

Changes in Drug Use and Out-of-Pocket Costs Associated with Medicare Part D Implementation: A Systematic Review

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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 the effect of Part D on drug use and out-of-pocket costs. In a systematic review of Medline from 2006 to October 2009, the literature about drug use and costs after implementation and during the transition period and coverage gap was summarized. Studies presenting original results regarding drug use and costs after Part D implementation were included. Case reports and series and simulation studies were excluded. Of 552 originally identified articles, 26 met selection criteria: 13 regarding the overall effect of Part D in the year(s) after implementation, seven describing the Part D transition period, and six concerning the coverage gap. Part D implementation was associated with a 6% to 13% increase in drug use and a 13% to 18% decrease in patient costs. The transition period was associated with no significant changes in use or costs for elderly dual-eligible beneficiaries, but effects in other populations were mixed. Entry into the coverage gap was associated with a 9% to 16% decrease in drug use and increases in costs of up to 89%. In summary, studies examining disparate data regarding the implementation of Part D found consistent positive effects on drug use and costs but revealed unfavorable trends in the coverage gap. The effect of the Part D transition period remains unclear. Although public-use data will validate these results, policymakers can use the existing evidence to inform changes and enhancements to Part D immediately. *J Am Geriatr Soc* 58:1764–1779, 2010.

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

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To improve older adults' 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 the effect of Part D on prescription drug use and beneficiaries' out-of-pocket costs, but the Part D legislation did not allow for use of Medicare prescription drug data for nearly 3 years. To date, 4 years after the inception of Part D, 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 the effect of Part D. This systematic review evaluates the peer-reviewed literature from 2006 to October 2009 and focuses on studies assessing the effect of Part D on older adults' drug use and out-of-pocket spending for prescription medications. Studies regarding the effect of Part D in the first year(s) of the benefit and 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, were examined. Studies that highlighted changes during the coverage gap (doughnut hole) when beneficiaries are responsible for 100% of drug costs were also examined. Taken together, these studies represent the best data available regarding the effect of Part D on Medicare beneficiaries' access to, use of, and spending for prescription drugs.

METHODS

Data Sources

A systematic search was performed to identify studies addressing the effect of Medicare Part D implementation on beneficiaries' drug use and out-of-pocket costs. Initial searches were limited to articles published in Medline between January 1, 2006, and October 31, 2009. The 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. Initial articles were mined for additional reference.

Study Selection

Articles were included if they reported original results, whether drawn from self-report surveys or prescription drug claims. Case reports and series and simulation and modeling studies were excluded. Two reviewers (WS, EK) evaluated the titles and abstracts of search results to identify potentially relevant articles, and two reviewers (JP, EK) assessed complete articles for inclusion.

Data Extraction

Three reviewers (JP, WS, EK) extracted data from selected articles and resolved differences by consensus. Variables assessed included the main research questions, Part D time period assessed, data sources, characteristics of the patient population, study design, results regarding drug use and costs, and patient progression through the four phases of the Part D benefit. Two reviewers [JP, WS] used the Newcastle-Ottawa Scale² to assess the quality of each cohort study. Studies were grouped into three main evidence tables: those that focused on the effect of Part D on drug use and costs during the year(s) after implementation (Table 1), the transition period (Table 2), and the coverage gap (Table 3). 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 use and costs in the year(s) after Part D implementation,^{3–15} seven described use and costs during the Part D transition period,^{16–22} and six examined the Part D coverage gap.^{23–28} One study⁸ reported data related to the year after implementation and to the coverage gap.

The Overall Effect of Part D in the Year(s) After Implementation

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 after 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 to 2006.⁵ An assessment using claims from a prescription transaction manager found that patients aged 65 and older filled 8.1% more prescriptions in 2006 than did those aged 58 to 64. Out-of-pocket costs for patients aged 65 and older were 17.2% less than those patients aged 58 to 64 in 2006.³

