetes-related classes include: oral hypoglycemic agents, ACE inhibitors, calcium channel blockers, beta-blockers, statins, digitalis glycosides, and combination antihypertensives. ACE inhibitors and ARBs are combined into a single class because they are commonly considered therapeutically interchangeable. The set of other drugs consists of those among the 9 most prevalent non-diabetes-related classes used by this set of beneficiaries that are neither brand- (generic dispensing rate [GDR] < 20%) nor generic-dominated (GDR > 80%): antidepressants and antiulcerants. (Other non-diabetes classes were brand- or generic-dominated, so patients had limited options, if any, in switching to generics. These were the only 2 non-diabetes drug classes which met those criteria.)

Diabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 70,284; non-LIS whites: n = 104,784; LIS blacks: n = 24,412; non-LIS blacks: n = 54,75; LIS Hispanics: n = 27,159; non-LIS Hispanics: n = 3736. Non-diabetes-related drug classes: LIS whites: n = 61,860; non-LIS whites: n = 76,652; LIS blacks: n = 19,054; non-LIS blacks: n = 3339; LIS Hispanics: n = 22,485; non-LIS Hispanics: n = 2668.

Black lines indicate 95% confidence intervals.

tes-related classes, but the difference was only statistically significant for whites.

Given that race/ethnicity is correlated with income, we re-estimated the models including median household income in the beneficiary’s zip code, and then predicted medication use in the coverage gap by race/ethnicity, holding household income constant at \$25,000 (Figure 3).² For the 9 diabetes-related classes combined, low-income Hispanics decreased medication use by 9pp in the gap relative to Hispanics receiving the LIS subsidy—a larger effect than that of Hispanics overall (6pp, Figure 1). Further, the effects were larger in more expensive classes. By contrast, the reduction in medication use among lower income blacks (5pp) and whites (3pp) was similar to that of blacks (4pp) and whites (3pp) overall (Figure 1).

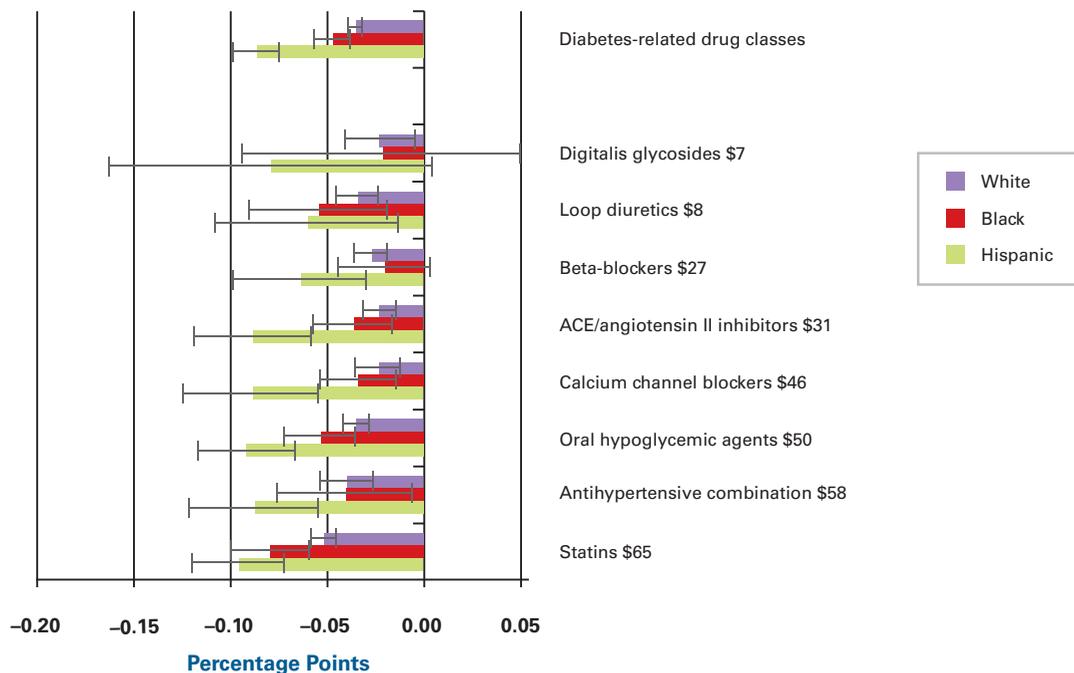
DISCUSSION

Our findings suggest that the Part D coverage gap is disruptive to drug therapy, particularly for minorities and

those who live in lower-income areas but do not receive subsidies. Older, unsubsidized Hispanics with diabetes reduced their use of diabetes-related medications by 6 pp during the coverage gap, compared with 4pp for blacks and 3pp for whites. The reduction in medication use reflected higher rates of medication discontinuation and only a fraction of patients who discontinued use in the coverage gap re-initiated therapy once coverage resumed the next year.

A large body of literature has demonstrated that out-of-pocket costs affect adherence.^{6,9} Yet, since most claims-based data sets do not contain information on race or ethnicity, this research has been silent as to whether minorities are more sensitive to the cost of prescription drugs than nonminorities. Our research begins to fill that gap. What remains unclear, however, is why Hispanic and black beneficiaries have a stronger response to changes in the price of medication. Some research suggests that older minorities may perceive drug therapies as less efficacious or essential in the treatment of chronic disease,¹⁰ and thus,

Figure 3. Regression-Adjusted Difference-in-Difference in Medication Possession Ratio (MPR), by Therapeutic Class and Race for the Near-Poor Population



MPR indicates medication possession ratio.

MPR is the fraction of days that a patient “possesses” or has access to medication, as measured by prescription fills.

Changes are based on results from multivariate models, which control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Angiotensin-converting-enzyme (ACE) inhibitors and angiotensin II receptor blocker (ARBs) are combined into a single class because they are commonly considered therapeutically interchangeable.

