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Changes in drug utilization and out-of-pocket costs associated with Medicare Part D implementation: a systematic review

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Abstract

Medicare Part D was implemented 4 years ago. Despite the fact that public-use Part D data were unavailable until late 2008, researchers have used alternate data to examine Part D's impact on drug utilization and out-of-pocket costs. In a systematic review of Medline from 2006 – October 2009, we sought to summarize the literature about drug use and costs after implementation and during the transition period and coverage gap. We included studies presenting original results regarding drug utilization and costs following Part D implementation. Case reports and series and simulation studies were excluded. Of 552 originally identified articles, 26 met selection criteria: 13 regarding Part D's overall impact in the year(s) following implementation, 7 describing the Part D transition period, and 6 concerning the coverage gap. Part D implementation was associated with a 6-13% increase in drug utilization and a 13-18% decrease in patients' costs. The transition period was associated with no significant changes in utilization or costs for elderly dual-eligible beneficiaries, but effects in other populations were mixed. Entry into the coverage gap was associated with a 9-16% decrease in drug utilization and increases in costs of up to 89%. In summary, studies examining disparate data associated Part D's implementation found consistent positive effects on drug utilization and costs but revealed unfavorable trends in the coverage gap. The effect of the Part D transition period remains unclear. While public-use data will validate

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these results, policymakers can use the existing evidence to inform changes and enhancements to Part D immediately.

Keywords

Medicare Part D; drug utilization; out-of-pocket costs; systematic review

Background

To improve seniors' access to prescription medications, Congress passed the Medicare Prescription Drug Improvement and Modernization Act.¹ The Act established a voluntary prescription drug insurance benefit, known as Medicare Part D (Part D) which began on January 1, 2006. Since the program's inception, policymakers and researchers have been eager to assess Part D's impact on prescription drug utilization and beneficiaries' out-of-pocket costs. However, the Part D legislation did not allow for use of Medicare prescription drug data for nearly 3 years. To date, 4 years after Part D's inception, no studies have been published using these data.

Despite this data limitation, researchers have turned to alternate data sources, including retail pharmacy transaction data and patient self-report surveys, to evaluate Part D's impact. In this systematic review, we evaluate the peer-reviewed literature from 2006 – October 2009 and focus on studies assessing Part D's effect on seniors' drug utilization and out-of-pocket spending for prescription medications. We examine studies regarding 1) Part D's impact in the first year(s) of the benefit and 2) in the early months of 2006, known as the transition period, during which many patients with previous drug insurance through Medicaid were automatically transitioned to Part D drug coverage. We also examine studies that highlight changes during the coverage gap (Donut Hole) when beneficiaries are responsible for 100% of drug costs. Taken together, these studies currently represent the best data available regarding Part D's impact on Medicare beneficiaries' access to, utilization of, and spending for prescription drugs.

Methods

Data sources

A systematic search was performed to identify studies addressing the impact of Medicare Part D implementation on beneficiaries' drug utilization and out-of-pocket costs. Initial searches were limited to articles published in Medline between January 1, 2006 and October 31, 2009. Our search focused on any term relating to Medicare Part D (e.g., [*Medicare AND drug benefit OR drug plan OR prescription*]). Articles containing at least one search term were included in the review. We reference mined articles from our initial search.

Study selection

Articles were included if they reported original results, whether drawn from self-report surveys or prescription drug claims. We excluded case reports and series as well as simulation and modeling studies. Two reviewers [W.S. and E.K.] evaluated the titles and abstracts of search results to identify potentially relevant articles. Complete articles were assessed for inclusion by two reviewers [J.P. and E.K.].

Data extraction

Data was extracted from selected articles by three reviewers [J.P., W.S., E.K.] and differences resolved by consensus. Variables assessed included the key research questions,

Part D time period assessed, data sources, characteristics of the patient population, study design, results regarding drug utilization and/or costs, and patients' progression through the four phases of the Part D benefit. Two reviewers [J.P. and W.S.] used the Newcastle-Ottawa Scale² to assess the quality of each cohort study. Studies were grouped into 3 main evidence tables: those that focused on Part D's impact on drug utilization and costs during 1) the year(s) following implementation 2) the transition period, and 3) the coverage gap. Data sources for each study are listed in the "Data sources and patient characteristics" column of each evidence table.

Results

Of 552 potentially relevant abstracts and titles screened, 42 were evaluated in full, and 26 met all inclusion and exclusion criteria. Thirteen articles described prescription drug utilization and costs in the year(s) following Part D implementation,³⁻¹⁵ 7 described use and costs during the Part D transition period,¹⁶⁻²² and 6 examined the Part D coverage gap.²³⁻²⁸ One study⁸ reported data related to the year after implementation and to the coverage gap.

Part D's overall impact in the year(s) following implementation (Table 1)

The first study used a random sample of 584,509,537 prescription claims from a large pharmacy chain.⁴ Researchers observed a 12.8% absolute increase in days of therapy and an absolute 18.5% decrease in out-of-pocket costs per day of therapy following Part D implementation. A second study using data from the same chain found a 5.9% increase in pill-days and a 13.1% decrease in out-of-pocket expenditures from 2005–2006.⁵ An assessment using claims from a prescription transaction manager found that compared with a cohort of patients aged 58–64, elderly patients 65+ experienced an increase in days supply of 8.1% from 2005–2006. Out-of-pocket costs for elderly patients decreased 17.2% relative to those of near-elderly patients from 2005–2006.³

Compared to a control group of patients in employer-sponsored drug plans, patients with hyperlipidemia who were newly enrolled in a Medicare Advantage Part D plan increased their number of monthly prescriptions by 44% in 2006 compared to 2005, but patients using oral anti-diabetic drugs did not.¹⁰ New Part D enrollees with hyperlipidemia immediately increased their out-of-pocket costs by \$17 in January 2006 as compared to December 2005 (a 31% change) and then an additional \$41 per month during 2006 (a 74% change) in comparison to the control group. Researchers using Medicare Current Beneficiary Survey (MCBS) data from 2004 and enrollment and pharmacy claims data from a large Part D plan in 2006 found a 7% increase in the number of prescriptions and a 16% decrease in out-of-pocket costs associated with Part D implementation.⁷ Cost effects were modified by type of Part D insurance. Low-income subsidy recipients saw costs decline from \$741 in 2004 to \$160 in 2006, while dually-eligible patients saw costs decline from \$164 in 2004 to \$45 in 2006. Part D enrollees with no subsidies saw costs increase slightly, from \$842 in 2004 to \$897 in 2006.