In 2006, patients with hyperlipidemia who were newly enrolled in a Medicare Advantage Part D plan filled 44% more monthly prescriptions than in 2005, but newly enrolled Part D patients using oral antidiabetes drugs did not have increases or decreases in use that were measurably different from those of the control group.¹⁰ The out-of-

pocket costs of New Part D enrollees with hyperlipidemia increased by \$17 more than those of the control group from December 2005 to January 2006 (a 31% change) and then an additional \$41 more per month during 2006 (a 74% change). Researchers using Medicare Current Beneficiary Survey 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 Type of Part D insurance modified cost effects. Low-income subsidy recipients saw costs decline from \$741 in 2004 to \$160 in 2006, whereas 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 the effect of Part D on specific types of drugs. Using claims from a large pharmacy chain from 2005 to 2006 to examine three psychotropic drug classes, the implementation of Part D 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 use changes for four drug classes.⁸ Defined daily dose increases were observed for statins (22%), clopidogrel (11%), and proton pump inhibitors (PPIs) (37%) during the year after Part D implementation. Warfarin use did not change. Copayments for all drugs except branded omeprazole declined significantly, with monthly copayments per 30 defined daily doses \$15 to \$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 use, which varied according to drug class: increased use of generic angiotensin-converting enzyme inhibitors (10%) and benzodiazepines (19%) but decreases in the use of generic antihyperlipidemics (–5%), nonsteroidal anti-inflammatories (–8%), antihistamines (–25%), and beta-blockers (–3%).⁹ When comparing patients' likelihood to fill a prescription for a generic medication in 2006 with the likelihood in 2005, Part D enrollees were 5% (95% confidence interval (CI) = –6% to –5%) less likely to fill a prescription for a generic medication in 2006 than in 2005 than were non-enrollees.

Three studies focused on specific populations. Using data from a large long-term care pharmacy provider, one study found little effect of Part D enrollment on long-term nursing home residents.¹¹ After enrollment, Part D enrollees used 0.50 fewer prescriptions per month than non-enrollees, a difference that resolved by December 2006. Part D enrollment was associated with a 3% decrease in out-of-pocket costs in 2006 from 2005. One study 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 of 42,801 patients with diabetes mellitus enrolled in two Medicare Advantage Part D plans.

Table 1. Overall Effect of Part D in the Year(s) After Implementation

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
Lichtenberg et al. ⁹	What was the effect of Part D on prescription drug use and out-of-pocket costs?	50% sample of prescription drug claims from Walgreens for September 2004 to December 2006. Two cohorts: ≥ 65 and < 65	Difference-in-difference comparisons of 2006 versus 2005 drug use and out-of-pocket costs	<ul style="list-style-type: none"> The number of prescriptions increased 14.4% from 2005 to 2006 in older adults and 4.5% in younger adults. The number of days of therapy per prescription rose 19.5% from 2005 to 2006 for older adults and 6.8% for younger adults. 	<ul style="list-style-type: none"> The amount paid by the patient per day of therapy decreased 18.8% from 2005 to 2006 for older adults and 0.4% for younger adults. The amount paid by the patient per prescription decreased 13.7% between 2005 and 2006 for older adults and 1.9% for younger adults. 		9
Chen et al. ¹¹	What was the effect of Part D on drug use and costs for the elderly population using psychotropic medications?	1.19 million patients in 2005, 1.28 million in 2006. Data collected from Walgreens retail pharmacy chain; mean age 75 ± 8 in 2005 and 75 ± 7 in 2006; $> 68\%$ female in both years	Interrupted time-series analysis using segmented linear regression over 24 months, 2005 to 2006. Assessed number of psychotropic drug prescriptions (antipsychotics, antidepressants, and benzodiazepines) 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 use but no subsequent changes throughout 2006. In contrast, there were no significant changes in the levels of antidepressant and antipsychotic use immediately after Part D implementation, but in each month of 2006, prescription use 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 19% for benzodiazepines. 		7
Ketcham et al. ⁸	How did prescription drug use and out-of-pocket costs change for elderly patients during the first 2 years of Part D?	Two cohorts drawn from Wolters Kluwer Health prescription drug transactions: Older cohort is always age-eligible for Part D (> 66 as of 2007), comparison cohort is always age ineligible (58–64 as of 2007) for Part D	Difference-in-difference comparisons of the aggregate change in drug use and out-of-pocket costs from January 2005 to December 2007	<ul style="list-style-type: none"> Elderly patients' days' supply increased 8.1% more from 2005 to 2006 than younger patients'. Days' supply for older adults increased 1.0% more from 2006 to 2007 than younger patients'. In 2006, the number of older adults filling any prescription increased 4.8% more than younger adults. 	<ul style="list-style-type: none"> Between 2005 and 2006, elderly patients' out-of-pocket costs decreased 17.2% more than those of younger patients and 15.9% absolutely. Between 2006 and 2007, elderly patients' out-of-pocket costs decreased an additional 5.8% more than those of younger patients. 		9
Madden et al. ¹⁹	What were the changes in CRN and forgoing basic needs to pay for drugs after Part D implementation?	24,234 Medicare beneficiaries participating in the Medicare Current Beneficiary Survey in 2004–2006. These patients'	Longitudinal panel survey during 2004–2006. CRN outcomes included deciding not to fill or refill a prescription, skipping doses, or taking smaller doses. Forgoing basic needs	<ul style="list-style-type: none"> There was a large absolute decrease in CRN after implementation of 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 much more modest. Forgoing basic needs decreased 3.5% 			NA

