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Effects of Transitioning to Medicare Part D on Access to Drugs for Medical Conditions among Dual Enrollees with Cancer

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Abstract

Objective—To evaluate the impact of transitioning from Medicaid to Medicare Part D drug coverage on use of non-cancer treatments among dual enrollees with cancer.

Methods—We leveraged a representative 5% national sample of all fee-for-service dual enrollees in the U.S. (2004–2007) to evaluate the impact of the removal of caps on the number of reimbursable prescriptions per month (drug caps) under Part D on (1) prevalence and (2) average days' supply dispensed for antidepressants, antihypertensives, and lipid-lowering agents overall and by race (white, black).

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Author Contributions

All of the authors meet minimal criteria for inclusion as co-authors. As the first author, Dr. Adams designed the study, supervised all analyses, interpreted the data, drafted the article and revised the manuscript based on critical review by the co-authors. Co-author Zhang was the statistician and primary analyst on the study and provided critical and final review of the manuscript. Dr. Griggs was the senior author on the study and was actively involved in the creation of the study design, providing clinical expertise, the intrepretation of the data and the revision of the manuscript. Drs. Madden, Lu, Ross-Degnan, Soumeari and Chawla, and Mr. Gilden all contributed methodologic, clinical and scientific expertise to the study design, interpretation of study findings, and critical review of the manuscript. Dr. Lee was responsible for data extraction and preparation and provided critical review of the manuscript.

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Results—The removal of drug caps was associated with increased use of lipid-lowering medications (days' supply: 3.63; 95% CI: 1.57, 5.70). Among blacks in capped states, we observed increased use of lipid-lowering therapy (any use: 0.08 percentage points; 95% CI: 0.05, 0.10; days' supply: 4.01; 95% CI: 2.92, 5.09), antidepressants (days' supply: 2.20; 95% CI: 0.61, 3.78) and increasing trends in antihypertensive use (any use: 0.01 percentage points; 95% 0.004, 0.01; days supply: 1.83; 95% CI: 1.25, 2.41). The white-black gap in use of lipid-lowering medications was immediately reduced (−0.09 percentage points; 95% CI: −0.15, −0.04). We also observed a reversal in trends toward widening white-black differences in antihypertensive (level: −0.08 percentage points; 95% CI: −0.12, −0.05; trend: −0.01 percentage points; −0.02, −0.01), and antidepressant use (−0.004; 95% CI: −0.01, −0.0004).

Conclusions—Our findings suggest that the removal of drug caps under Part D had a modest impact on treatment of hypercholesterolemia overall and may have reduced white-black gaps in use of lipid-lowering and antidepressant therapies.

Keywords

Medicaid; Medicare; Dual Eligibles; Part D; comorbidity; disparities

INTRODUCTION

Patients eligible for both Medicare and Medicaid (dual enrollees) are the fastest growing segment of the Medicare population.[1–3] Primarily having fee-for-service coverage, these vulnerable patients are disproportionately non-white and at higher risk for multi-morbidity. In 2006, the Medicare Modernization Act (MMA) shifted prescription drug coverage for dual enrollees from Medicaid to privately-administered Medicare Part D plans.[4] Similar transitions in drug coverage occur to the present day as newly eligible dual enrollees are moved to Part D after a 2-year waiting period.[3]

One key feature of Medicare Part D is that, unlike many state Medicaid programs, Medicare Part D prohibits the use of limits, or caps, on the number of medications reimbursed per month.[4] Patients with multi-morbidity, who often require multiple medications, are more likely to encounter such caps, which may affect their decisions about treatment as they anticipate the limit on their coverage.[5,6] For example, to avoid the cap, patients may forgo adding a new medication to already complex regimens or forgo medications that prevent future adverse events (e.g., antihypertensives) in favor of those perceived to address more immediate needs (e.g., cancer treatment).[4,6,7] Prior studies have demonstrated the adverse effects that drug caps can have on treatment rates and risk of adverse health outcomes among vulnerable, low income patients.[5,8,9]

Dual enrollees with cancer, particularly racial and ethnic minorities, may be disproportionately affected by changes in prescription drug coverage due to financial distress associated with cancer treatment and high rates of comorbidity requiring ongoing medication management.[10–15] Antihypertensive, lipid-lowering and antidepressant medications are among the most commonly used prescription medications in this vulnerable population and adherence to these treatments is suboptimal.[16–18] Improving access to clinically effective medications for dual enrollees with cancer is critical given that dual

enrollment and comorbid hypertension, diabetes and depression are independently associated with delayed cancer diagnosis, lower quality cancer treatment and adherence, and post-operative complications.[19,20]

In addition, dual enrollees with cancer are less likely to receive guideline-consistent cancer treatment than non-dually enrolled Medicare beneficiaries.[19] Further, multi-morbidity has been identified as a potential determinant of persistent racial disparities in cancer mortality more generally, and African Americans, who are disproportionately represented among dual enrollees, may be at greater risk for both multi-morbidity and cost-related underuse of essential medications.[20–26]

Few studies have explored the impact of the MMA, including transition to Part D, on the quality of cancer care and related outcomes for dual enrollees.[27–31] As a consequence, little is known about the impact of the transition to Part D, including the removal of drug caps, on treatment of common comorbidities among dual enrollees with cancer.