Several studies examined Part D's impact on specific types of drugs. Using claims from a large pharmacy chain from 2005–2006 to examine 3 psychotropic drug classes, Part D's implementation was associated with a monthly increase of 1,679 prescriptions for antidepressants and 567 prescriptions for antipsychotics.⁶ There were no changes in benzodiazepine use. The proportion of costs paid out-of-pocket decreased 18% for antidepressants and 21% for antipsychotics, but increased 19% for benzodiazepines. A second study in patients who had no drug insurance in 2005 and had the opportunity to enroll in Part D in 2006 examined drug utilization changes for four drug classes.⁸ Defined daily dose increases were observed for statins (22%), clopidogrel (11%), and proton pump inhibitors (37%) during the year following Part D implementation. Warfarin use did not

change. Co-payments for all drugs except branded omeprazole declined significantly, with monthly co-payments per 30 defined daily doses \$15-\$80 lower during the stable Part D period than in 2005. In another study using retail pharmacy data, Part D implementation was associated with changes in generic utilization which varied by drug class: increased use of generic ACE inhibitors (10%) and benzodiazepines (19%) but decreases in the use of generic anti-hyperlipidemics (-5%), NSAIDs (-8%), antihistamines (-25%), and beta-blockers (-3%).⁹ Overall, Part D enrollees were 5% (95% CI, -6% to -5%) less likely to fill a prescription for a generic medication in 2006 than in 2005 compared to non-enrollees.

Three studies focused on specific populations. Using data from a large long-term care pharmacy provider, Breisacher et al, found little impact of Part D enrollment among long-term nursing home residents.¹¹ As compared to non-enrollees, Part D enrollees had a 0.50 prescription per month decrease in utilization following enrollment, a decline that resolved by December 2006. Part D enrollment was associated with a 3% decrease in out-of-pocket costs in 2006 as compared to 2005. Kim et al. quantified the average number of prescriptions and the costs of Part D coverage for 16,655 patients with atrial fibrillation.¹² In 2006, these beneficiaries filled 46 prescriptions on average, and 58.8% reached the coverage gap. Patients spent \$3,457 out-of-pocket in 2006, but atrial fibrillation drugs accounted for only 15% of that spending, suggesting that comorbidities drove spending. A second limited descriptive study quantified costs among 42,801 patients with diabetes enrolled in 2 Medicare Advantage Part D plans. Total drug spending averaged \$2,182, and out-of-pocket spending averaged \$807 in 2006.¹⁵

Finally, two studies assessed changes in the prevalence of cost-related non-adherence to medications (CRN) using 2004–2007 MCBS data.^{13, 14} Part D implementation was associated with a significant reduction in CRN prevalence, from 14.1% in 2005 to 11.5% in 2006. More modest reductions were seen between 2004-2005¹⁴ and 2006-2007.¹³

The Part D transition period (Table 2)

Most studies of the Part D transition period examined the experiences of patients dually-eligible for Medicare and Medicaid. Basu et al. spotlighted elderly dual-eligibles' experiences using a 5% random sample of pharmacy chain data. The Part D transition appeared to have no effect on medication continuation, discontinuation, initiation, and initiation of a generic drug, as rates of these behaviors were comparable in dual-eligible elderly patients and in near-elderly Medicaid patients. There were no observed changes in out-of-pocket expenditures. Shrank et al. similarly found no drug utilization differences during the transition period among elderly dual-eligibles for five drug classes: warfarin, proton pump inhibitors, statins, clopidogrel, and benzodiazepines.²¹ After Part D, elderly dual-eligible warfarin users experienced significant decreases in out-of-pocket costs of \$0.41 per 30 days' supply, while statin, proton pump inhibitor and clopidogrel payments did not change. Users of benzodiazepines, which were not covered under Part D because of safety concerns, saw co-payments increase 91% post-Part D. Drug switching, possibly due to Part D plan coverage issues, was modest and no significant differences were seen in 2006 as compared to 2005 in each class studied except proton pump inhibitors (2.99% switching rate), a class where all drugs have similar efficacy and safety profiles. Golden et al. further explored benzodiazepine use by dual-eligibles in Florida's Medicaid program, which contracted with an outside pharmacy benefits provider to fill prescriptions not covered by Part D.¹⁸ Seventy percent of all prescriptions filled were for benzodiazepines, suggesting that because Medicaid programs continued to provide coverage, Part D's goal of reducing benzodiazepine use was not met. In contrast, Hall et al. observed Part D transition difficulties among 325 non-elderly dual-eligibles in Kansas who participated in a telephone survey.¹⁹ During the transition to Part D, 20% reported prescription filling difficulties and

8% reported discontinuations. Many patients (46%) reported increased out-of-pocket costs under Part D.

Das-Douglas et al. conducted a cross-sectional study among 125 homeless and marginally-housed individuals with HIV.¹⁷ Of 14 patients who reported HIV treatment interruptions during the first quarter of 2006, 10 (71%) were Part D insured, and 9 of these cited plan coverage restrictions as a cause. Of 44 patients who enrolled in Part D, almost 60% reported increased costs for HIV medications. However, it is unclear whether all patients were transitioning to Part D, as some had other drug insurance coverage in 2006.

Finally, two studies reported the results of a cross-sectional survey of psychiatrists to assess the experiences of dual-eligibles with mental illness.^{20, 22} Psychiatrists surveyed reported that 44% of their 1,816 dual-eligible patients experienced a psychiatric medication access problem during the transition period. Of these, 35% were unable to access refills or new prescriptions, 19% were switched to a different drug because of coverage issues, and 22% had access difficulties due to cost.²⁰

Part D's impact in the coverage gap (Table 3)

Sun and Lee focused on Part D enrollees who reached the coverage gap by June but did not reach the catastrophic coverage period in 2006.²⁷ Compared to non-enrollees who reached the coverage gap spending threshold but did not experience a gap, enrollees decreased their prescription days purchased by an average of 16% in the coverage gap. During the gap, generic drug utilization increased by 25% in the Part D group but only 5% in the non-enrollee group. Average total costs in the Part D group decreased 28% in the coverage gap, but out-of-pocket costs increased 89%, while total costs in the non-enrollee group increased 2% and out-of-pocket costs decreased 6%. Zhang et al. found similar drug utilization decreases of 14% in the coverage gap among Medicare Advantage Part D plan enrollees.²⁸ Pedan et al. observed that patients who reached the coverage gap filled an average of 4.86 prescriptions per 30 days in the initial coverage period and 4.40 prescriptions per 30 days in the coverage gap, a 9.47% decrease.²⁵ In Schneeweiss' study, prescription use during the coverage gap also showed per month declines: clopidogrel -5%, warfarin -4.8%, and statins -6.3%.⁸ Out-of-pocket expenditures during the coverage gap increased between \$12 (warfarin) and \$65 (clopidogrel) per 30 defined daily doses compared with pre-coverage gap costs.