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Table 1. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
Yin et al. ¹⁰	What changes in prescription use and out-of-pocket expenditures are attributable to the implementation of Part D?	Characteristics were weighted to represent the overall population of community-dwelling Medicare beneficiaries.	Interrupted time-series analysis using segmented linear regression from September 2004 through April 2007. Assessed monthly average out-of-pocket costs and prescription use measured as pill-days.	<p>from 2005 to 2006, compared with a slight increase from 2004 to 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 after Part D implementation for the most vulnerable subgroups (disabled, fair to poor health, and > 4 comorbidities). 	<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%, compared with those who enrolled during the stable period, who had declines of 5.6%. 		9
Zhang et al. ¹⁴	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 (66–79) patients eligible for Part D (N = 117,648); younger (60–63) patients ineligible for Part D (N = 59,663).	Difference-in-difference comparisons. Outcome was whether each prescription claim was for a generic drug.	<p>Across all drug classes, 56% of all prescriptions were generic in 2005, rising to 58% in 2006, although changes in generic use proportions varied by drug class.</p> <ul style="list-style-type: none"> After adjusting for secular trends, baseline differences between Part D enrollees and non-enrollees, and other potential confounding factors, Part D was associated with 10% greater (95% CI = 5–14%) use of generic 	<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

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Table 1. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
Briesacher et al. ¹⁶	What was the effect of 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 2005/06	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	<p>angiotensin-converting enzyme inhibitors and 19% greater (95% CI = 4–35%) use of generic benzodiazepines. Part D was associated with less use of generic drugs in four drug classes (antihyperlipidemics (OR = 0.95, 95% CI = 0.92–0.98), nonsteroidal anti-inflammatories (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 than in non-enrollees.</p> <ul style="list-style-type: none"> • When examining changes in use from 2005 to 2006, Part D beneficiaries were 5% less likely (95% CI = 0.94–0.95) to fill a generic prescription in 2006 than 2005 than were non-enrollees. 	<ul style="list-style-type: none"> • Nursing home residents with no drug coverage under 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 fell 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
Joyce et al. ¹²	What was the effect of Part D on drug use and spending?	In the baseline period, patients from the 2004 MCBS were studied. For the follow-up period, 2006 enrollment and claims	Before-and-after design. MCBS spending was adjusted from 2004 to 2006 using the consumer price index prescription drug series. Spending and number of fills	<ul style="list-style-type: none"> • Part D was associated with a 7% increase in the number of prescriptions. 	<ul style="list-style-type: none"> • Part D was associated with a 16% annual decrease in out-of-pocket spending for enrollees. • Changes appeared to be concentrated in those eligible for the low-income subsidy (out-of-pocket 		NA