The purpose of this study was to examine the effect of the removal of state-level caps under Part D on use of non-cancer drugs among dual enrollees with cancer. We hypothesized that the transition to Part D drug coverage would be associated with an increase in access to non-cancer therapies among dual enrollees living in states where stringent Medicaid drug caps were in use. Further, we explored whether response to the policy varied by race, given prior evidence of cost related underuse among African Americans with cancer and the importance of comorbidity as an underlying determinant of survival in this subgroup.[22–27]

METHODS

Study Design

We used a quasi-experimental design (interrupted time series with comparison series)[32] to examine changes in use of lipid-lowering, antihypertensive and antidepressant drugs before (2004–2005) and after (2006–2007) the transition of dual enrollees from Medicaid to Medicare Part D drug coverage. As described in previous publications,[33–35] we compared dual enrollees in states with and without exposure to Medicaid drug caps before the transition to Part D. Each subgroup served as its own historical control by providing a baseline level and time trend. Since state residency, while not random, should be unrelated to changes in use of non-cancer drugs at the time of the transition of dual enrollees to Part D. Therefore, this natural experimental design should provide strong evidence of the effects of removing drug caps. Lastly, we also examined temporal trends in utilization among a subgroup of black and white patients in capped and no-capped states to explore variation in use by race.

Our study protocol was reviewed and deemed exempt by the Institutional Review Boards of the Kaiser Foundation Research Institute.

Data Sources and Study Population

We used data from a 5% nationally representative sample of linked Medicaid, Medicare, and Part D drug claims for dual enrollees for the years 2004 through 2007 provided by the

Centers for Medicare and Medicaid Services to identify patients for this analysis.[Figure 1] We extracted data for patients with at least one inpatient or two outpatient diagnoses of common cancers (breast (174.0–174.9, 175.0, 175.9), colorectal (153.0–153.9, 154.0–154.3, 154.8), prostate (185), lung (162.0–162.9) or cervical cancer (180, 180.1, 180.8, 180.9, 182.0)) at any time during baseline (2004–2005) or follow up (2006–2007). We required continuous four-year dual enrollment, except in the case of death, with no enrollment in Medicare or Medicaid managed care. We excluded 72 enrollees residing in Ohio, Arizona, and Louisiana due to data anomalies in those states, such as concurrent changes in coding and reporting methods.[36] In addition, we excluded 492 patients who were institutionalized for more than three months during the calendar year.

Using publically available data,[37,38] we were able to categorize the remaining states and Washington, DC into three Medicaid drug cap policy categories prior to Part D implementation: capped (5 or fewer prescriptions of any kind or 3 or fewer prescriptions for brand name drugs per month), non-capped, and other state policies that were difficult to categorize due to generous cap thresholds and lenient waiver policies. We categorized 196 patients living in Texas, Oklahoma, Mississippi, and Arkansas as residing in capped states.

We identified a comparison subgroup of 642 dual enrollees who lived in 31 non-capped states (full list provided in Figure 1 and Table 1) and the District of Columbia. Eleven states (AL, CA, GA, IL, KS, KY, ME, NC, NY, PA, SC) fell into the “other” category and were excluded from the analysis to reduce possible misclassification. In addition, we excluded Tennessee, which instituted a drug cap policy during the baseline period.[37,38] Our analysis focused on the 838 patients living in states in one of the first two categories, and our primary exposure of interest was a dichotomous indicator for whether the beneficiary lived in a capped versus non-capped state in 2005.

Measures

Drugs of interest included antihypertensive medications, antidepressant agents, and lipid-lowering drugs and were identified through Medicaid and Part D pharmacy claims using National Drug Codes. Our primary outcomes were monthly indicators for (1) prevalence of medication use (proportion of patients with medication available during the month based on current and prior dispensing) per therapeutic drug class per month and (2) intensity of medication use, calculated as the number of days’ supply dispensed per therapeutic drug class per month across the entire cohort. Days’ supply is robust to possible changes in the quantity allowed per prescription fill between Medicaid and Part D (e.g., 30 vs. 90 day fills).

Data on patient race/ethnicity (white, black, Hispanic, Asian, other), age (categorized as < 54, 55–64, 65–74, ≥ 75) and sex (male, female) were obtained from Medicaid and Medicare administrative files. Race and ethnicity data in the CMS files were derived from the Social Security Administration. Sensitivity and specificity are high for blacks (97.4, 98.8). Sensitivity is high for whites (99.3%), though specificity is lower at 61.7%. Due to poor sensitivity and specificity for other racial/ethnic subgroups, we excluded these groups from subgroup analysis.[38] We examined changes in use of study drugs by black and white race to assess the differential impacts of the transition to Part D on these groups. Sample sizes for other racial/ethnic categories were too small to allow subgroup analyses.

To characterize the patient populations at baseline, we categorized a subgroup of patients as having incident cancer if they had no evidence of cancer in 2004 based on a combination of diagnosis codes (ICD 9) and procedure codes (ICD9, revenue, HCPC codes).[40] We used enrollment and claims data to identify use of cardiotoxic cancer-directed therapy, diagnosis of hypertension, diabetes, or depression, as well as deaths during the study period. Cardiotoxic cancer-directed therapies were defined as those associated with increased cardiovascular risk (epirubicin, doxorubicin, mitoxantrone, daunorubicin, daunorubicin, 5-flurouacil, capecitabine, trastuzumab) were identified using a combination of NDC and HCPC codes.[41] Comorbid hypertension, diabetes, and depression were identified using ICD-9 codes from inpatient and outpatient claims. Last, we identified several additional comorbidities associated with cancer or its treatment (haemolytic anemia, glomerulonephritis, Grave's disease, multiple sclerosis, myasthenia gravis, myocarditis, polymyositis, dermatomyositis, rheumatic fever and heart disease, rheumatoid arthritis, scleroderma, systemic lupus erythematosus, human immunodeficiency virus, hepatitis C, Crohn's disease, Parkinson's disease, and epilepsy).[42–45] The specific codes used to create these measures are available in a footnote on Table 1.