We defined the “near-poor” as white, black, and Hispanic beneficiaries residing in zip codes with a median household income below \$25,000 (the bottom quartile of the sample’s income distribution). Whites who received the Low-Income Subsidy (LIS): n = 74,452; non-LIS whites: n = 115,333; LIS blacks: n = 26,140; non-LIS blacks: n = 6131; LIS Hispanics: n = 29,113; non-LIS Hispanics: n = 4311. Black lines indicate 95% confidence intervals.

may be more likely to discontinue use when out-of-pocket costs increase suddenly or exceed some threshold.¹¹ We, however, found that while minorities were more likely to stop taking a medication after reaching the gap than white beneficiaries, they were also more likely to resume therapy once coverage restarted in January. We found a strong relationship between the price of the drug and the response to the coverage gap; declines in medication use were larger in drug classes costing more than \$60 per month. Other studies have shown that racial/ethnic minorities are more adversely affected by cost-related nonadherence and have poorer overall adherence to medication in Medicare Part D.¹²⁻¹⁶ Unlike a change in co-payment, the coverage gap is temporary and 2-fold: it increases the current out-of-pocket cost of medication, while simultaneously lowering the expected future out-of-pocket cost of a drug if the beneficiary reaches the catastrophic threshold. Changes in drug benefits have been associated with substantial morbidity and mortality in certain high-risk populations.¹⁷⁻²¹ Reductions in medication use as a result of the Part D coverage gap raise concerns about deleterious health effects that may

manifest over time. The median beneficiary is subject to the gap for 3 to 4 months each year. Behavioral responses to the coverage gap may mitigate potential health effects. Black, white, and Hispanic beneficiaries increased their use of generic medications, particularly for diabetes-related drug classes (see Figure 2), after reaching the coverage gap, and 11% to 40% within each group switched to more generous plans the next year (see eAppendix Table).

Limitations

First, our proxy for socioeconomic status did not fully account for the variation by race and ethnicity in adherence in the coverage gap. While near-poor Hispanics decreased medication use in the gap more than higher-income Hispanics, income had little impact on the response of white and blacks to the coverage gap. Since our income measure is at the zip code level, we are unable to perfectly disentangle the effect of socioeconomic status from race. Previous work using similar SES data found that individuals living in lower-income areas were more price-sensitive than their higher-income counterparts.²²

Second, beneficiaries receiving the full LIS were obviously poorer, and more likely to be female, nonwhite, and sicker on average than the non-LIS. Our results may be biased if the LIS also differ in unobserved ways that make them an inappropriate control group. Two points mitigate these concerns: first, the LIS had a constant level of prescription drug use before and after the coverage gap, which is consistent with them being unaffected by the gap. Second, our empirical approach compared medication use before and after the coverage gap within beneficiary group and within race/ethnicity, thereby using each group as its own control.

Third, we identified the chronically ill from claims data. The main concern with this approach is the distraction of false positives if “rule-out” diagnoses are recorded on the claims. We tried to minimize this error by restricting our analysis to users of disease-specific drugs, requiring multiple physician visits or hospitalizations for the condition, and exploiting a long panel of Parts A and B claims (2002 to 2008). The use of claims data also obscures the level of disease severity, but this potential bias is also minimized by the difference-in-differences strategy.

Lastly, our results may overstate the impact of the coverage gap on prescription drug use if beneficiaries obtained free samples from their providers or paid for medications in cash at discount outlets after reaching the gap.²³ An increasing number of retail pharmacies (eg, WalMart, Target) sell a broad range of generic drugs for \$4 per prescription. While there is little empirical data on the extent of this behavior, a pre-Part D study found that 6% of enrollees in a Kaiser Permanente Medicare Advantage plan purchased prescriptions outside of their plan after reaching the annual benefit limit.²⁴ We observed a substantial and rapidly increasing number of \$4 claims in the Part D data, thus the extent of bias from uncaptured claims is likely to be small. Further, since entry into the catastrophic phase was based on accumulating out-of-pocket expenses, beneficiaries had an incentive to purchase all of their medication—even \$4 script—through the Part D program.

CONCLUSIONS

Although the coverage gap is being phased out under the Affordable Care Act (ACA), beneficiaries will continue to face a break in coverage until 2020. In addition, like Part D, the ACA continues the trend toward “consumer-directed” healthcare. While compelling patients to take a more active role in choosing a plan and managing their healthcare is generally positive, protecting vulnerable groups in the healthcare marketplace requires more

than just premium subsidies. Patient education is a first step, but more substantive improvements in adherence will require changes in healthcare delivery. The shift from a fee-for-service model to bundled payments under the ACA will reward providers for better patient outcomes, for which medication adherence is critical. Similarly, new investments in health information technology will allow more providers and health plans to contact patients who do not fill or refill a prescription on a timely basis, and to discuss with them the reasons behind their decision, allowing them to intervene when applicable. While the success of these types of changes has not been demonstrated, it is difficult to imagine that targeted interventions would not be cost-beneficial given the clinical and financial consequences of poor adherence among older beneficiaries with chronic diseases.