In looking at adherence, Raebel et al's study noted that declines in medication adherence were similar between Part D enrollees who experienced a gap in coverage and non-Part D enrollees who reached the coverage gap spending threshold (but whose coverage was uninterrupted) with the exception of 2 drug classes, the anti-hypertensives and anti-diabetic agents, where discontinuation rates were higher among Part D enrollees in the coverage gap.²⁶ Cronk et al. found that in the coverage gap, 20% of Part D enrollees discontinued a medication because of cost compared to only 5% of non-enrollees who reached the coverage gap spending threshold.²³ Part D enrollees were 5 times (95% CI, 2—13) more likely to use medication cost-lowering strategies in the gap than were non-Part D enrollees. Hsu et al. surveyed Part D enrollees who did and did not reach the coverage gap in 2006 about their drug cost-coping behaviors.²⁴ Compared to beneficiaries who were not aware of the coverage gap, the 36% of beneficiaries who knew about the gap were 11% (95% CI, 0.8—21.9%) more likely to report a behavior to reduce drug costs.

Discussion

In this review, we identified 26 studies evaluating the effect of Medicare Part D implementation on drug utilization and out-of-pocket costs. As expected, Part D's inception

was associated with a consistent overall increase in drug utilization and a decrease in out-of-pocket costs for enrollees. The transition to Part D went smoothly for many elderly dual-eligible patients, but other vulnerable populations appear to have experienced difficulties. Finally, the Part D coverage gap was associated with decreased drug utilization and increased out-of-pocket costs.

There was little variation in effect estimates among studies evaluating the effect of Part D implementation: a 6-13% increase in drug utilization and a 13-18% decrease in out-of-pocket drug costs. Changes in utilization and costs varied by drugs, disease and/or population studied, underscoring the need to consider such factors when assessing Part D's impact. However, there was little indication that Part D selectively led to increased use of essential, underused drugs as compared to overused medications.¹³

In studies of the Part D transition period, elderly dual-eligible beneficiaries generally fared well, while other populations seemed to experience problems. Two hypotheses may explain these disparate experiences. Due to concerns about the Part D transition for dual-eligibles, many of whom are elderly, both the Centers for Medicaid Services and the states instituted a variety of mechanisms to ease the change, including auto-enrollment and temporary continuation of Medicaid drug coverage during early 2006.²⁹ In contrast, vulnerable populations, such as those with HIV or mental illness, may have had difficulties with the transition due to factors associated with their illnesses.

A second hypothesis is that studies using claims data were unable to identify medication access problems because claims reflected only successfully filled prescriptions, not attempted fills, whereas the survey-based studies were able to tease out these problems. Using claims data, no changes were seen in medication continuity for benzodiazepines.²⁶ Similar methodology might be used to examine continuity of other medications during the transition period, shedding light on the ability of drug claims versus survey-based data to expose medication access problems.

Finally, across all studies, Part D beneficiaries' entry into the coverage gap was associated with decreased drug utilization of 9-16% (an amount similar in magnitude to the increases seen after Part D implementation) and increased out-of-pocket costs with changes as high as 89%. Patients who entered the coverage gap were 5-11% more likely to report discontinuing, switching and/or failing to initiate a medication than were patients who did not enter the coverage gap. Use of generic drugs increased 20% during the coverage gap. These studies suggest that when patients enter the coverage gap, the cost burden dramatically and immediately affects drug utilization and moves patients towards more affordable generic drugs.

The consistency of these findings has important implications. Similarly structured benefit gaps (e.g., drug caps) have been associated with adverse outcomes such as death and increased non-elective healthcare use.³⁰ As Part D reforms are contemplated, policymakers must consider whether drug cost savings during the gap offset the benefits of drug coverage, with the gap potentially leading to adverse health outcomes and even greater spending on healthcare services.

The conclusions drawn from studies in this systematic review must be interpreted with caution. Even though research has found that elderly patients fill 97% of prescriptions within a single pharmacy chain,³¹ studies that rely on retail prescription claims may miss prescriptions for patients who use more than one pharmacy chain. Studies evaluating patients without prior drug insurance did not have Part D enrollment files for patients but rather estimated Part D coverage using cost algorithms, so there is likely some misclassification. Finally, these studies offer little or no evidence regarding the impact of

Part D on health outcomes. Because the primary goal of Part D was to improve the health of Medicare beneficiaries, such studies are desperately needed.

Using different data sources, designs, and analytic approaches, the studies included in this systematic review showed consistent estimates of Part D's impact in the initial year(s) of the benefit as well as during the coverage gap period. Conflicting results regarding the Part D transition period can be further examined using existing data and methodologies applied to specific drug classes and populations. While we look forward to studies that employ public-use Part D claims, we believe that the currently available evidence documents Part D's role in improving medication access for Medicare beneficiaries and highlights Part D benefit features such as the coverage gap that merit reconsideration and potential improvement. As the fate of the Part D benefit and the coverage gap are pondered, data about effects on health outcomes are urgently needed.