Statistical Analysis

Using interrupted time series (ITS) methods,[32,46] we examined changes in the level and slope of the two study outcomes separately for each drug class from before to after the transition to Part D, stratifying by capped versus non-capped state status. We excluded observations during one month before and three months following the transition to Part D (December 2005–March 2006) to allow for temporary state coverage that may have distorted outcomes during the transition period.

To estimate policy effects across racial subgroups, we first conducted stratified analyses, calculating changes in each of the outcomes before and after policy implementation within subgroups defined by race and cap status (e.g., change in the proportion using antidepressants among whites in capped states). To directly estimate the impact of the policy by race, we then calculated changes over time in the difference in outcomes within capped and non-capped states, respectively (e.g., change in the gap between white and black patients in use of lipid-lowering agents before and after Part D in capped states). This analysis was carried out in the same way for each of the three drug classes.

ITS models are advantageous in that they control for autocorrelation and pre-existing trends in medication use. The non-capped states served as a comparison group to help control for changes unrelated to Part D transition, such as changes in the economy and drug availability. The primary threats to validity in these models are policies that change at the same time as the policy change being investigated.[32] Our use of a continuously enrolled cohort rules out sudden changes in case mix related to age, sex or comorbidity.

Given that the ITS models required multiple testing (3 therapeutic classes and 2 outcomes per class), we estimated that the probability of observing a significant result by chance within any subgroup would be equal to $1-(1-0.05)^6$ or 27%. To reduce the possibility of false positives, we applied a Bonferroni correction in which we divided the usual 0.05 level for significance by 6, resulting in a p value of 0.008 to judge statistical significance.[47] With

this correction, the probability of observing a significant result by chance was reduced to 1-(1-0.008)^6 or 5%. All statistical analyses were conducted using the SAS system (SAS, v.9.0, Durham, NC).[48]

Results

Enrollee Characteristics

Baseline patient characteristics are presented in Table 1. Compared to patients in non-capped states, dual enrollees in non-capped states were more likely to be white (56% vs. 67%; p=0.04) and over the age of 75 (44% vs. 33%; p=0.001). Dual enrollees in capped states were less likely to have diagnoses of depression (5% vs. 12%; p=0.004) or of other comorbidities associated with cancer or its treatment (8% vs. 13%; p=0.05). We found no statistically significant differences in sex, cancer type, incident cancer, use of cardiotoxic therapy, or death by cap status.

Baseline Use of Non-Cancer Drugs by State Cap Status

Baseline (January 2005–November 2006) utilization rates for capped and non-capped states are presented in Table 2. Compared to dual enrollees in non-capped states, dual enrollees in capped states had lower utilization of antidepressants (13% vs. 25%; p<0.01) and lipid-lowering therapies (21% vs. 31%; p<0.01) at baseline. The mean days' supply was consistently significantly lower (p<0.01) among dual enrollees in capped states for all three drug classes (antidepressants: 5.10(1.75) vs. 12.1 (1.19); antihypertensives 36.2 (4.28) vs. 54.2 (4.09); lipid-lowering agents: 6.75 (1.80) vs. 11.57 (1.11)).

Changes in Use Following the Transition to Part D by State Cap Status

We observed no statistically significant (p<0.008) changes after Part D in the proportion of patients with any use of any class of interest in either capped or non-capped states following the transition to Part D (Table 3). However, there was a large, marginally significant increase in antihypertensive days of supply in capped states [days' supply: 8.60; 95% CI: 1.22, 16.0] that was not present in non-capped states. We also observed a statistically significant reduction (difference in days supplied: 3.63; 95%: 1.57, 5.70) in the gap in days' supply of lipid-lowering drugs between dual enrollees in capped states (days' supply 2.71; 95% CI: −0.15, 5.56) relative to those in non-capped states (days' supply −1.13;95% CI: −2.21, −0.05).

Variation in Response by Race

To explore variation in policy response by race, we stratified the models above by white and black race and estimated the difference by race within state subgroups (Table 4). The transition from Medicaid to Medicare Part D was associated with an immediate increase in the prevalence of use of lipid-lowering drugs among blacks in capped states (8 percentage points;95% CI: 0.05, 0.10); trend change 0.4 percentage points;95% CI: 0.002, 0.005)) (Table 4). Black patients in capped states also experienced an increasing trend in monthly prevalence of use of antihypertensive agents (1 percentage point; 95% CI: 0.004, 0.01). There were no corresponding changes in prevalence of use for these medications among blacks in non-capped states or among whites in either capped or non-capped states.

Among black patients, the transition to Part D was also associated with increased intensity of use of antidepressants (2.20 days supplied; 95% CI: 0.61, 3.78) and of lipid-lowering agents (4.01 days supplied; 95% CI: 2.92, 5.09). Blacks in capped states also experienced an increasing trend in the intensity of antihypertensive use (1.83 days supplied per month; 1.25, 2.41). Among whites in capped states, a level increase in intensity of use of antihypertensives (12.27 days supplied; 95% CI: 2.11, 22.43) did not reach our more conservative threshold for statistical significance. There was also an increasing trend in the intensity of antidepressant use among whites in non-capped states (0.16 days per month, p=0.006) that was not observed among whites in capped states or among blacks regardless of cap status pre-Part D.