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REFERENCES

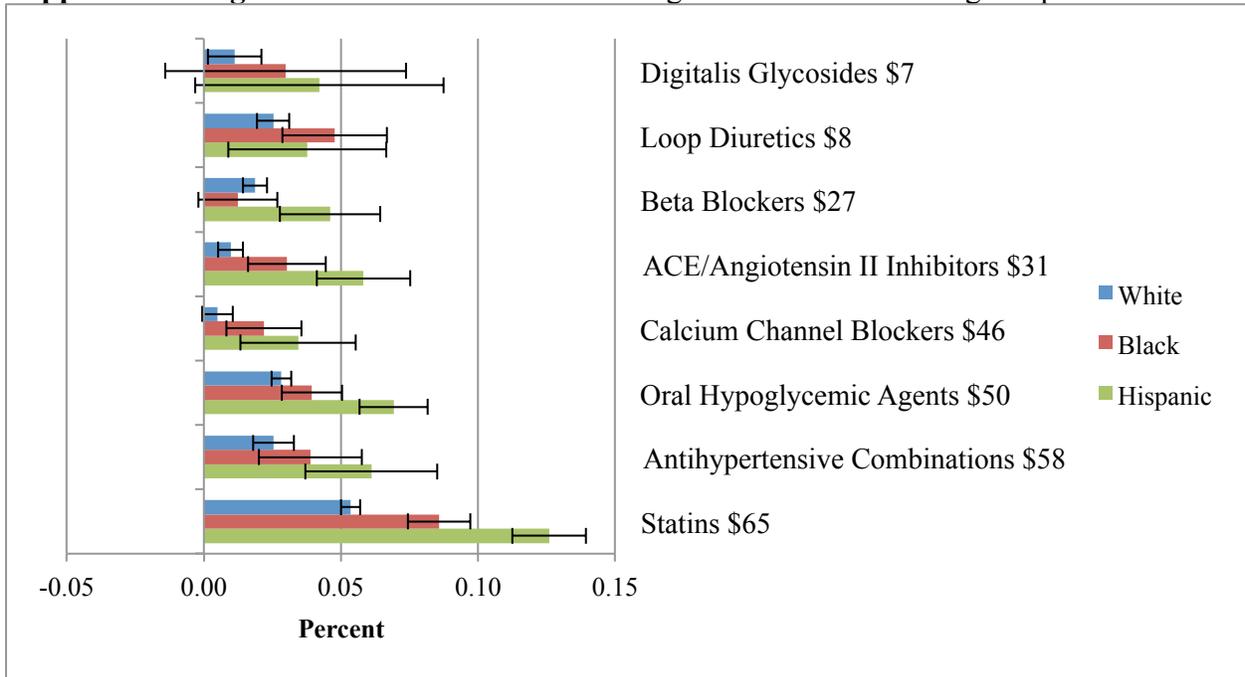
1. KRC Research. Seniors' Opinions About Medicare Rx: Sixth Year Update. Washington, DC: KRC Research; 2011.
2. Joyce GF, Zissimopoulos J, Goldman DP. Digesting the doughnut hole. *J Health Econ.* 2013;32(6):1345-1355.
3. Goldman DP, Smith JP. Can patient self-management help explain the SES health gradient? *Proc Natl Acad Sci U S A.* 2002;99(16):10929-10934.
4. Haviland AM, Elliott MN, Weech-Maldonado R, Hambarsoomian K, Orr N, Hays RD. Racial/ethnic disparities in Medicare Part D experiences. *Med Care.* 2012;50 suppl:S40-S47.
5. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329(14):977-986.
6. Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. *JAMA.* 2002;288(14):1733-1739.
7. Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA.* 2004;291(19):2344-2350.
8. Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA.* 2007;298(1):61-69. Review.

9. Huskamp HA, Deverka PA, Epstein AM, Epstein RS, McGuigan KA, Frank RG. The effect of incentive-based formularies on prescription-drug utilization and spending. *N Engl J Med*. 2003;349(23):2224-2232.
10. Le TT, Bilderback A, Bender B, et al. Do asthma medication beliefs mediate the relationship between minority status and adherence to therapy? *J Asthma*. 2008;45(1):33-37.
11. Mann DM, Ponieman D, Leventhal H, Halm EA. Predictors of adherence to diabetes medications: the role of disease and medication beliefs. *J Behav Med*. 2009;32(3):278-284.
12. Gellad WF, Haas JS, Safran DG. Race/ethnicity and nonadherence to prescription medications among seniors: results of a national study. *J Gen Intern Med*. 2007;22(11):1572-1578.
13. Zhang Y, Baik SH. Race/ethnicity, disability, and medication adherence among Medicare beneficiaries with heart failure. *J Gen Intern Med*. 2013;29(4):602-607.
14. Ngo-Metzger Q, Sorkin DH, Billimek J, Greenfield S, Kaplan SH. The effects of financial pressures on adherence and glucose control among racial/ethnically diverse patients with diabetes. *J Gen Intern Med*. 2012;27(4):432-437.
15. Tseng CW, Tierney EF, Gerzoff RB, et al. Race/ethnicity and economic differences in cost-related medication underuse among insured adults with diabetes: the translating research into action for diabetes study. *Diabetes Care*. 2008;31(2):261-266.
16. Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare Part D beneficiaries after acute myocardial infarction [published online December 10, 2013]. *Circulation*. 2013;129(7):754A-763A. doi:10.1161/CIRCULATIONAHA.113.002658.
17. Johnson RE, Goodman MJ, Hornbrook MC, Eldredge MB. The impact of increasing patient prescription drug cost sharing on therapeutic classes of drugs received and on the health status of elderly HMO members. *Health Serv Res*. 1997;32(1):103-122.
18. Tambllyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA*. 2001;285(4):421-429.
19. Gaynor M, Li J, Vogt WB. Substitution, Spending Offsets, and Prescription Drug Benefit Design. *Forum Health Econ Policy*. 2007;10(2):1-33.
20. Chandra A, Gruber J, McKnight R. Patient cost-sharing and hospitalization offsets in the elderly. *Am Econ Rev*. 2010;100(1):193-213.
21. Lurie N, Ward NB, Shapiro MF, Gallego C, Vaghaiwalla R, Brook RH. Termination of Medi-Cal benefits. a follow-up study one year later. *N Engl J Med*. 1986;314(19):1266-1268.
22. Chernew M, Gibson TB, Yu-Isenberg K, Sokol MC, Rosen AB, Fendrick AM. Effects of increased patient cost sharing on socioeconomic disparities in health care. *J Gen Intern Med*. 2008;23(8):1131-1136.
23. Tseng CW, Brook RH, Keeler E, Steers WN, Mangione CM. Cost-lowering strategies used by medicare beneficiaries who exceed drug benefit caps and have a gap in drug coverage. *JAMA*. 2004;292(8):952-960.
24. Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. *N Engl J Med*. 2006;354(22):2349-2359. ■

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Supplemental Table and Figures for “Did Medicare Part D Reduce Disparities?”

Supplemental Figure 1. Cessation of Diabetes Drug Classes in the Coverage Gap in 2007



ACE indicates angiotensin-converting-enzyme; LIS indicates Low-Income Subsidy.