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Table 1. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
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 or exited the coverage gap in 2006? 	<p>data from a large Part D plan were analyzed.</p> <p>16,655 patients with diagnosis of AF aged ≥65 NS enrolled in a Medicare Advantage Part D plan. Mean age 74; 57% male</p>	<p>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.</p> <p>Descriptive study. Three patient populations with AF were defined:</p> <ul style="list-style-type: none"> Patients with AF as the primary discharge diagnosis after a 2005 hospitalization Patients with AF as the secondary discharge diagnosis after a 2005 hospitalization 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. Mean time to reach the coverage gap threshold was 199 ± 83 days, and mean time to reach the catastrophic coverage threshold was 257 ± 71 days in all patients with AF. 	NA
Madden et al. ¹⁸	<p>Did decreases in CRN to medications and forgoing basic</p>	<p>Patients enrolled in the MCBS who were community dwelling in 2004 to 2007</p>	<p>Prevalence rates of CRN were calculated for 2004 to 2007 for the whole population and for four subgroups: elderly (≥65)</p>	<ul style="list-style-type: none"> The prevalence of CRN and forgoing basic needs was consistently higher for younger disabled beneficiaries than elderly beneficiaries 			NA

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Table 1. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
	needs observed in Part D enrollees in 2006 persist or change in 2007?		versus younger disabled (<65) subdivided into 0–2 versus ≥3 morbidities. ORs were estimated for 2007 versus 2005 and 2007 versus 2006.	and for sicker than healthier beneficiaries. <ul style="list-style-type: none"> The prevalence of CRN and forgoing basic needs declined significantly from 2005 to 2007 for the overall population and for all four subgroups (ORs between 0.58 and 0.77, all $P < .05$). Between 2006 and 2007, there was a small decrease in CRN for the overall population (OR = 0.91, 95% CI 0.84–0.99). The decrease in younger disabled was also significant (OR = 0.74, 95% CI = 0.60–0.92). 			
Schmittziel et al. ²⁰	In Medicare beneficiaries with diabetes mellitus, what were total drug costs, out-of-pocket drug costs, and rates of entry and exit into the Part D coverage gap?	There were 42,801 beneficiaries in two Medicare Advantage Part D plans who had diabetes mellitus and met study criteria.	Cross-sectional, descriptive study of patient experiences during 2006		<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 toward the end of the year as out-of-pocket costs increased. 	<ul style="list-style-type: none"> 26% of patients with diabetes mellitus entered the coverage gap in 2006; 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
Schneeeweiss et al. ¹³	What was the effect of Part D on the use of selected essential drugs in 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, to December 31, 2006. DDDs and copayments for four essential medication classes were assessed: clopidogrel, PPIs, statins, and warfarin.	<ul style="list-style-type: none"> Drug use increased 22% for statins, 11% for clopidogrel, and 37% for PPIs after Part D implementation. Warfarin use did not increase. 	<ul style="list-style-type: none"> During the Part D transition period, copayments for all drugs except brand name omeprazole declined significantly. Monthly copayments 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

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Table 1. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Progression Through the Phases of the Part D Benefit	Newcastle-Ottawa Scale Score
Zhang et al. ¹⁵	Did drug use after Part D implementation affect health services use and potentially produce savings in Parts A and B?	All patients were continuously enrolled in Medicare Advantage plans offered by a large Pennsylvania insurer. Four groups were 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 and current \$350 quarterly cap on drug spending; and a comparison group of 9,487 with no previous or current drug cap.	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 between groups. Outcomes were expenditures for drugs and nondrug medical care per member per month. Prescription refills for patients with hyperlipidemia and diabetes mellitus were also measured.	<ul style="list-style-type: none"> After Part D implementation, enrollees with no previous insurance with hyperlipidemia increased their number of monthly prescriptions by 44% more than the no-cap comparison group. No changes in the number of oral diabetes medications were observed between the two groups after Part D implementation. 	<ul style="list-style-type: none"> After the implementation of Part D, enrollees with no previous insurance had a \$17 change in drug spending per month (95% CI = \$9–25), representing a 31% greater increase than the no-cap comparison group in December 2005. Enrollees with no previous insurance increased average monthly drug spending by \$41 in each month after Part D implementation, 74% more than the no-cap comparison group's December 2005 spending. The \$150 quarterly cap group saw an immediate increase of \$8 (95% CI = \$1–15) with implementation of Part D, whereas the \$350 quarterly cap group saw an immediate increase of \$10 (95% CI = \$2–19). Average drug spending increase \$27 more per month in the \$150 cap group (a 27% increase) and \$13 more per month in the \$350 cap group (an 11% increase) than December 2005 spending in the no-cap comparison group. 		9

CRN = cost-related nonadherence; OR = odds ratio; CI = confidence interval; MCBS = Medicare Current Beneficiary Survey; AF = atrial fibrillation; DDD = defined daily dose; proton pump inhibitor = PPI.