In the differenced time series [Table 4, Figure 2], there was an immediate reduction of 9 percentage points [95%CI: −0.15, −0.04] in the gap between whites and blacks in the proportion using lipid-lowering agents in capped states following Part D implementation. In addition, a prior trend of increasing white-black differences in antihypertensive use was reversed following Part D [−8 percentage points; 95%CI: −0.12, −0.05; trend change: −0.01 percentage points per month; 95%CI: −0.02, −0.01]. We observed a similar reversal in the white-black difference trend for antihypertensive days supplied [trend change: −1.83 days supplied per month; 95%CI: −2.81, −0.85]. For antidepressants in capped states, comparable reversals in what had previously been upward trends in white-black difference for both outcome measures approached, but did not attain, statistical significance [Table 4, Figure 2].

Discussion

In summary, among dual enrollees with cancer, we observed a modest increase in antihypertensive days' supply, as well as reduction in the difference in days' supply of lipid-lowering therapy between capped and non-capped states. Part D was not associated with overall changes in overall use of antidepressants among dual enrollees with cancer in capped relative to non-capped states. These findings are consistent with our prior findings among dual enrollees with diabetes showing an increase in use of lipid-lowering agents, but contrast with our previous evaluations that showed an increase in use of antidepressants overall. [33,34]

We also found that the transition from capped state Medicaid programs to Part D was associated with evidence of an increase in use of non-cancer drugs among black patients in capped states. The largest effect among the three classes we examined was for lipid-lowering therapy. Differential effects of the policy by race may reflect differences in how patients choose between medications in the presence of drug caps, including higher out of pocket costs of lipid-lowering drugs relative to antihypertensives.[37,38] In addition, the ways in which patients weigh the benefits and costs of adding medications will likely be influenced by how they value medications, which others have reported varies by patient race and ethnicity.[49] However, patient decision-making in the face of drug caps is also likely influenced by other factors, such as patient-provider communication and the site of care. More research is needed to understand the mechanisms responsible for these differences and how they might be leveraged to address persistent disparities in treatment.

This study has some important limitations that merit discussion. First, the analysis, particularly the differenced time series by race, is based on small subgroups of patients. Therefore, suggesting that more evidence is needed from studies with larger sample sizes to examine changes within clinically appropriate subgroups of patients before we can draw conclusions about the overall effects of the transition among dual enrollees with cancer and comorbid chronic conditions. However, it is important to note that the patients in each of the subgroups come from a 5% stratified random sample of all Medicare beneficiaries and, therefore, represent a much larger number of patients. Importantly, in ITS models, power is also determined by the number of observations before and after the interruption and their correlation over time, with the number of subjects contributing primarily to the underlying variation in the observed rates. In this case, we had 23 observations before and 22 after the intervention.[32,46]

The small sample size limited our ability to explore additional subgroup analyses by cancer diagnosis type or among patients with a concurrent comorbidity diagnosis (e.g., breast cancer and hypertension). As a result, we cannot evaluate the clinical appropriateness of observed changes in utilization, particularly by race. In addition, we were unable to assess differences in outcomes by cancer stage and prognosis since these variables are not reported reliably in claims data. Both stage and prognosis may impact prescribing and use of other non-cancer therapies.

Due to poor sensitivity and specificity of racial/ethnic identification in subgroups other than blacks and whites, we excluded other subgroups and may have missed important differences by race/ethnicity.[39] For example, previous studies suggest that Latinos, a growing subset of the dual enrollee population, may experience considerable barriers to guideline-concordant cancer and supportive care.[1,2,50–51] Moreover, our findings regarding black patients likely reflect the complex myriad social, economic, biological, and cultural factors for which race is a proxy.[52] Therefore, race alone is unlikely to serve as a strong or reliable predictor of future response as new dual enrollees continue to transition to Part D following the 2-year waiting period. Importantly, race may reflect differences in where and from whom patients receive care, as well as patient-provider communication about treatment, which may be an especially important modifier of racial differences in treatment decision-making and response to changes in coverage.[7,53,54]

No true control group exists for this analysis since all dual enrollees made the transition from Medicaid to Part D drug coverage. However, our use of ITS models should protect against confounding due to gradual changes in case mix within subgroups over time by allowing each subgroup to act as its own control. It is important to note that some generic versions of branded lipid-lowering (e.g. simvastatin) and antidepressant medications became available around the time of the policy change. If the availability of these drugs varied across states, such changes could bias our findings. However, the generic substitution rate for all state Medicaid programs in 2006 was high at 89% and slightly higher for dual enrollees post Part D implementation.[55] In addition, the rate of generic substitution was relatively stable across states, ranging from 83% to 91%, suggesting that variation in generic availability is not a significant confounder in this analysis.

Our decision to restrict analyses to continuously-enrolled patients reduces the generalizability of our findings although including patients who died during the year may have reduced the impact of this decision. Since this is an observational study, we could not control for any confounders that occurred simultaneously with the policy, such as state outreach or educational efforts that carried on well after policy implementation.

This study also has a number of strengths. The quasi-experimental design is one of the strongest observation study designs for evaluating policy effects. In addition, the use of a large, representative sample of dual enrollees with cancer increases the generalizability of study findings.