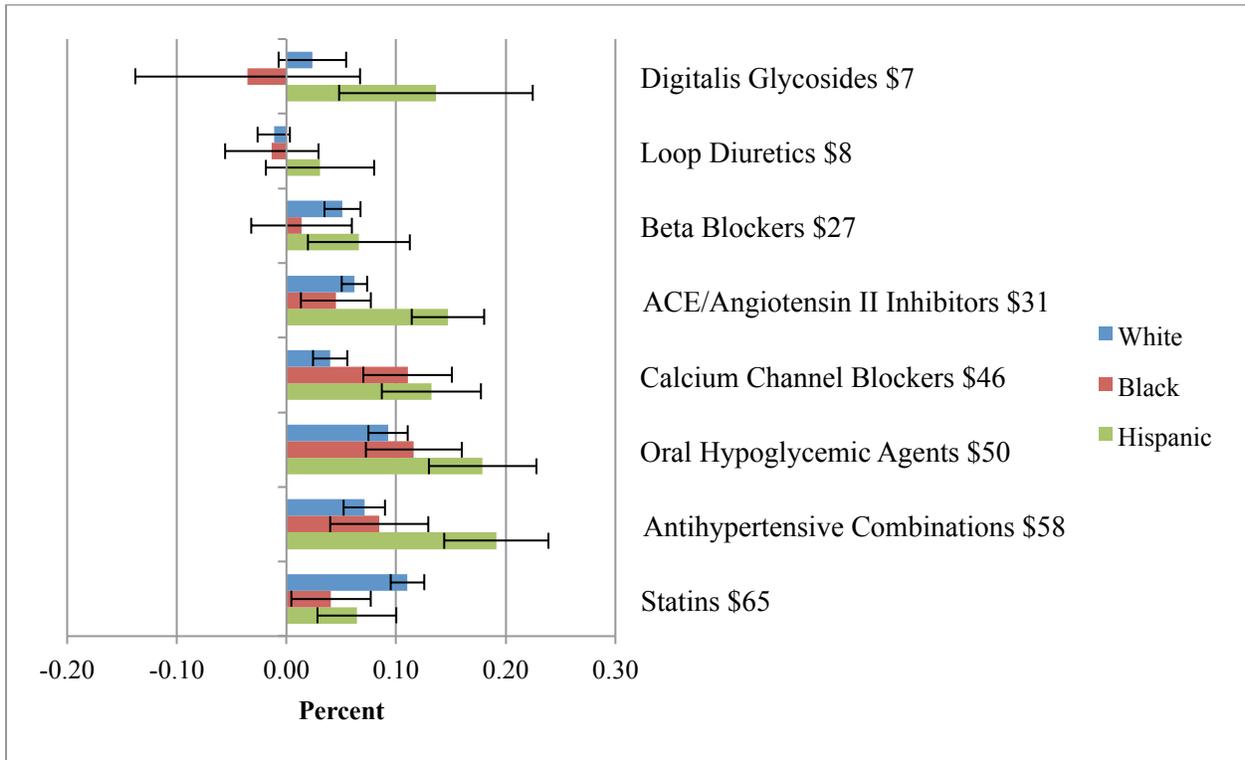
Percent of non-LIS stoppers minus percent of LIS stoppers, in the coverage gap in 2007. The number of “stoppers” is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007. Among stoppers, the difference in percent of non-LIS who resumed and percent of LIS who resumed in the first quarter of 2008.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

The sample (relevant sample for this table) is individuals aged 65 years and older with diabetes who reached the coverage gap in 2007 and remained in the coverage gap for at least 40 days. (Fewer than 40 days in the coverage gap would be too brief a period to observe cessation or resumption behavior.)

Supplemental Figure 2. Resumption of Diabetes Drug Classes in 2008 if Stopped in the Coverage Gap in 2007



ACE indicates angiotensin-converting-enzyme; LIS indicates Low-Income Subsidy.

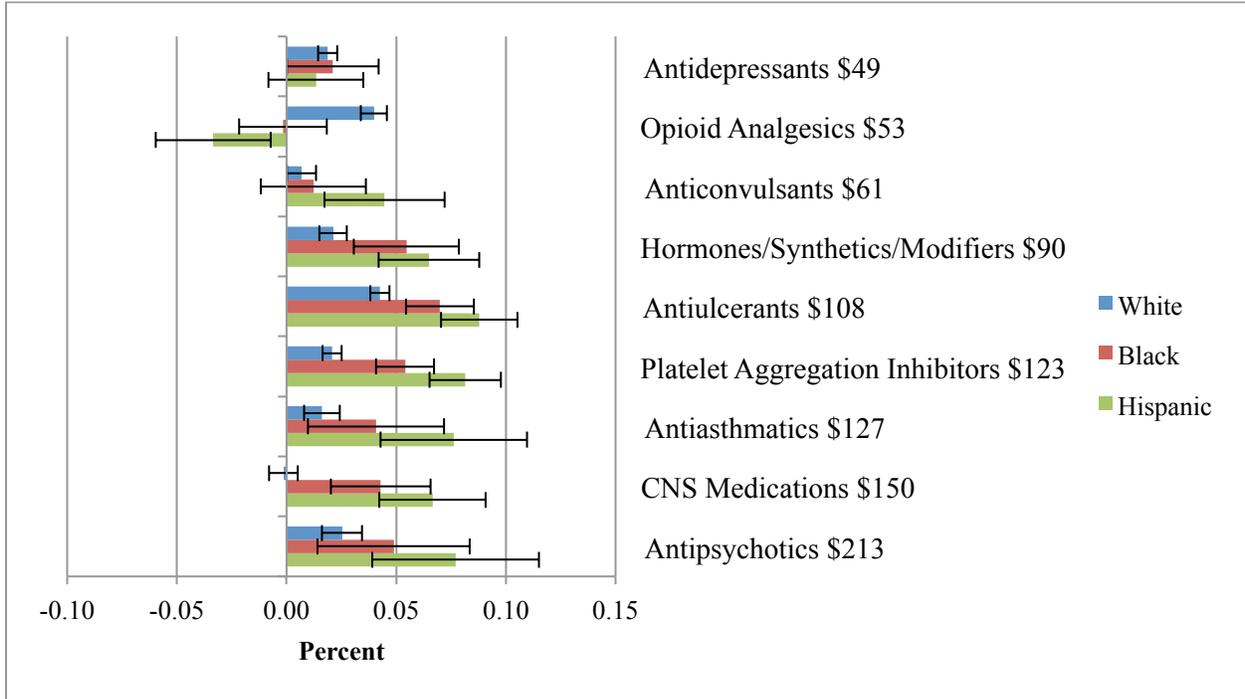
The number of “resumers” is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007 and stopped medications in at least 1 drug class.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

The sample (relevant sample for this table) is individuals aged 65 years and older with diabetes who reached the coverage gap in 2007 and remained in the coverage gap for at least 40 days. (Fewer than 40 days in the coverage gap would be too brief a period to observe cessation or resumption behavior.) The sample for ‘resumes drug’ is further restricted to individuals who stopped a drug in the coverage gap in 2007 and resumed the drug in the first quarter of 2008.