Table 2. The Part D Transition Period

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Newcastle-Ottawa Scale Score
Hall et al. ²⁴	How did the Part D transition affect access to drugs for dually eligible adults < 65?	328 (55% response rate) working dually 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, and 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 obtain documentation to continue their prescriptions, a process that for 50% of patients took more than 5 days. 13% reported that they were required to switch a medication, and of those, 60% were required to switch to a generic form. 		NA
West et al. ²⁷	<p>What was the extent of medication access or continuity problems for dually eligible beneficiaries with psychiatric diagnoses during the Part D transition period?</p> <ul style="list-style-type: none"> How did medication disruptions or access problems affect clinical events? How do the features of Part D plans affect the likelihood of medication access problems? 	<ul style="list-style-type: none"> 1,193 randomly sampled psychiatrists from the American Medical Association Physician Masterfile who met inclusion criteria of seeing at least one dually eligible patient during their last typical work week Self-reported survey data submitted on 1,193 dual eligible patients. 	Mailed-in, practice-based survey conducted in January to April 2006. Each psychiatrist was asked to report on the experiences of the next dually eligible patient treated.	<ul style="list-style-type: none"> Psychiatrists reported that, after Part D implementation, patients had difficulty accessing refills (31%) or 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 (95% CI = 1.4–4.2) times the likelihood of an access problem as 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 as patients in Part D plans without this requirement. 		NA
Basu et al. ²¹	<p>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, and total drug expenditures?</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 Walgreens. Treatment group consisted of dually eligible	Difference-in-difference multivariate regression design to examine total number of prescriptions per month, pill-days, monthly out-of-pocket costs, total prescription expenditures, and changes in	<ul style="list-style-type: none"> Dually eligible beneficiaries filled a prescription in both the pre- and post-Part D periods for 17.5% of medications, filled a prescription period in the pre- but not the post-Part D period for 42.5% of medications (discontinuation), and filled a new prescription in the post-Part D period for 40% of medications (initiation). These proportions were nearly identical to those in the 	<ul style="list-style-type: none"> There were no significant changes in trends in dually eligible beneficiaries' out-of-pocket expenditures and total monthly 	9

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Table 2. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Newcastle-Ottawa Scale Score
	<ul style="list-style-type: none"> How was medication adherence and discontinuation affected? 	adults aged 65–78 on January 1, 2005, and a control group of younger patients with Medicaid coverage aged 60–63 as of January 1, 2005.	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>younger control group patients.</p> <ul style="list-style-type: none"> Dually eligible adults 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 younger control group. There were no significant changes in trends in dually eligible adult pill days and total number of prescriptions because of Part D. 	<p>expenditures because of Part D.</p>	
Shrank et al. ²⁶	What were the medication use, out-of-pocket spending, and drug switching experiences of dually eligible beneficiaries during the transition period to Part D?	13,302 dually eligible beneficiaries who were patrons of 1 large pharmacy chain operating in 34 states	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 PPIs.	<ul style="list-style-type: none"> There were no statistically significant increases or decreases in days' supply of any of the drugs after implementation of Part D. There were trends toward more use of warfarin, statins, clopidogrel, and PPIs and a trend toward less use of benzodiazepines. Higher switching rates (2.99%, 95% CI = 1.34–4.65%) than those observed before Part D were observed only for PPIs after Part D implementation. 	<ul style="list-style-type: none"> Warfarin copayments per 30 days' supply decreased \$0.41, a significant change, after 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 transition to Part D. 	9
Das-Douglas et al. ²²	What was the effect of implementation of Part D on the likelihood of antiretroviral treatment interruptions in patients with the human immunodeficiency virus?	125 homeless and marginally housed individuals in a longitudinal cohort study (Research on Access to Care in the Homeless)	Cross-sectional questionnaire assessed Part D insurance status and antiretroviral treatment interruptions of 48 hours or longer. Multivariate logistic regression was used to examine predictors of experiencing a treatment interruption.	<ul style="list-style-type: none"> 14 (11.2%) participants reported a treatment interruption; 10 of the 14 (71.4%) were insured under Part D; 3 (21.4%) had other prescription drug coverage. In multivariate models, patients with Part D coverage were 7.5 times (95% CI = 1.96–28.58) as likely to have reported a treatment interruption as patients with other prescription drug coverage. Nine of the 10 patients with Part D coverage and treatment interruptions attributed the interruption to an aspect of the new Part D plan in which they were enrolled. 	<ul style="list-style-type: none"> Almost 50% of Part D patients reported greater expenditures for prescription drugs under Part D. 	NA
Golden et al. ²³	What were the experiences of dually eligible beneficiaries enrolled in Part D who also had a supplemental pharmacy benefit?	2,959 dually eligible beneficiaries in Florida aged ≥65 who were home-bound and met criteria for nursing home eligibility. All patients were enrolled in a Florida	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 those prescriptions were refills. 		NA