Conclusion

Dual enrollees with cancer are a highly vulnerable subgroup of the Medicare population. [1,2,51] Our findings suggest that the removal of caps due to the transition of dual enrollees from Medicaid to Medicare Part D may have had a modest overall impact on access to non-cancer therapies among patients with cancer. However, we found some evidence of racial differences in response, indicating that blacks may have benefitted more than whites from the transition. Given substantial growth in the dual enrollee population as a result of Medicaid expansions under the Affordable Care Act [56] and the continued use of strict drug caps as a cost containment tool within state Medicaid programs,[37,38] understanding the reasons behind differential response to this transition is critical to assessing whether the ongoing transition of dual enrollees to Part D will result in improved access to care. Specifically, exploring the mechanisms by which this and similar changes in coverage affect access to non-cancer therapies can inform the development of strategies to maximize the potential for such policies to ensure access to clinically essential services, especially among groups of patients that experience disparities in access due to restricted coverage.

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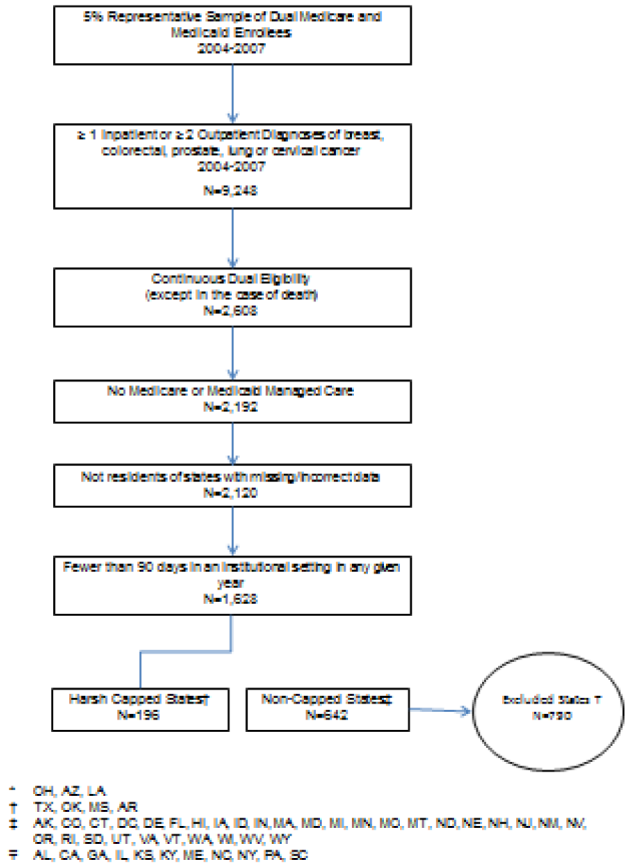

Figure 1.
Cohort Selection Process for Analysis of Dual Enrollees with Cancer

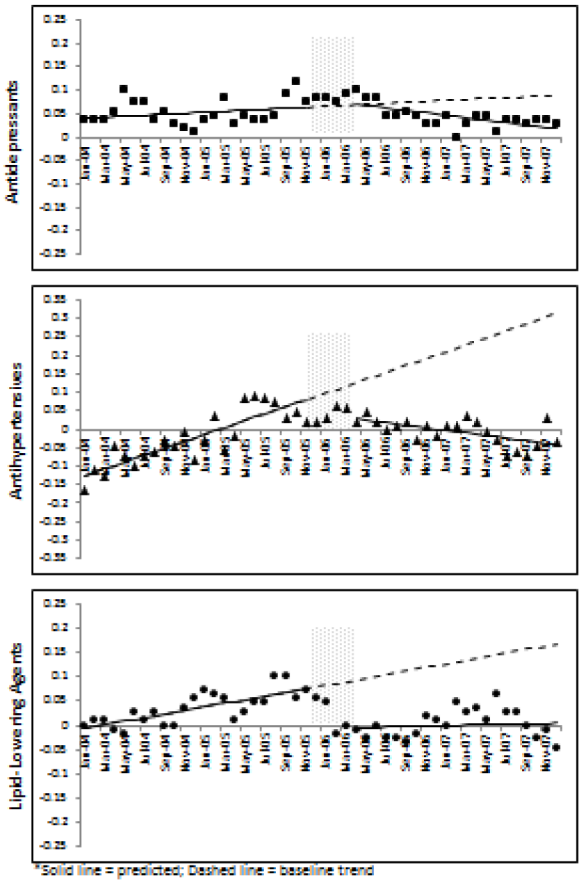

Figure 2.

Estimated difference (white-black) in the proportion of patients with any use by drug class among dual enrollees with cancer in capped states (2004–2007)*

Table 1

Baseline (2005) Characteristics of Dual Enrollees with Cancer in States with and without Restrictive Drug Caps