Supplemental Figure 3. Cessation of Non-Diabetes Drug Classes in the Coverage Gap in 2007



CNS indicates central nervous system; LIS indicates Low-Income Subsidy.

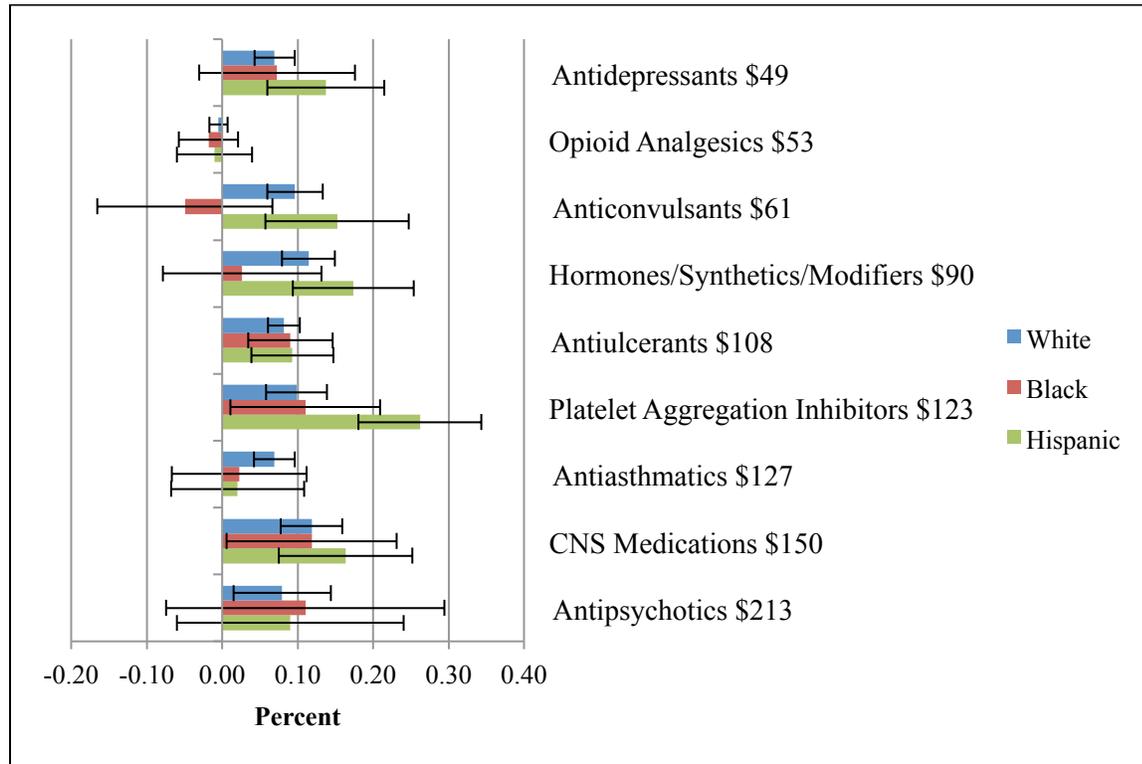
Percent of non-LIS stoppers minus percent of LIS stoppers, in the coverage gap in 2007. The number of “stoppers” is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007. Among stoppers, the difference in percent of non-LIS who resumed and percent of LIS who resumed in the first quarter of 2008.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

The sample (relevant sample for this table) is individuals aged 65 years and older with diabetes who reached the coverage gap in 2007 and remained in the coverage gap for at least 40 days. (Fewer than 40 days in the coverage gap would be too brief a period to observe cessation or resumption behavior.)

Supplemental Figure 4. Resumption of Non-Diabetes Drug Classes in 2008 if Stopped in the Coverage Gap in 2007



CNS indicates central nervous system; LIS indicates Low-Income Subsidy. Percent of non-LIS stoppers minus percent of LIS stoppers, in the coverage gap in 2007.

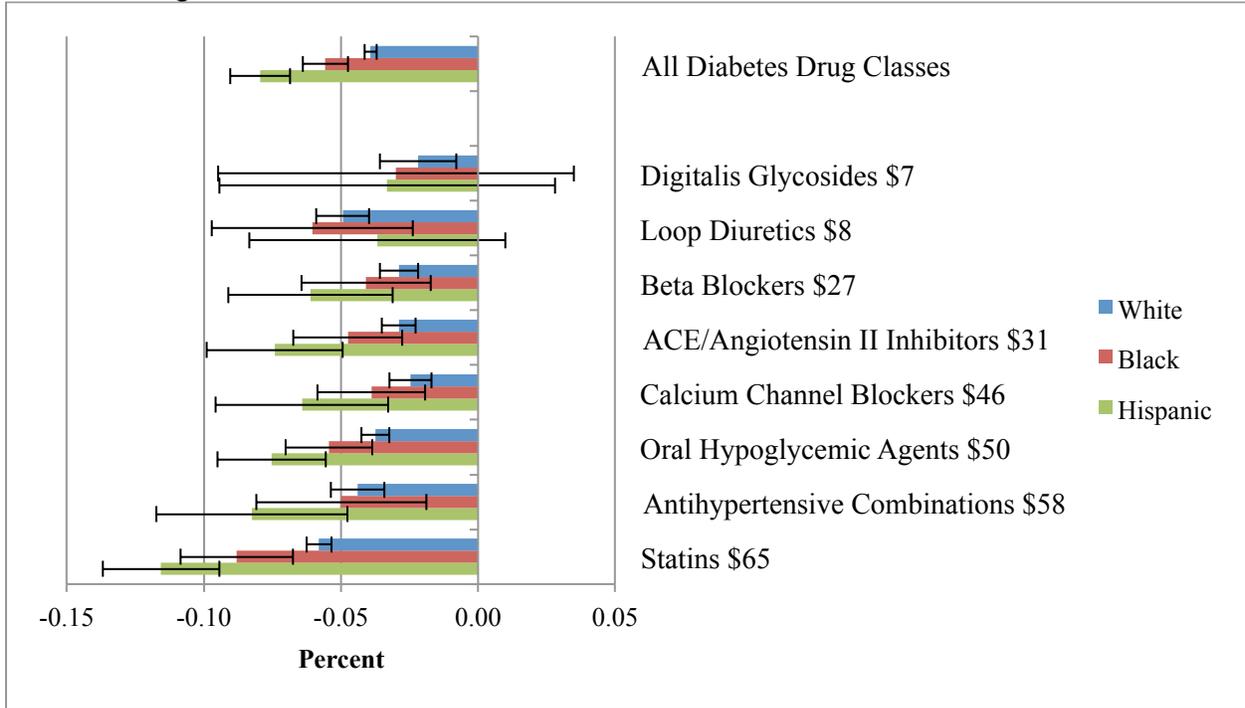
The number of “resumers” is the number of individuals of the particular race who spent at least 40 days in the coverage gap in 2007 and stopped medications in at least 1 drug class.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

The sample (relevant sample for this table) is individuals aged 65 years and older with diabetes who reached the coverage gap in 2007 and remained in the coverage gap for at least 40 days. (Fewer than 40 days in the coverage gap would be too brief a period to observe cessation or resumption behavior.) The sample for ‘resumes drug’ is further restricted to individuals who stopped a drug in the coverage gap in 2007 and resumed the drug in the first quarter of 2008.