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Table 1

	Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
1	Lichtenberg et al. ⁹	What was the impact of Medicare Part D on prescription drug utilization and out-of-pocket costs?	50% sample of prescription drug claims from Walgreen's for September 2004 - December 2006. 2 cohorts: elderly aged 65+, non-elderly aged < 65	Difference in difference comparisons of 2006 versus 2005 drug utilization and out-of-pocket costs	<ul style="list-style-type: none">Compared to 2005 levels, the number of prescriptions among the elderly increased 14.4% in 2006. Among the non-elderly, this increase was 4.5% in 2006.Among the elderly, the number of days of therapy per prescription rose 19.5% between 2005 and 2006 while among the non-elderly the increase was 6.8%.	<ul style="list-style-type: none">Among the elderly, the amount paid by the patient per day of therapy decreased 18.8% between 2005 and 2006, while among the non-elderly the decrease was 0.4%.Among the elderly, the amount paid by the patient per prescription decreased 13.7% between 2005 and 2006.For the non-elderly, it increased 1.9%.		9
2	Chen et al. ¹¹	What was the impact of Medicare Part D on the drug utilization and costs for the elderly population using psychotropic medications?	1.19 million patients in 2005, 1.28 million in 2006. Data collected from Walgreen's retail pharmacy chain. Mean age in 2005 was 75±8 in 2005, 75±7 in 2006. Over 68% in both years were female.	Interrupted time-series analysis using segmented linear regression over 24 months, 2005-2006. Assessed number of psychotropic drug (antipsychotics, antidepressants and benzodiazepines) prescriptions filled in each month and proportion of prescription paid out-of-pocket.	<ul style="list-style-type: none">After Part D implementation, there was an immediate 5% drop in the level of benzodiazepine utilization, but no subsequent changes throughout 2006.In contrast, there were no significant changes in the levels of antidepressant and antipsychotic utilization immediately following Part D implementation, but in each month of 2006, prescription utilization increased for the antidepressants (+1,679 prescriptions per month) and for the antipsychotics (+567 prescriptions per month).	<ul style="list-style-type: none">In 2006, the proportion of drug costs paid out-of-pocket decreased 18% for antidepressants and 21% for antipsychotics. The proportion of drug costs paid out-of-pocket increased by 19% for benzodiazepines.		7
3	Ketcham et al. ⁸	How did prescription drug utilization and out-of-pocket costs change for elderly patients during the first 2 years of Medicare Part D?	2 cohorts drawn from Wolters Kluwer Health prescription drug transactions: Elderly cohort is always age-eligible for Part D (age >66 as of 2007), comparison cohort of near elderly is always age ineligible (age 58-64 as of 2007) for Medicare Part D	Difference-in-difference comparisons of the aggregate change in drug utilization and out-of-pocket costs from January 2005 - December 2007.	<ul style="list-style-type: none">Elderly patients' days' supply increased 8.1% in 2006 versus 2005 levels, compared with non-elderly patients.Days' supply among the elderly increased 1.0% from 2006 to 2007 compared with non-elderly patients.In 2006, there was a 4.8% relative increase in the number of elderly filling any prescription compared to the non-elderly.	<ul style="list-style-type: none">Between 2005 and 2006, elderly patients' out-of-pocket costs decreased 17.2% relative to non-elderly patients and 15.9% absolutely.Between 2006 and 2007, there was an additional 5.8% relative decrease in out-of-pocket costs for the elderly compared to the non-elderly.		9
4	Madden et al. ¹⁹	What were the changes in cost-related non-adherence (CRN) and forgoing basic needs to pay for drugs	24,234 Medicare beneficiaries participating in the Medicare Current Beneficiary Survey (MCBS) in 2004 - 2006.	Longitudinal panel survey during 2004 - 2006. CRN outcomes included deciding not to fill or refill a prescription, skipping doses,	<ul style="list-style-type: none">There was a large absolute decrease in CRN following implementation of Medicare Part D, from 14.1% in 2005 to 11.5% in 2006. In contrast, the decrease from 2004 (15.2%) to 2005 (14.1%) was			NA

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
				<p>much more modest. Forgoing basic needs decreased 3.5% from 2005 - 2006, compared with a slight increase from 2004 - 2005.</p> <ul style="list-style-type: none">Beneficiaries in 2006 were 15% (95% CI, 2% - 26%) less likely to report CRN and 41% (95% CI, 28% - 52%) less likely to report forgoing basic needs than in 2005.There were no significant changes in CRN following Part D implementation for the most vulnerable subgroups (disabled, fair to poor health, and > 4 comorbidities).			
5	What changes in prescription utilization and out-of-pocket expenditures are attributable to the implementation of Part D?	These patients' characteristics were weighted to represent the overall population of community-dwelling Medicare beneficiaries.	or taking smaller doses. Forgoing basic needs outcomes included spending less money on food, heat or other basic needs in order to pay for medications.	<ul style="list-style-type: none">During the Part D ramp up period from January - May 2006, the implementation of Part D was associated with a 1.1% (95% CI, 0.5% - 1.7%) increase in pill-days in the 66-79 year old age group.In the stable Part D period, Part D implementation was associated with a 5.9% (95% CI, 5.1% - 6.7%) increase in pill-days in the group aged 66-79.Increases in utilization varied by the time of Part D enrollment, with those who enrolled during the stable period showing a 32.6% increase in pill-days versus ramp-up enrollees at 16.1% increase in pill-days.	<ul style="list-style-type: none">In the ramp-up period, out-of-pocket costs decreased 8.8% (95% CI, -6.6% to -11.0%) in the group aged 66-79.In the stable Part D period, out-of-pocket costs decreased 13.1% (95% CI, -16.6% to - 9.6%) in the group aged 66-79.Those who enrolled in the ramp-up period had the greatest decline in out-of-pocket costs, 20.4% as compared to those who enrolled during the stable period, who had declines of 5.6%.		9
6	Were there changes in the use of generic medications and related costs associated with Part D?	5% random sample of unique Walgreens' retail or mail-order customers who filled at least one prescription in 2005 and in 2006. Elderly patients eligible for Part D ages 66-79 (N=117,648); near-elderly patients ineligible for Part D, ages 60-63 (N=59,663).	Interrupted time-series analysis using segmented linear regression from September 2004 through April 2007. Assessed monthly average out-of-pocket costs and prescription utilization measured as pill days.	<ul style="list-style-type: none">Across all drug classes, 56% of all prescriptions were generic in 2005, rising to 58% in 2006. However, changes in generic use proportions varied by drug class.After adjusting for secular trends, baseline differences between Part D enrollees and non-enrollees and other potential confounding factors, Part D was associated with a 10% increase (95% CI, 5 - 14%) in use of generic ACE inhibitors and a 19% increase (95% CI, 4 - 35%) in use of generic benzodiazepines. Part D was associated with decreased use of generic drugs in 4 drug classes: antihyperlipidemics	<ul style="list-style-type: none">On average, generic prescriptions in 2006 saved patients and insurers a combined \$119.25 annually (95% CI, \$118.97 - \$119.53).		9