(Continued)

Table 2. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results: Use	Results: Costs	Newcastle-Ottawa Scale Score
Huskamp et al. ²⁵	<ul style="list-style-type: none"> What was the frequency of medication access problems for dually eligible beneficiaries with mental illness as they transitioned into Part D? What was the frequency of psychiatric emergency department use and use of inpatient care in patients who did or did not experience a medication access problem during this transition? 	Home and Community-based Medicaid Waiver Program 1,193 randomly sampled psychiatrists from the American Medical Association Physician Masterfile who met inclusion criteria of seeing at least one dually eligible patient during their last typical work week. Data were available on 1,816 patients.	Observational, clinician-reported surveys using a cross-sectional assessment strategy. Surveys were administered in September to December 2006 and asked psychiatrists to report on the experiences of the next dually eligible patient treated using a randomly assigned start date.	<ul style="list-style-type: none"> Upon transition to Part D, 400 (44%) dually 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 taking was not covered or approved, and 200 (22%) had difficulty accessing medication because of copayments. 		NA

CI = confidence interval; PPI = proton pump inhibitor.

Table 3. The Effect of Part D on the Coverage Gap

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results-Use	Results-Costs	Newcastle-Ottawa Scale Score
Sun et al. ²⁷	How did entry into the coverage gap affect beneficiaries' drug use 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	Difference-in-difference study approach. The precoverage gap period (Jan 1–June 30, 2006) was compared with the postcoverage gap period (July 1–Dec 31, 2006).	<ul style="list-style-type: none"> The Part D coverage gap was estimated to have reduced medication use by 187.5 days of therapy and raised the generic use rate by 7.3%. 	<ul style="list-style-type: none"> The coverage gap was estimated to have increased out-of-pocket costs by \$796.49. 	9
Cronk A, Humphries TL, Clark D, Morris B (2008) ²⁸	What strategies did 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 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-	Cross-sectional mailed survey to examine 2006 coverage gap behaviors, administered in February and March 2007. The survey had a 42% response rate.	<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 as employer-based plan enrollees switched to different medications because of cost (32.1% vs 10.9%) or did not fill a new prescription because of cost (21.8% vs 6.1%). 		8

(Continued)