Supplemental Figure 5. Percent Changes in Medication Use upon Entering the Coverage Gap: Diabetes Drugs



ACE indicates angiotensin-converting-enzyme; MPR, medication possession ratio, which is the fraction of days that a patient “possesses,” or has access to, medication, as measured by prescription fills.

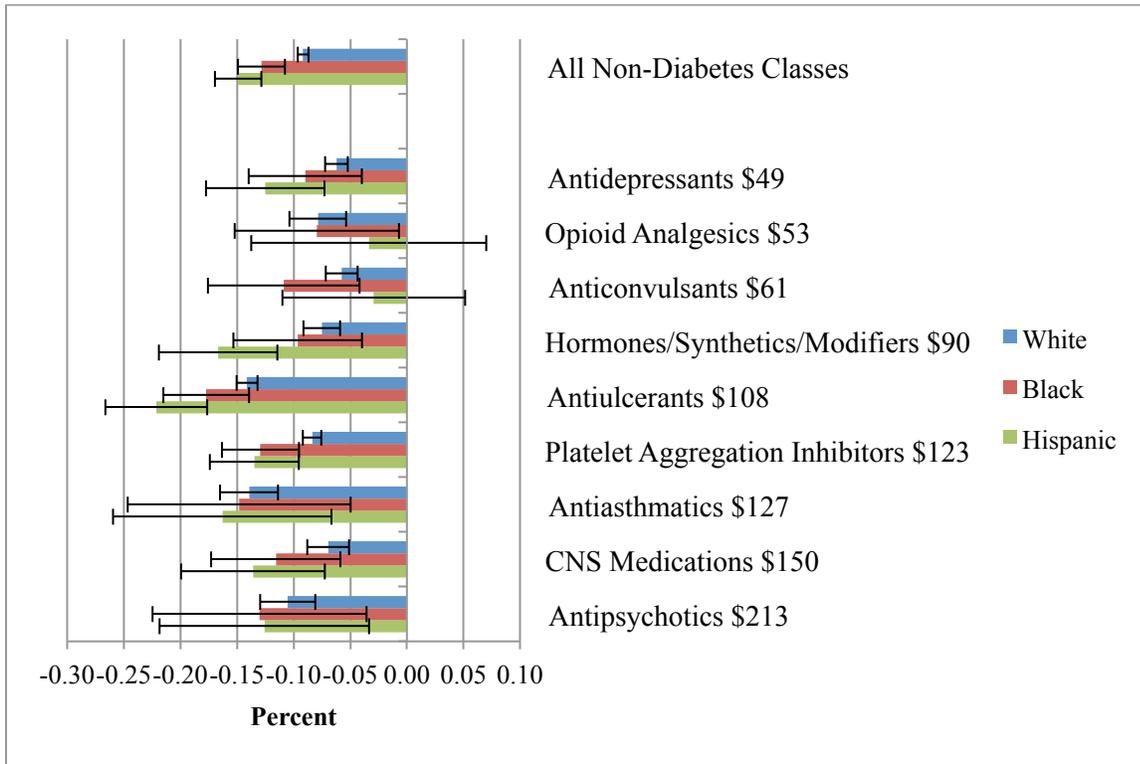
Changes are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Diabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 74,452; whites who did not receive the Low-Income Subsidy (non-LIS): n = 115,333; LIS blacks: n = 26,140; non-LIS blacks: n = 6131; LIS Hispanics: n = 29,113; non-LIS Hispanics: n = 4311.

Supplemental Figure 6. Percent Changes in Medication Use upon Entering the Coverage Gap: Nondiabetes Drugs



CNS indicates central nervous system; MPR, medication possession ratio, which is the fraction of days that a patient “possesses,” or has access to, medication, as measured by prescription fills.

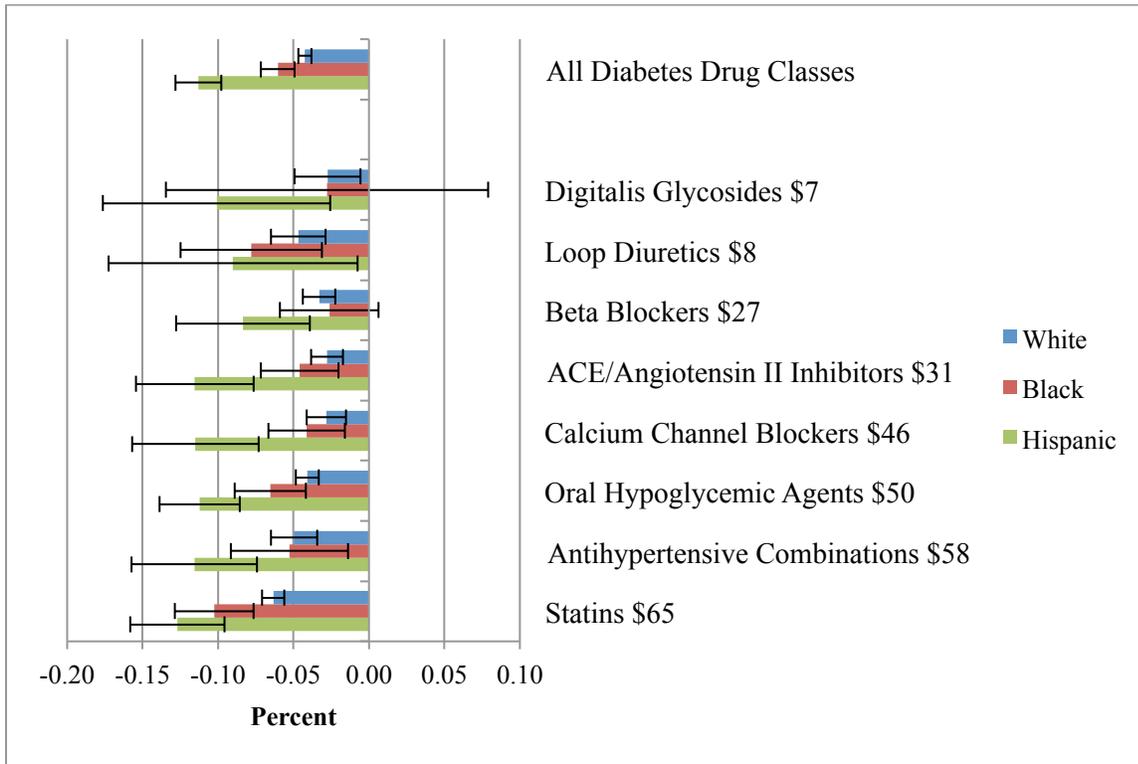
Changes are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Nondiabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 65,062; non-LIS whites: n = 89,927; LIS blacks: n = 21,337; non-LIS blacks: n = 4373; LIS Hispanics: n = 25,083; non-LIS Hispanics: n = 3464.