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
				(OR=0.95, 95% CI, 0.92-0.98), NSAIDs (OR=0.92, 95% CI 0.87-0.97), antihistamines (OR=0.75, 95% CI 0.70-0.82) and beta-blockers (OR=0.97, CI 0.94-0.99) in Part D enrollees as compared to non-enrollees. <ul style="list-style-type: none">Overall, Part D beneficiaries were 5% less likely (95% CI, 0.94-0.95) to fill a generic prescription versus a brand prescription in 2006 compared to 2005 as compared to non-enrollees.			
7	What was the impact of Medicare Part D in the nursing home setting?	Data from a long-term care pharmacy provider: 861,082 long-stay Medicare enrollees in 16,000 nursing homes, with 2,535,684 person-months and 106,038,595 prescription records during 2005 - 2006.	Interrupted time-series with segmented linear regression to examine changes in drug use with the onset of Part D and descriptive analysis of patterns of costs and average drug use before and after Part D.	<ul style="list-style-type: none">In time series regressions, Part D enrollees decreased the average number of prescriptions per month by 0.51 prescriptions from 2005 to 2006, while non-enrollees saw no changes in their prescription use.Nursing home residents without any drug coverage in 2005 saw average monthly drug use decrease by 0.77 prescriptions. In contrast, patients with Medicaid in 2005 decreased average monthly drug use in 2006 by 0.50 prescriptions, and for residents with private party coverage in 2005, by 0.29 prescriptions in 2006.	<ul style="list-style-type: none">Nursing home residents with no drug coverage in Part D had the largest decrease in the proportion of drug costs paid out-of-pocket, from 100% in 2005 to 34% in 2006. For those with Medicaid coverage, this decrease went from 4% in 2005 to 2% in 2006, and for those with third party coverage in 2005, from 14% in 2005 to 9% in 2006. Overall, the proportion of out-of-pocket costs decreased from 11% in 2005 to 8% in 2006.		9
8	What was the effect of Part D on drug utilization and spending?	In the baseline period, patients from the 2004 Medicare Current Beneficiary Survey (MCBS) were studied. For the follow-up period, 2006 enrollment and claims data from a large Part D plan were analyzed.	“Before and after” design. MCBS spending was adjusted from 2004 to 2006 using the consumer price index prescription drug series. Both spending and number of fills were adjusted upward by 15% to adjust for the undercount of drug spending. Demographic weights were constructed and used to reweight the Part D data to match the MCBS for each age-sex-state-subsidy cell. Low-income subsidy eligibility in the MCBS was approximated based on household income <150% of the federal poverty line.	<ul style="list-style-type: none">Part D was associated with a 16% annual decrease in out-of-pocket spending among enrollees.Changes appeared to be concentrated among those eligible for the low income subsidy (out-of-pocket spending declined from \$741 in 2004 to \$160 in 2006) and the dual-eligibles (out-of-pocket spending declined from \$164 in 2004 to \$45 in 2006) versus the general population, where out-of-pocket costs increased slightly, from \$842 in 2004 to \$897 in 2006.			NA

	Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
9	Kim et al. ¹⁷	<ul style="list-style-type: none">What were the Part D prescription costs for elderly patients with atrial fibrillation?How many of these patients entered/exited the coverage gap in 2006?	16,655 patients with diagnosis of atrial fibrillation (AF), age 65+, enrolled in a Medicare Advantage Part D plan. Mean age was 74 and 57% of patients were men.	Descriptive study. Three patient populations with atrial fibrillation (AF) were defined: 1) patients with AF as the primary discharge diagnosis after a 2005 hospitalization; 2) patients with AF as the secondary discharge diagnosis after a 2005 hospitalization; and 3) patients with outpatient-managed AF with no hospitalization during 2005.	<ul style="list-style-type: none">In 2006, each patient with AF filled an average of 46 prescriptions; 14.4% of all prescriptions were for rate-control drugs, 10.0% for anticoagulants, and 2.6% for rhythm control drugs.	<ul style="list-style-type: none">Mean total prescription costs for patients with AF were \$3,457.16, but AF-related drugs accounted for only 15% of those costs.	<ul style="list-style-type: none">In 2006, 58.8% of patients with AF reached the coverage gap threshold and 21.2% of all patients with AF reached the catastrophic coverage threshold.The mean time to reach the coverage gap threshold was 199 ± 83 days and the mean time to reach the catastrophic coverage threshold was 257 ± 71 days among all patients with AF.	NA
10	Madden et al. ¹⁸	Did decreases in cost-related non-adherence to medications and forgoing basic needs observed among Part D enrollees in 2006 persist or change in 2007?	Patients enrolled in the Medicare Current Beneficiary Survey who were community-dwelling in 2004 - 2007.	Prevalence rates of cost-related non-adherence were calculated for 2004 - 2007 for the whole population and for 4 subgroups: elderly (aged 65+) versus non-elderly disabled (aged < 65), each group categorized as 0-2 versus 3+ morbidities. Odds ratios were estimated for 2007 versus 2005 and 2007 versus 2006.	<ul style="list-style-type: none">The prevalence of cost-related non-adherence and forgoing basic needs was consistently higher for non-elderly disabled beneficiaries as compared to elderly beneficiaries and for sicker versus healthier beneficiaries.Compared with 2005, the prevalence of cost-related non-adherence and forgoing basic needs declined significantly in 2007 for the overall population and for all 4 subgroups (Odds ratios between 0.58 and 0.77, all p values <0.05).Between 2006 and 2007, there was a small decrease in cost-related non-adherence for the overall population (OR=0.91, 95% CI 0.84 - 0.99). The decrease among the non-elderly disabled with 3 or more comorbidities			NA

	Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
					was also significant (OR=0.74, 95% CI, 0.60 - 0.92).			
11	Schmittidel et al. ²⁰	Among Medicare beneficiaries with diabetes, what were total drug costs, and out-of-pocket drug costs, and rates of entry and exit into the Medicare Part D coverage gap?	There were 42,801 beneficiaries in 2 Medicare Advantage Part D plans who had diabetes and met study criteria.	Cross-sectional, descriptive study of patients' experience during the 2006 calendar year.		<ul style="list-style-type: none">On average, total drug spending was \$2,182, with average out-of-pocket spending of \$807.For those who entered the coverage gap, total drug costs were much higher overall and decreased towards the end of the year as out-of-pocket costs increased.	<ul style="list-style-type: none">26% of patients with diabetes entered the coverage gap in 2006. However, only 2% exited the coverage gap and entered the catastrophic period in 2006.More than half of the patients who entered the coverage gap did so after August 31.	NA
12	Schnee weiss et al. ¹³	What was Part D's effect on the use of selected essential drugs among seniors who previously lacked drug coverage?	114,766 patients with no drug insurance in 2005 who were continuous users of a pharmacy chain and who lacked drug coverage in 2005.	Time-trend analysis using segmented linear regression from January 1, 2005 - December 31, 2006. Defined daily doses (DDD's) and copayments for four essential medication classes were assessed: clopidogrel, proton pump inhibitors, statins, and warfarin.	<ul style="list-style-type: none">Drug use increased by 22% for statins, 11% for clopidogrel, and 37% for PPIs following Part D implementation. Warfarin use did not increase.	<ul style="list-style-type: none">During the Part D transition period, copays for all drugs except brand name omeprazole declined significantly.Monthly copays per 30 DDDs were \$15-\$80 lower during the stable Part D period than the pre-Part D period.	<ul style="list-style-type: none">12% (n=7,325) reached the coverage gap in 2006.	9
13	Zhang et al. ¹⁵	Did drug utilization after Part D implementation impact health services use and potentially produce savings in Medicare Parts A and B?	All patients were continuously enrolled in Medicare Advantage plans offered by a large Pennsylvania insurer. There were 4 groups under observation: 3,939 Part D enrollees with no previous drug coverage; 2,662 enrollees with a previous and current \$150 quarterly cap on drug spending; 19,014 enrollees with a previous	Time series analysis using segmented linear regression with comparison group, from 2004 - 2007. Inverse probability of treatment weighting of propensity scores was used to balance characteristics among groups. Outcomes were expenditures for drugs and non-drug medical care per member per month. Prescription refills for patients with hyperlipidemia	<ul style="list-style-type: none">Following Part D implementation, Part D enrollee patients with no previous insurance with hyperlipidemia increased their number of monthly prescriptions by 44% compared to the no cap comparison group. No changes in the number of oral diabetes medications were observed following Part D implementation between the two groups.	<ul style="list-style-type: none">After the implementation of Part D, Part D enrollees with no previous insurance had a \$17 level change in drug spending per month (95% CI, \$9 - \$25), representing a 31% increase compared to the no cap comparison group in December 2005. Part D enrollees with no previous insurance increased average monthly drug spending by \$41 in each month following Part D implementation, a 74% increase over the no cap		9

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Progression through the phases of the Part D benefit	Newcastle-Ottawa scale score
		and current \$350 quarterly cap on drug spending; and a comparison group of 9,487 with no previous or current drug cap.	and diabetes were also measured.		<div><div>comparison group's December 2005 spending.</div><div><div></div><div>The \$150 quarterly cap group saw an immediate increase of \$8 (95% CI, \$1 - \$15) with implementation of Part D, while the \$350 quarterly cap group saw an immediate increase of \$10 (95% CI, \$2 - \$19). Average drug spending increased \$27 per month in the \$150 cap group (a 27% increase) and \$13 per month in the \$350 cap group (an 11% increase) compared to December 2005 spending in the no cap comparison group.</div></div></div>		

Table 2

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
1	Hall et al. ²⁴ How did the Part D transition affect access to drugs for dually-eligible adults aged < 65?	328 (55% response rate) working dual-eligible adults who were enrollees in the Kansas Medicaid Buy In program, Working Healthy.	Cross-sectional telephone survey during February and March 2006 to examine medication access difficulties.	<ul style="list-style-type: none"> 66 patients (20%) reported problems with getting prescriptions filled. 8% reported that they had stopped taking at least one medication because of access problems. Of 56 patients who explained their difficulties, 46% reported having to pay the entire cost of the drug or more than they would have paid through Medicaid after the transition to Part D. 34% needed a drug that was not on their Part D formulary, while 11% had difficulties with dosage or refill timing restrictions imposed by the Part D plan. 15/41 patients reported difficulty obtaining a drug in a protected class (antineoplastics, antiepileptics, antidepressants, antipsychotics, immunosuppressants, and antiretrovirals). 14% of all patients reported that they were required to get documentation to continue their prescriptions, a process that for 50% of patients took more than 5 days. 13% reported that they were required to 		NA

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
				switch a medication, and of those, 60% were required to switch to a generic form.		
2 West et al. ²⁷	<ul style="list-style-type: none"> What was the extent of medication access or continuity problems for dual-eligibles with psychiatric diagnoses during the Part D transition period? How did medication disruptions or access problems affect clinical events? How do Part D plans' features affect the likelihood of medication access problems? 	<p>1,193 randomly sampled psychiatrists from the American Medical Association's Physician Masterfile who met inclusion criteria of seeing at least one dual eligible patient during their last typical work week. Self-reported survey data submitted on 1,193 dual eligible patients.</p>	<p>Mailed-in, practice-based survey conducted in January - April 2006. Each psychiatrist was asked to report on the experiences of the next dual-eligible patient he/she treated.</p>	<ul style="list-style-type: none"> Psychiatrists reported that after Part D implementation, patients had difficulty accessing refills (31%), accessing benzodiazepines (24%) or discontinued a drug because of the copayments (23%) or lack of coverage (23%). Patients in Part D plans with prior authorization had 2.5 times the likelihood of an access problem compared to patients in plans without this requirement. Patients with limits on the number or dosing of medications had 1.7 (95% CI, 1.0 - 3.0) times the likelihood medication access problems compared to patients in Part D plans without this requirement. 		NA
3 Basu et al. ²¹	<ul style="list-style-type: none"> What was the effect of Part D on patients dually eligible for Medicare and Medicaid in terms of their drug usage, out-of-pocket costs, 	<p>5% random sample of unique pharmacy customers who filled at least 1 prescription in 2005 and 2006 at any retail or mail order member of</p>	<p>Difference-in-difference multivariate regression design to examine total number of prescriptions per month, pill-days, monthly out-of-pocket</p>	<ul style="list-style-type: none"> Dual-eligibles filled a prescription for 17.5% of medications in both the pre- and post-Part D periods, filled a prescription in the pre-period but not the post-Part D period for 42.5% of medications (discontinuation), and filled a new 	<ul style="list-style-type: none"> There were no significant changes in trends in dual-eligibles' out-of-pocket expenditures and total monthly 	9