	All N=838	Cap States* N=196	Non Cap States** N=642	p-value
State with Drug Caps				
No	642 (77%)	0	642 (100%)	
Yes	196 (23%)	196 (100%)	0	
Race/Ethnicity				0.040
White	542 (65%)	110 (56%)	432 (67%)	
Black	177 (21%)	55 (28%)	122 (19%)	
Asian	37 (4%)	<10 (4%)	29 (4%)	
Hispanic	60 (7%)	16 (8%)	44 (7%)	
Other	22 (3%)	<10 (4%)	15 (2%)	
Gender				0.780
Male	164 (20%)	37 (19%)	127 (20%)	
Female	674 (80%)	159 (81%)	515 (80%)	
Age				0.001
≤54	113 (13%)	15 (8%)	98 (15%)	
55–64	117 (14%)	18 (9%)	99 (15%)	
65–74	309 (37%)	77 (39%)	232 (36%)	
≥75	299 (36%)	86 (44%)	213 (33%)	
New Cancer Diagnosis				
No	338 (40%)	72 (37%)	266 (41%)	0.241
Breast	168 (20%)	37 (19%)	131 (20%)	0.640
Prostate	18 (2%)	-- (1%)	15 (2%)	0.496
Colorectal	164 (20%)	43 (22%)	121 (19%)	0.340
Cervical	94 (11%)	27 (14%)	67 (10%)	0.195
Lung	56 (7%)	14 (7%)	42 (6%)	0.768
Cardiotoxic Cancer Treatment				0.831
No	710 (85%)	167 (85%)	543 (85%)	
Yes	128 (15%)	29 (15%)	99 (15%)	
Hypertension Diagnosis†	542 (65%)	136 (69%)	406 (63%)	0.115
Diabetes Diagnosis†	277 (33%)	60 (31%)	217 (24%)	0.406
Depression Diagnosis†	89 (11%)	10 (5%)	79 (12%)	0.004
Other Comorbid Conditions†	102 (12%)	16 (8%)	86 (13%)	0.050

	All N=838	Cap States* N=196	Non Cap States** N=642	p-value
Died	127 (15%)	29 (15%)	98 (15%)	0.645

*TX, OK, MS, AR

**AK, CO, CT, DE, FL, HI, IA, ID, IN, MA, MD, MN, MO, MT, ND, NE, NH, NM, NV, OR, RI, SD, UT, VA, VT, WA, WI, NV, WY, Washington, DC

†Evidence of the following diagnoses at any time between 2004 and 2007. Hypertension: ICD9-CM=401,401.0, 401.1, 401.9, 402, 403, 403.0, 403.1, 404, 405, 405.0, 405.01, 405.11; Diabetes: ICD9-CM=250.XX; Depression: ICD9-CM=296.20–296.26; 296.30–296.36; 296.89; 298.0, 300.4, 301.12, 309, 309.0, 309.1, 309.28, 311; Other comorbid conditions: haemolytic anemia: 283.0–283.2; glomerulonephritis: 580.0–583.9; Graves disease: 242.00–242.91; multiple sclerosis: 340; myasthenia gravis: 358.0; myocarditis: 130.3, 422.0, 422.0, 429.0; polymyositis/dermatomyositis: 710.3, 710.4; rheumatic fever and heart disease: 390–398.9; rheumatoid arthritis: 714.0–714.2; diffuse diseases of connective tissue (includes systemic lupus, scleroderma): 710.0–710.5, 710.8, 710.9; Human Immunodeficiency Virus: 042; hepatitis C: 070.54; Crohn's disease: 555.0, 555.1, 555.9; Parkinson's disease: 332.0, 332.1; and epilepsy: 345.00, 345.10, 345.11, 345.2, 345.3, 345.40, 345.41, 345.50, 345.51, 345.70, 345.71, 345.80, 345.81,345.90, 345.91

Table 2

Baseline (Pre-Part D) Differences in Non-Cancer Drug Use by Drug Cap Status

	% with Any Use (min, max)			Mean Days' Supply (St Dev)		
	Antidepressants*	**Antihypertensives**	**Lipid Lowering***	**Antidepressants***	**Antihypertensives***	**Lipid Lowering***
Capped	13% (9.7, 16.3)	60% (39.3, 64.3)	21% (15.3, 24.0)	5.10 (1.75)	36.2 (4.28)	6.75 (1.80)
Non- Capped	25% (22.6, 26.8)	57% (49.5, 60.0)	31% (23.0, 32.7)	12.1 (1.19)	54.2 (4.09)	11.57 (1.11)

* p value<0.01

Table 3

Changes in the Proportion of Patients Using Non-Cancer Drugs by Class, State Cap Status*