Supplemental Figure 7. Percent Changes in Medication Use of the Near-Poor Population Upon Entering the Coverage Gap: Diabetes Drug Classes



ACE indicates angiotensin-converting-enzyme; MPR, medication possession ratio, which is the fraction of days that a patient “possesses,” or has access to, medication, as measured by prescription fills.

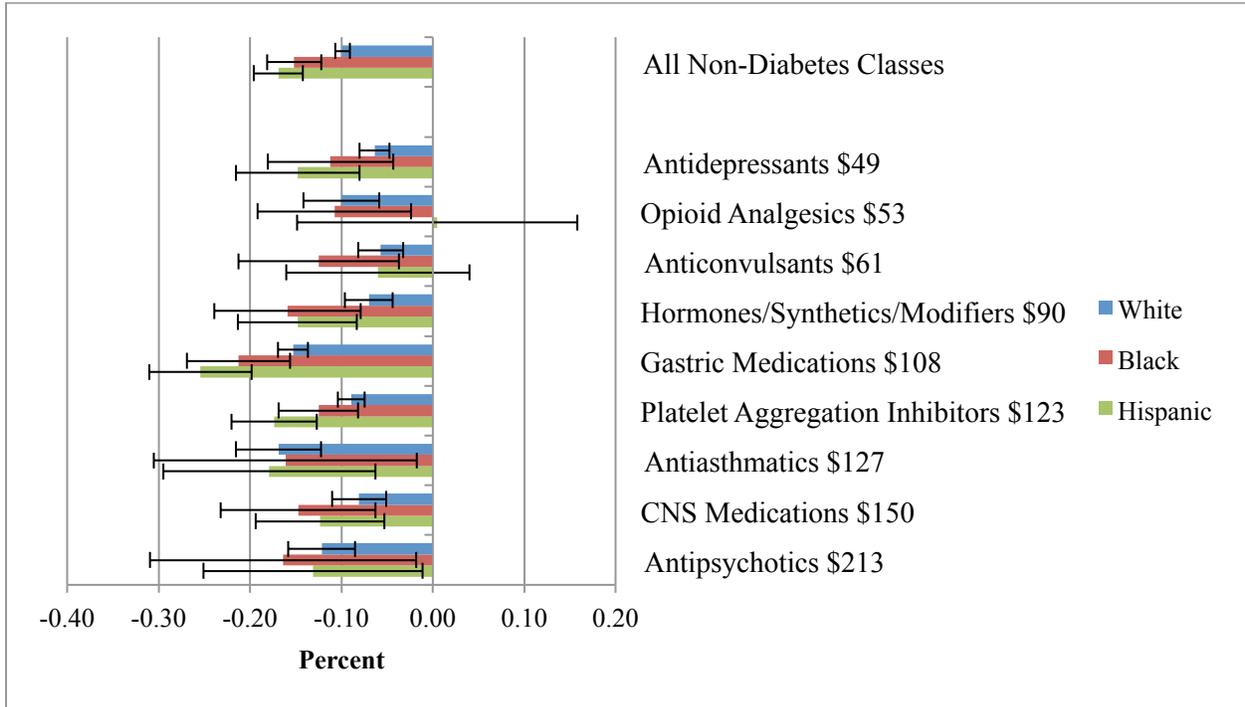
Changes are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Diabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 74,452; whites who did not receive the Low-Income Subsidy (non-LIS): n = 115,333; LIS blacks: n = 26,140; non-LIS blacks: n = 6131; LIS Hispanics: n = 29,113; non-LIS Hispanics: n = 4311.

Supplemental Figure 8. Percent Changes in Medication Use of the Near-Poor Population Upon Entering the Coverage Gap: Nondiabetes Drug Classes



CNS indicates central nervous system; MPR, medication possession ratio, which is the fraction of days that a patient “possesses,” or has access to, medication, as measured by prescription fills.