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
	<p>and total drug expenditures?</p> <ul style="list-style-type: none"> How was medication adherence and discontinuation affected? 	<p>Walgreen's. Treatment group consists of dual eligibles ages 65-78 on January 1, 2005 and a control group of near elderly patients with Medicaid coverage aged 60-63 as of January 1, 2005.</p>	<p>costs, total prescription expenditures, and changes in the overall percentage of generic prescriptions. Multinomial regressions were used to estimate the probability of continuing, discontinuing, or initiating a medication between the pre-Part D period and the stable Part D period.</p>	<ul style="list-style-type: none"> prescription in the post-Part D period for 40% of medications (initiation). These proportions were nearly identical to those among the non-elderly control group patients. Dual-eligibles were 4.8% more likely to fill a prescription for a generic medication in the post-Part D period than in the pre-period. A similar change was observed in the non-elderly control group. There were no significant changes in trends in dual-eligibles' pill days and total number of prescriptions due to Part D. 	<p>expenditures due to Part D.</p>	
4 Shrank et al. ²⁶	<p>What were the medication use, out-of-pocket spending, and drug switching experiences of dual-eligible beneficiaries during the transition period to Medicare Part D?</p>	<p>13,302 dually-eligible beneficiaries who were patrons of 1 large pharmacy chains operating in 34 states.</p>	<p>Time-trend analysis using segmented linear regression. Outcomes included days' supply of medication and copayments per 30 days supply for each calendar month for five medication classes: warfarin, statins, clopidogrel, benzodiazepine, and proton pump inhibitors.</p>	<ul style="list-style-type: none"> There were no statistically significant increases or decreases in the days' supply of any of the drugs after implementation of Part D. There were trends towards higher use of warfarin, statins, clopidogrel and proton pump inhibitors and a trend towards decreased use of benzodiazepines. Higher switching rates (2.99%, 95% CI, 1.34 - 4.65%) than those observed pre-Part D were observed only for the proton pump inhibitors following Part D implementation. 	<ul style="list-style-type: none"> Warfarin copayments per 30 days' supply decreased \$0.41, a significant change, following transition to Part D. Statin, warfarin and clopidogrel payments decreased but were not significantly different from pre-Part D copayments. Benzodiazepine copayments increased 91% after the 	9

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
					transition to Part D.	
5	What was the effect of Part D's implementation on the likelihood of anti-retroviral treatment interruptions among patients with HIV?	125 homeless and marginally housed individuals in a longitudinal cohort study (Research on Access to Care in the Homeless-REACH)	Cross-sectional questionnaire assessed Part D insurance status and anti-retroviral treatment interruptions of 48 hours or more. Multivariate logistic regression was used to examine predictors of experiencing a treatment interruption.	<ul style="list-style-type: none"> 14 (11.2%) of participants reported a treatment interruption. 10 of the 14 (71.4%) were insured under Medicare Part D and 3 of the 14 (21.4%) had other prescription drug coverage. In multivariate models, patients with Part D coverage were 7.5 times (95% confidence interval, 1.96 - 28.58) more likely to have reported a treatment interruption than were patients with other prescription drug coverage. 9 of the 10 patients with Medicare Part D coverage and treatment interruptions attributed the interruption to an aspect of the new Medicare Part D plan in which they were enrolled. 	<ul style="list-style-type: none"> Almost 50% of Part D patients reported increased expenditures for prescription drugs under Part D. 	NA
6	What were the experiences of dual-eligible beneficiaries enrolled in Medicare Part D who also had a supplemental pharmacy benefit?	2,959 dual-eligible beneficiaries in Florida aged 65+ who were home-bound and met criteria for nursing home eligibility. All patients were enrolled in a Florida Home and	Observational, descriptive study of patients' filling of medications and vitamins not covered by the Part D plan but covered by the supplemental pharmacy benefit	<ul style="list-style-type: none"> 203 (6.9%) beneficiaries received 241 medications and vitamins not covered by their Part D plan through this supplemental plan. Benzodiazepines accounted for 70.1% of all prescriptions filled, and 95.4% of 		NA

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
		Community-based Medicaid Waiver Program		those prescriptions were refills.		
7 Huskamp et al. 25	<ul style="list-style-type: none"> What was the frequency of medication access problems for dual-eligible beneficiaries with mental illness as they transitioned into Medicare Part D? What was the frequency of psychiatric emergency department use and use of inpatient care among patients who did or did not experience a medication access problem during this transition? 	<p>Community-based Medicaid Waiver Program</p> <p>1,193 randomly sampled psychiatrists from the American Medical Association's Physician Masterfile who met inclusion criteria of seeing at least one dual eligible patient during their last typical work week. Data was available on 1816 patients.</p>	<p>Observational, clinician-reported surveys using a cross-sectional assessment strategy. Surveys were administered in September-December 2006 and asked psychiatrists to report on the experiences of the next dually eligible patient treated using a randomly assigned start date.</p>	<ul style="list-style-type: none"> Upon transition to Part D, a total of 400 (44%) of dual-eligible patients experienced a medication access problem: 318 (35%) were unable to access clinically indicated refills or new prescriptions because the drugs were not covered or approved; 170 (19%) were switched to a different drug because the drug they had been taken was not covered or approved; and 200 (22%) had difficulty accessing medication due to copayments. 		NA