Table 3. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results-Use	Results-Costs	Newcastle-Ottawa Scale Score
Hsu J, Fung V, Price M, Huang J, Brand R, Hui R, Fireman B, Newhouse JP (2008) ²⁹	How did Part D enrollees who reached the coverage gap respond to drug costs during this period?	sponsored plan who had reached the coverage gap spending threshold before October 2006 but did not experience a gap in coverage. 1,040 continuously enrolled Medicare Advantage Part D plan beneficiaries aged ≥65 from Kaiser Permanente—Northern California. Dually eligible and low-income subsidy beneficiaries were excluded. Response rate was 74.9%.	Cross-sectional telephone survey administered beginning January 2007 with a stratified random sample of 2000 Medicare Advantage Part D plan members, half of whom had reached the coverage gap in 2006 and half of whom did not. Main outcome of interest was whether beneficiaries had engaged in any of 13 behaviors because of medication costs in 2006.	<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 financial burden. The frequency of changes in drug behaviors increased as beneficiaries' 2006 drug costs increased. • 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 regard to financial burden, 5% reported going without another necessity. 		NA
Raebel M, Delate T, Ellis JL, Bayliss EA (2008) ³¹	How did the coverage gap affect healthcare use and medication adherence?	Beneficiaries who self-enrolled in one of two Medicare Advantage plans or who were retirees in employer-based plans administered by Kaiser Permanente Colorado. Beneficiaries were aged ≥65 and survived during the 2-year period.	Retrospective cohort study during 2005/06	<ul style="list-style-type: none"> • For 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 did entry into the coverage gap and the catastrophic coverage period affect beneficiaries' drug use patterns?	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 the catastrophic coverage period. 		6
Schneeweiss S, Patrick AR, Pedan A, Varasteh L, Levin	How did entry into the coverage gap affect beneficiaries' drug use and out-of-pocket costs?	114,766 patients with no drug insurance in 2005 who were continuous users of a pharmacy chain from 2005 to	Time-trend analysis using segmented linear regression from January 1, 2005, to December 31, 2006. DDDs	<ul style="list-style-type: none"> • For 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 use declined 4.8% 	<ul style="list-style-type: none"> • Out-of-pocket copayments increased between \$12 per 30 DDDs for warfarin to 	9

(Continued)

Table 3. (Contd.)

Reference	Research Question	Data Sources and Patient Characteristics	Design	Results-Use	Results-Costs	Newcastle-Ottawa Scale Score
R, Liu N, Shrank WH (2009) ¹³		2006 formed the primary cohort.	and copayments for four essential medication classes were assessed: clopidogrel, PPIs, statins, and warfarin.	(95% CI = 3.8–5.7%) and statin use declined 6.3% (95% CI 4.8–7.8%) per month.	\$65 per 30 DDDs for clopidogrel in the coverage gap.	
Zhang Y, Donohue JM, Newhouse JP, Lave JR (2009) ²⁸	<ul style="list-style-type: none"> • What were beneficiaries' out-of-pocket costs during the coverage gap? • Did beneficiaries change their drug use 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 had 14% less drug use (0.7 prescriptions per month) than beneficiaries with coverage of generic and brand name drugs. • Beneficiaries with generic coverage during the gap decreased use by 0.14 prescriptions per month (decrease of 0.5 brand name and 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

CI = confidence interval; DDD = defined daily dose.

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 nonadherence to medications (CRN) using 2004 to 2007 Medicare Current Beneficiary Survey 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 2004/05¹⁴ and 2006/07.¹³

The Part D Transition Period

Most studies of the Part D transition period examined the experiences of patients dually eligible for Medicare and Medicaid. One study spotlighted the experiences of older dually adults using a 5% random sample of pharmacy chain data. The Part D transition appeared to have no effect on medication initiation, continuation, or discontinuation or initiation of a generic drug, with rates of these behaviors comparable in dually eligible elderly patients and in Medicaid patients aged 60 to 63.¹⁶ There were no observed changes in out-of-pocket expenditures. Another study similarly found no drug use differences during the transition period in older dually eligible adults for five drug classes: warfarin, PPIs, statins, clopidogrel, and benzodiazepines.²¹ After Part D, elderly dually eligible warfarin users experienced significant decreases in out-of-pocket costs of \$0.41 per 30 days' supply, whereas statin, PPI, and clopidogrel payments did not change. Users of benzodiazepines, which were not covered under Part D because of safety concerns, saw copayments increase 91% after the institution of Part D. Drug switching, possibly due to Part D plan coverage, was modest, and no significant differences were seen in 2006 from 2005 in any class studied except PPIs (3.0% switching rate), a class in which all drugs have similar efficacy and safety profiles. One study further explored benzodiazepine use by dually eligible beneficiaries 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, the goal of Part D of reducing benzodiazepine use was not met. In contrast, another study found Part D transition difficulties in 325 younger dually eligible beneficiaries 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 greater out-of-pocket costs under Part D.