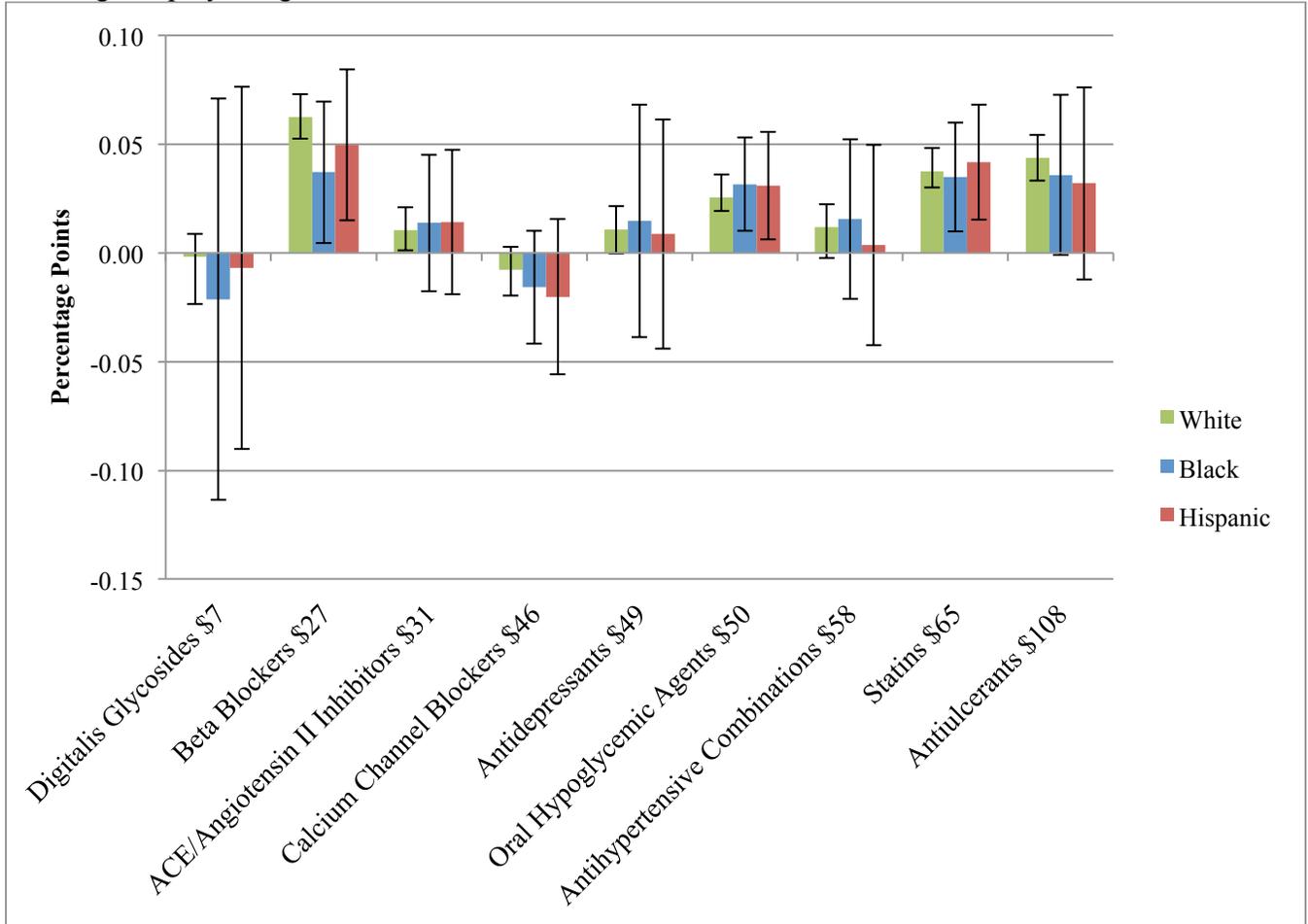
Changes are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Nondiabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 65,062; non-LIS whites: n = 89,927; LIS blacks: n = 21,337; non-LIS blacks: n = 4373; LIS Hispanics: n = 25,083; non-LIS Hispanics: n = 3464.

Supplemental Figure 9. Percentage Point Changes in Use of Generic Drugs upon Entering the Coverage Gap by Drug Class^a



ACE indicates angiotensin-converting-enzyme; GDR is the generic dispensing rate. Drug classes shown are those that are neither brand- (generic dispensing rate [GDR] < 20%) nor generic-dominated (GDR > 80%).

Changes are based on results from multivariate models that control for age, age-squared, gender, comorbid conditions, and socioeconomic status. This analysis is limited to therapeutic classes that are neither brand- nor generic-dominated. Diabetes-related classes include: oral hypoglycemic agents, ACE inhibitors, calcium channel blockers, beta-blockers, statins, digitalis glycosides, and combination antihypertensives. GDR for the angiotensin-converting-enzyme (ACE) inhibitors/angiotensin II receptor blocker (ARB) class is for ACE inhibitors only since the ARB class is brand-dominated. The set of other drugs consists of those among the 9 most prevalent nondiabetes-related classes used by this set of beneficiaries that are neither brand- nor generic-dominated: antidepressants and antiulcerants.

Black lines indicate 95% confidence intervals.

Prices shown reflect the average price paid in the sample for a 30-day supply of medication in the therapeutic class.

Diabetes-related drug classes: whites who received the Low-Income Subsidy (LIS): n = 70,284; non-LIS whites: n = 104,784; LIS blacks: n = 24,412; non-LIS blacks: n = 5475; LIS Hispanics: n = 27,159; non-LIS Hispanics: n = 3736. Nondiabetes-related drug classes: LIS whites: n = 61,860; non-LIS whites: n = 76,652; LIS blacks: n = 19,054; non-LIS blacks: n = 3339; LIS Hispanics: n = 22,485; non-LIS Hispanics: n = 2668.

Supplemental Table. Beneficiaries' Plan-Switching from Year 2007 to 2008

	White		Black		Hispanic	
	LIS (n = 62,342)	Non-LIS (n = 102,898)	LIS (n = 21,179)	Non-LIS (n = 4457)	LIS (n = 24,325)	Non-LIS (n = 3688)
Switched Plans, %	27.0	14.0	28.1	11.8	39.6	11.4
Change in OOP, \$	-12.65	-153.0	-7.22	-198.8	9.3	-167.4
Change in OOP, %	-2.8	-7.4	-1.7	-9.6	2.7	-7.6
Did Not Switch Plans, %	73.0	86.0	71.9	88.2	60.4	88.6
Change in OOP, \$	16.67	-51.5	7.82	-98.4	16.44	-82.44
Change in OOP, %	3.4	-2.3	1.6	-4.8	4.1	-4.0
Plan Change Type						
Added gap coverage, %	0.2	16.5	0.2	14.7	0.1	20.1
Lowered premium, %	32.6	25.4	47.1	25.8	28.9	18.2
Lowered deductible, %	17.2	25.8	17.8	32.8	24.6	27.0
Other, %	50.0	32.3	34.9	26.7	46.4	34.6

LIS indicates low-income subsidy; OOP, out-of-pocket costs.

Sample is individuals aged 65 years and older with diabetes who reached the coverage gap in 2007.

Individuals who switched from LIS to non-LIS status or vice versa are excluded from this analysis. Changes are from year 2007 to year 2008. Changes in OOP include premiums.