Table 3

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
1 Sun et al. ³²	How did entry into the coverage gap impact beneficiaries drug utilization and out of pocket costs?	Beneficiaries enrolled in standard Part D plans who reached the part D coverage gap in June 2006 but did not reach the threshold for catastrophic care in 2006.	A difference-in-difference study approach. The pre-coverage gap period (Jan 1- June 30, 2006) was compared to the post-coverage gap period (July 1- Dec 31, 2006).	<ul style="list-style-type: none"> The Medicare Part D coverage gap was estimated to have reduced medication utilization by 187.49 days of therapy and raised the generic utilization rate by 7.33%. 	<ul style="list-style-type: none"> The coverage gap was estimated to have increased out-of-pocket costs by \$796.49. 	9
2 Cronk A, Humphries TL, Clark D, Morris B (2008) ²⁸	What strategies did Medicare Part D beneficiaries use when they reached the Part D coverage gap?	All participants drawn from Kaiser Permanente Colorado Medicare Advantage plans in 2006. 332 Medicare Part D self-enrollees who had reached the coverage gap spending threshold before October 2006 and experienced a gap in coverage were compared with 290 enrollees in an employer-sponsored plan who had reached the coverage gap spending threshold before October 2006 but did not experience a gap in coverage.	<p>Cross-sectional mailed survey to examine 2006 coverage gap behaviors, administered in February and March, 2007. The survey had a 42% response rate.</p>	<ul style="list-style-type: none"> 20% of Part D enrollees reported stopping a medication in 2006 because of cost, compared with 4.6% of employer-based plan enrollees. Three times as many Part D enrollees switched to different medications because of cost (32.1% versus 10.9%) and/or did not fill a new prescription because of cost (21.8% versus 6.1%) as compared to employer-based plan enrollees. 		8
3 Hsu J, Fung V, Price M, Huang J, Brand R, Hui R, Fireman B, Newhouse JP. (2008) ²⁹	How did Medicare Part D enrollees who reached the coverage gap respond to drug costs during this period?	1,040 continuously enrolled Medicare Advantage Part D plan (MA-PD) beneficiaries aged 65+ from Kaiser Permanente-Northern California. Dual eligible and LIS beneficiaries were excluded.	Cross-sectional telephone survey administered beginning January 2007 with a stratified random sample of 2000 MA-PD members, half of whom had reached the coverage gap in	<ul style="list-style-type: none"> 36% of beneficiaries reported changing their drug behavior because of costs (95% CI, 32-41%). 26% reported a cost-coping behavior, and 9% reported frequency of changes in drug behaviors increased as beneficiaries' 2006 drug costs increased. 		NA

Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
			2006 and half of whom did not. Main outcome of interest was whether beneficiaries had engaged in any of 13 behaviors due to medication cost in 2006.	<ul style="list-style-type: none"> 15% of beneficiaries reported decreasing adherence, with 8% reporting they did not refill a prescription (8%) The most frequently reported cost-coping behavior was switching to a cheaper drug (15%). With regards to financial burden, 5% reported going without another necessity. 		
Raebel M, Delate T, Ellis JL, Bayliss EA (2008) ³¹	How did the coverage gap impact healthcare utilization and medication adherence?	Beneficiaries who self-enrolled in one of two Medicare Advantage plans or who are retirees in employer-based plans administered by Kaiser Permanente Colorado. Beneficiaries were aged 65+ and survived during the two year period.	Retrospective cohort study during 2005-2006	<ul style="list-style-type: none"> Among all beneficiaries who reached the coverage gap threshold, adherence declined after reaching the threshold, with statistically significant reductions in adherence to antihyperlipidemic agents, antihypertensives, antidepressants, and diuretics. Declines in adherence ranged from 3.4% for diabetes medications to 8.3% for diuretics. 		9
Pedan A, Lu J, Varasteh LT (2009) ³⁰	How are beneficiaries' drug utilization patterns affected by entry into the coverage gap and the catastrophic coverage period?	96,579 patients aged 65+ filling prescriptions in 2 large retail pharmacy chains with at least 1 prescription in the last 2 months of 2006 and the first 2 months of 2008 who were enrolled in Part D in 2007. Patients eligible for Medicaid or who received a low-income subsidy were excluded.	Retrospective cohort study during 2007	<ul style="list-style-type: none"> Patients who reached the coverage gap but did not reach the catastrophic coverage period filled an average of 4.86 prescriptions per 30 days in the initial coverage period and 4.40 prescriptions per 30 days in the coverage gap (9.47% decrease). Patients who reached both the coverage gap and catastrophic coverage periods filled 7.59 prescriptions per 30 days in the initial coverage period, 8.38 in the coverage gap, and 7.86 in 		6

	Reference	Research question	Data sources and patient characteristics	Design	Results-Utilization	Results-Costs	Newcastle-Ottawa scale score
					the catastrophic coverage period.		
6	Schneeweiss S, Patrick AR, Pedan A, Varasteh L, Levin R, Liu N, Shrank WH (2009) ¹³	How did entry into the coverage gap impact beneficiaries drug utilization and out of pocket costs?	114,766 patients with no drug insurance in 2005 who were continuous users of a pharmacy chain from 2005 - 2006 formed the primary cohort.	Time-trend analysis using segmented linear regression from January 1, 2005 - December 31, 2006. Defined daily doses (DDDs) and copayments for four essential medication classes were assessed: clopidogrel, proton pump inhibitors, statins, and warfarin.	<ul style="list-style-type: none"> Among patients who reached the coverage gap, the proportion of patients who filled prescriptions declined: clopidogrel use declined 5% per month (95% CI, 3.2-6.8), warfarin and statin use declined 4.8% (95% CI, 3.8-5.7) and 6.3 (95% CI 4.8-7.8) per month. 	<ul style="list-style-type: none"> Out-of-pocket copayments increased between \$12 per 30 DDDs for warfarin to \$65 per 30 DDDs for clopidogrel in the coverage gap. 	9
7	Zhang Y, Donohue JM, Newhouse JP, Lave JR (2009) ³³	<ul style="list-style-type: none"> What were beneficiaries out of pocket costs during the coverage gap? Did beneficiaries change their drug utilization during the coverage gap? 	Beneficiaries in Pennsylvania-based Medicare Advantage plans. Part D plan enrollees (N=11,661) were compared with beneficiaries in employer group plans (N=2,793).	Interrupted time series using segmented linear regression in 2006	<ul style="list-style-type: none"> During the coverage gap, beneficiaries with no coverage decreased drug utilization by 14% (0.7 prescriptions per month) compared with beneficiaries with coverage of both generic and brand name drugs. Beneficiaries with generic coverage during the gap decreased utilization by 0.14 prescriptions per month (decrease of 0.5 brand name and an increase of 0.36 generic drugs). Those with generic coverage during the gap filled an average of 16 monthly generic prescriptions; those without generic coverage filled 8. 		9