In a cross-sectional study of 125 homeless and marginally housed individuals with the human immunodeficiency virus (HIV),¹⁷ of 14 patients who reported HIV treatment interruptions during the first quarter of 2006, 10 (71%) were Part D insured, and nine of these cited plan coverage restrictions as a cause. Of 44 patients who enrolled in Part D, almost 60% reported higher costs for HIV medications, although it is unclear whether all patients were transitioning to Part D, because 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 dually eligible beneficiaries with mental illness.^{20,22} Psychiatrists

surveyed reported that 44% of their 1,816 dually 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 limitations, and 22% had access difficulties because of cost.²⁰

The Effect of Part D in the Coverage Gap

One study focused on Part D enrollees who reached the coverage gap by June but did not reach the catastrophic coverage period in 2006.²⁷ Enrollees had an average of 16% fewer prescription days purchased in the coverage gap than nonenrollees who reached the coverage gap spending threshold but did not experience a gap. After reaching the coverage gap spending threshold, generic drug use increased 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%, whereas total costs in the non-enrollee group increased 2%, and out-of-pocket costs decreased 6%. Similar drug use decreases of 14% were found in the coverage gap for Medicare Advantage Part D plan enrollees.²⁸ It was 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—9.5% fewer.²⁵ In another 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 from pre-coverage gap costs.

In examining adherence, one study noted that declines in medication adherence were similar for Part D enrollees who experienced a gap in coverage and non-enrollees who reached the coverage gap spending threshold (but whose coverage was uninterrupted) with the exception of two drug classes—antihypertensive and antidiabetic agents—for which discontinuation rates were higher for Part D enrollees in the coverage gap.²⁶ Another study found that, in the coverage gap, 20% of Part D enrollees discontinued a medication because of cost, compared with only 5% of nonenrollees who reached the coverage gap spending threshold.²³ Part D enrollees were 5 times (95% CI = 2–13%) as likely to use medication cost-lowering strategies in the gap as were non-enrollees. Among Part D enrollees who did and did not reach the coverage gap in 2006, a survey which asked about their drug cost-coping behaviors found that 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 than beneficiaries who were not aware of the coverage gap.²⁴

DISCUSSION

This review identified 26 studies evaluating the effect of Medicare Part D implementation on drug use and out-of-pocket costs. As expected, the inception of Part D was associated with a consistent overall increase in drug use and a decrease in out-of-pocket costs for enrollees. The transition to Part D went smoothly for many older dually eligible patients, but other vulnerable populations appear to have experienced difficulties. Finally, the Part D coverage gap was associated with less drug use and higher out-of-pocket costs.

There was little variation in effect estimates between studies evaluating the effect of Part D implementation: a 6% to 13% increase in drug use and a 13% to 18% decrease in out-of-pocket drug costs. Changes in use and costs varied according to drug, disease, and population studied, underscoring the need to consider such factors when assessing the effect of Part D, although there was little indication that Part D selectively led to greater use of essential, underused drugs than of overused medications.¹³

In studies of the Part D transition period, elderly dually eligible beneficiaries generally fared well, whereas other populations seemed to experience problems. Two hypotheses may explain these disparate experiences. Because of concerns about the Part D transition for dually eligible beneficiaries, many of whom are elderly, the Centers for Medicare and 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 because of 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 uncover 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, entry of Part D beneficiaries into the coverage gap was associated with 9% to 16% less drug use (of an amount similar in magnitude to the increases seen after Part D implementation) and higher out-of-pocket costs, with changes as high as 89%. Patients who entered the coverage gap were 5% to 11% more likely to report discontinuing, switching, 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 use 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 greater nonelective healthcare use.³⁰ As Part D reforms are implemented, policymakers and researchers must evaluate 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

probably some misclassification. Finally, these studies offer little or no evidence regarding the effect 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 analytical approaches, the studies included in this systematic review showed consistent estimates of the effect of Part D 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. Although studies that employ public-use Part D claims are eagerly awaited, the currently available evidence documents the role of Part D 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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