	% with any use				Days' Supply			
Coefficient 95% Confidence Interval P value	**Intercept**	**Baseline Trend**	**Level Change**	**Change in Trend**	**Intercept**	**Baseline Trend**	**Level Change**	**Change in Trend**
Antidepressants								
Capped states (N=196)	0.11 (0.10, 0.13) <0.001	0.001 (0.0003, 0.003) 0.016	−0.02 (−0.05, 0.001) 0.059	−0.001 (−0.003, 0.001) 0.312	4.93 (3.61, 6.24) <0.001	0.01 (−0.08, 0.11) 0.759	0.63 (−1.46, 2.72) 0.547	−0.06 (−0.21, 0.08) 0.402
Non-capped states (N=642)	0.26 (0.25, 0.26) <0.001	−0.001 (−0.001, −0.0004) <0.001	−0.0004 (−0.01, 0.01) 0.907	0.0005 (0.00001, 0.001) 0.047	12.38 (11.61, 13.14)br1> <0.001	−0.02 (−0.08, 0.03)br1> 0.426	0.37 (−0.85, 1.59)br1> 0.545	0.10 (0.02, 0.19) 0.08
Difference	−0.14 (−0.16, −0.12) <0.001	0.002 (0.001, 0.003) 0.003	−0.02 (−0.04, 0.01) 0.167	−0.001 (−0.003, 0.0004) 0.118	−7.46 (−9.33, −5.60) <0.001	0.03 (−0.10, 0.17) 0.600	0.33 (−2.63, 3.30) 0.821	−0.16 (−0.37, 0.04) 0.113
Antihypertensives								
Capped states	0.47 (0.35, 0.58) <0.001	0.01 (0.0005, 0.01) 0.037	−0.06 (−0.19, 0.06) 0.297	−0.01 (−0.02, 0.01) 0.308	34.71 (30.1, 39.3) <0.001	0.12 (−0.21, 0.46) 0.459	8.60 (1.22, 16.0) 0.023	0.56 (0.04, 1.07) 0.035
Non-capped states	0.53 (0.48, 0.59) <0.001	0.001 (−0.002, 0.005) 0.396	−0.01 (−0.07, 0.05) 0.714	0.0002 (−0.005, 0.006) 0.953	54.61 (50.68, 58.5) <0.001	−0.03 (−0.32, 0.25) 0.810	3.79 (−2.45, 10.04) 0.227	0.27 (−0.16, 0.70) 0.218
Difference	−0.04 (−0.10, 0.10) 0.107	0.005 (0.002, 0.01) 0.006	−0.05 (−0.13, 0.02) 0.159	−0.005 (−0.13, 0.02) 0.065	−19.90 (−23.56, −16.24) <0.001	0.159 (−0.11, 0.43) 0.235	4.80 (−1.02, 10.63) 0.103	0.29 (−0.12, 0.69) 0.162
Lipid Lowering Drugs								
Capped states	0.20 (0.18, 0.22) <0.001	0.001 (−0.0002, 0.003) 0.100	0.005 (−0.03, 0.04) 0.789	0.002 (−0.0003, 0.004) 0.087	6.89 (5.06, 8.65) <0.001	−0.01 (−0.14, 0.12) 0.890	2.71 (−0.15, 5.56) 0.063	0.03 (−0.17, 0.23) 0.754
Non-capped states	0.26 (0.24, 0.29) <0.001	0.003 (0.002, 0.005) <0.001	−0.02 (−0.05, 0.01) 0.245	−0.001 (−0.004, 0.001) 0.271	10.58 (9.88, 11.27) <0.001	0.08 (0.31, 0.13) 0.002	−1.13 (−2.21, −0.05) 0.041	0.72 (−0.003, 0.15) 0.061
Difference	−0.08 (−0.10, −0.05) <0.001	−0.001 (−0.003, 0.0003) 0.110	0.02 (−0.01, 0.06) 0.209	0.002 (−0.0005, 0.005) 0.121	−3.92 (−5.21, −2.62) <0.001	−0.07 (−0.17, 0.02) 0.119	**3.63 (1.57, 5.70) <0.001**	−0.05 (−0.20, 0.09) 0.460

*Corrected p value<0.008 used to assess statistical significance; Statistically significant effects are in bold; 95% confidence intervals shown.

Table 4

Changes in the Proportion of Patients Using Non-Cancer Drugs by Race, Class, State Cap Status *

	Any Use				Days of Supply			
Coefficient 95% Confidence Interval P value	**Intercept**	**Trend**	**Level Change**	**Change in Trend**	**Intercept**	**Trend**	**Level Change**	**Change in Trend**
Antidepressant use								
Capped								
Among whites	0.13 (0.12, 0.15) <0.001	0.001 (0.0004, 0.002) 0.006	0.02 (−0.04, 0.001) 0.057	−0.002 (−0.003, −0.0003) 0.018	4.62 (3.58, 5.66) <0.001	−0.02 (−0.09, 0.06) 0.667	1.08 (−0.58, 2.74) 0.195	−0.03 (−0.15, 0.08) 0.562
Among blacks	0.09 (0.06, 0.12) <0.001	0.0003 (−0.002, 0.003) 0.757	−0.02 (−0.07, 0.02) 0.308	0.002 (−0.001, 0.005) 0.221	4.96 (3.97, 5.96) <0.001	−0.06 (−0.13, 0.01) 0.117	**2.20 (0.61, 3.78) 0.008**	0.05 (−0.06, 0.17) 0.345
Difference (whites-blacks)	0.04 (0.01, 0.07) 0.013	0.001 (−0.001, 0.003) 0.340	0.005 (−0.04, 0.05) 0.839	−0.004 (−0.01, −0.0004) 0.031	−0.34 (−1.25, 0.57) 0.454	0.04 (−0.02, 0.11) 0.183	−1.07 (−2.52, 0.38) 0.144	−0.10 (−0.20,0. 005) 0.062
Non-Capped								
Among whites	0.30 (0.30, 0.31) <0.001	−0.0002 (−0.001, 0.0002) 0.275	−0.01 (−0.02, −0.001) 0.035	0.0002 (−0.0004, 0.001) 0.549	15.3 (14.2, 16.3) <0.001	−0.02 (−0.10, 0.05) 0.537	−0.13 (−1.76, 1.51) 0.875	**0.16 (0.05, 0.28) 0.006**
Among blacks	0.13 (0.12, 0.14) <0.001	−0.00003 (−0.001, 0.001) 0.934	−0.01 (−0.02, 0.002) 0.109	0.0004 (−0.001, 0.001) 0.378	5.24 (4.28, 6.20) <0.001	0.02 (−0.05, 0.09) 0.600	−1.89 (−3.42, −0.36) 0.017	0.07 (−0.04, 0.17) 0.198
Difference (whites-blacks)	0.17 (0.16, 0.18) 0.003	−0.0002 (−0.001, 0.0006) 0.657	0.003 (−0.01, 0.02) 0.725	−0.0003 (−0.001, 0.001) 0.560	10.04 (8.30, 11.79) <0.001	−0.04 (−0.16, 0.09) 0.551	1.49 (−1.28, 4.27) 0.284	0.10 (−0.09, 0.29) 0.294
Antihypertensives								
Capped								
Among whites	0.48 (0.36, 0.59) <0.001	0.01 (0.001, 0.01) 0.032	−0.07 (−0.20, 0.07) 0.328	−0.01 (−0.02, 0.004) 0.180	35.07 (28.69, 41.46) <0.001	0.13 (−0.33, 0.60) 0.563	12.27 (2.11, 22.43) 0.019	0.03 (−0.68, 0.74) 0.929
Among blacks	0.70 (0.67, 0.73) <0.001	−0.005 (−0.01, −0.002) <0.001	0.01 (−0.04, 0.07) 0.596	**0.01 (0.004, 0.010) <0.001**	44.05 (39.05, 49.05) <0.001	−0.09 (−0.46, 0.28) 0.628	3.96 (−3.97, 11.89) 0.320	**1.83 (1.25, 2.41) <0.001**

	Any Use				Days of Supply			
Coefficient 95% Confidence Interval P value	**Intercept**	**Trend**	**Level Change**	**Change in Trend**	**Intercept**	**Trend**	**Level Change**	**Change in Trend**
Difference (whites-blacks)	−0.16 (−0.16, −0.11) <0.001	0.01 (0.01, 0.01) <0.001	**−0.08 (−0.12, −0.05) <0.001**	**−0.01 (−0.02, −0.01) <0.001**	−8.19 (−16.77, 0.39) 0.061	0.18 (−0.46, 0.82) 0.571	9.77 (−3.96, 23.49) 0.158	**−1.83 (−2.81, −0.85) <0.001**
Non-Capped								
Among whites	0.50 (0.44, 0.55) <0.001	0.002 (−0.001, 0.005) 0.192	−0.02 (−0.08, 0.04) 0.581	−0.0003 (−0.005, 0.005) 0.915	48.52 (44.93, 52.11) <0.001	0.01 (−0.25, 0.27) 0.939	5.56 (−0.15, 11.27) 0.056	0.21 (−0.19, 0.60) 0.298
Among blacks	0.69 (0.65, 0.74) <0.001	−0.002 (−0.005, 0.0003) 0.082	−0.008 (−0.07, 0.05) 0.783	0.004 (−0.0002, 0.01) 0.062	86.46 (77.39, 95.54) <0.001	−0.37 (−1.04, 0.29) 0.260	1.58 (−12.86, 16.02) 0.826	0.60 (−0.41, 1.60) 0.236
Difference (whites- blacks)	−0.17 (−0.19, −0.16) <0.001	0.003 (0.002, 0.004) <0.001	−0.01 (−0.04, 0.01) 0.194	**−0.002 (−0.004, −0.001) 0.007**	−37.95 (−45.43, −30.46) <0.001	0.38 (−0.16, 0.93) 0.162	3.98 (−7.93, 15.89) 0.503	−0.39 (−1.22, 0.44) 0.346
Lipid Lowering Drugs								
Capped								
Among whites	0.20 (0.16, 0.24) <0.001	0.002 (−0.0001, 0.0005) 0.057	−0.03 (−0.09, 0.02) 0.269	−0.001 (−0.005, 0.003) 0.716	8.00 (6.04, 9.97) <0.001	0.03 (−0.11, 0.17) 0.675	1.93 (−1.21, 5.07) 0.221	−0.11 (−0.33, 0.11) 0.310
Among blacks	0.23 (0.21, 0.24) <0.001	−0.002 (−0.003, −0.001) <0.001	**0.08 (0.05, 0.10) <0.001**	**0.004 (0.002, 0.005) <0.001**	5.87 (5.19, 6.55) <0.001	−0.05 (−0.10, −0.002) 0.042	**4.01 (2.92, 5.09) <0.001**	0.10 (0.02, 0.17) 0.014
Difference (whites-blacks)	−0.01 (−0.04, 0.02) 0.551	0.004 0.001, 0.01) 0.003	**−0.09 (−0.15, −0.04) <0.001**	−0.003 (−0.01, 0.04) 0.082	2.00 (−0.22, 4.22) 0.076	0.09 −0.07, 0.26) 0.252	−2.30 (−5.84, 1.24) 0.197	−0.22 (−0.47, 0.03) 0.079
Non-Capped								
Among whites	0.28 (0.27, 0.29) <0.001	0.003 (0.002, 0.004) <0.001	−0.01 (−0.02, 0.01) 0.212	−0.001 (−0.002, 0.0003) 0.171	11.15 (9.68, 12.63) <0.001	0.11 (0.01, 0.50) 0.037	−1.41 (−3.43, 0.61) 0.168	0.05 (−0.10, 0.21) 0.500
Among blacks	0.26 (0.23, 0.28) <0.001	0.0002 (−0.002, 0.002) 0.783	0.01 (−0.02, 0.06) 0.455	0.002 (−0.001, 0.005) 0.172	7.44 (6.52, 8.36) <0.001	0.002 (−0.06, 0.07) 0.958	1.07 (−0.40, 2.53) 0.149	0.11 (0.01, 0.22) 0.031
Difference (whites-blacks)	0.02 (−0.01, 0.04) 0.159	0.003 (0.001, 0.005) 0.001	−0.03 (−0.07, 0.01) 0.121	−0.003 (−0.005, −0.0003) 0.030	3.66 (1.99, 5.34) <0.001	0.11 (−0.01, 0.23) 0.084	−2.00 (−4.67, 0.66) 0.137	−0.09 (−0.28, 0.09) 0.306

*Corrected p value<0.008 used to assess statistical significance; Statistically significant effects are in bold; 95% confidence intervals shown.