Beneficiaries With Cardiovascular Disease and the Part D Coverage Gap

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Background—Medicare Part D improved access to cardiovascular medications. Increased cardiovascular drug use and resulting health improvements could be derailed when beneficiaries enter the coverage gap and must pay 100% of drug costs. The coverage gap remains the subject of Congressional debate; evidence regarding its impact on cardiovascular drug use and health outcomes is needed.

Methods and Results—We followed 122,255 Medicare beneficiaries with cardiovascular conditions with linked prescription and medical claims who reached the coverage gap spending threshold in 2006 or 2007. Beneficiaries entered the study on reaching the threshold and were followed until an event, the catastrophic coverage spending threshold, or year’s end. We matched 3980 beneficiaries who reached the threshold and received no financial assistance (exposed) to 3980 with financial assistance during the gap period (unexposed), using propensity score and high-dimensional propensity score approaches. We compared rates of cardiovascular drug discontinuation, drug switching, and death or hospitalization for acute coronary syndrome (ACS) plus revascularization, congestive heart failure, or atrial fibrillation. In propensity score–matched analyses, exposed beneficiaries were more likely to discontinue (hazard ratio, 1.57; 95% confidence interval, 1.39 to 1.79; risk difference, 13.76; 95% confidence interval, 10.99 to 16.54 drugs/100 person-years) but no more or less likely to switch cardiovascular drugs. There were no significant differences in rates of death (propensity score–matched hazard ratio, 1.23; 95% confidence interval, 0.89 to 1.71) or other outcomes.

Conclusions—Part D beneficiaries with cardiovascular conditions with no financial assistance during the coverage gap were at increased risk for cardiovascular drug discontinuation; however, the impact of this difference on health outcomes is not clear. (Circ Cardiovasc Qual Outcomes. 2012;5:400-00.)

Key Words: epidemiology — part D coverage gap — cardiovascular drugs — cardiovascular morbidity and mortality

The expanded use of essential cardiovascular medications has been associated with decreasing rates of cardiovascular-related morbidity and mortality over the past several decades. The 2006 implementation of Medicare Part D further improved access to, and use of, cardiovascular drugs by reducing the out-of-pocket cost burden. Cardiovascular drugs account for the largest proportion of spending (25%) and prescription volume (36%) in the Part D program. Evidence suggests that Part D’s investment in improved access to cardiovascular medications may have led to corresponding decreases in beneficiaries’ cardiovascular-related morbidity and mortality, potentially offsetting Part D costs or even producing net savings. Initial increased use of cardiovascular medications and any corresponding health improvements associated with Part D drug insurance may be disrupted when a beneficiary with a cardiovascular condition reaches the Part D coverage gap. An estimated 3.8 million beneficiaries reach the coverage gap each year, following a period of initial coverage ($2250 in total drug spending in 2006; $2400 in 2007) and remain in the coverage gap until out-of-pocket spending reaches a catastrophic coverage spending threshold ($3600 in 2006; $3850 in 2007), when drug cost-sharing is dramatically reduced, or year’s end. Recent research has documented increased rates of drug discontinuation among beneficiaries who enter the coverage gap and are responsible for 100% of their drug costs; however, no study has specifically addressed the coverage gap experience of beneficiaries with cardiovascular conditions, many of whom take numerous drugs and manage multiple comorbidities. The health consequences of drug discontinuation during the gap may be particularly acute for these beneficiaries, and, as such, they may behave differently when faced with changes in cost-sharing.

In this study, we evaluate the coverage gap’s impact on drug use and health outcomes among beneficiaries with cardiovascular conditions.
lar conditions. We examine the likelihood of cardiovascular drug discontinuation and drug switching, as well as the risk of death and hospitalization for cardiovascular conditions, comparing those who had no financial assistance during the coverage gap (Part D enrollees with no subsidies) with those who did (Part D enrollees with subsidies, retirees).

Although the 2010 Affordable Care Act contains provisions that will gradually eliminate the coverage gap over the next decade, there are no short-term solutions to closing the gap, and recent Congressional budget proposals aim to repeal these reforms. Our study provides evidence about the effect of the coverage gap, as initially implemented, on beneficiaries with cardiovascular conditions and serves as a baseline by which any reforms may be judged.

**WHAT IS KNOWN**

- Entry into the Part D coverage gap is associated with increased rates of drug discontinuation and decreased rates of drug adherence.

**WHAT THE STUDY ADDS**

- Compared to beneficiaries with financial assistance, Part D beneficiaries with cardiovascular conditions with no financial assistance during the coverage gap were 57% more likely to discontinue a cardiovascular drug.
- The impact of this difference in drug discontinuation on health outcomes is not clear.

### Methods

#### Study Design

We conducted 2 prospective open cohort studies with eligible Medicare beneficiaries in 2005 to 2006 (Early Part D Cohort) and 2006 to 2007 (Established Part D Cohort). Beneficiaries entered the cohort on the date when they reached the coverage gap spending threshold, defined as combined plan + beneficiary out-of-pocket spending of $2250 in 2006 and $2400 in 2007 (Figure 1).

#### Data Sources and Study Population

We studied Medicare beneficiaries age ≥65 on January 1 of the baseline year with prescription drug coverage through either a stand-alone Part D plan or a retiree drug plan in 2006 or 2007 that was administered by CVS Caremark, a pharmacy benefits management company that adjudicates approximately 660 million prescriptions per year. Diagnostic, healthcare use, and demographic data from Medicare Parts A, B, and enrollment files were linked to Caremark prescription drug claims.

Beneficiaries in both the Early and Established Part D cohorts had Medicare eligibility and ≥1 Medicare Part A or B claim in both the baseline and study years. Because drug claims for Part D were not available until after the program’s inception in January 2006, Early Part D beneficiaries were required to have ≥1 prescription claim only in the study year, 2006. Established Part D beneficiaries had continuous Caremark eligibility and ≥1 prescription drug claim in both the baseline year (2006) and the study year (2007). To ensure at least some drug information for all beneficiaries, both cohorts were limited to beneficiaries who reached the coverage gap spending threshold ≥60 days after plan enrollment in the study year. We limited both cohorts to beneficiaries with at least 1 inpatient or outpatient cardiovascular diagnosis in the baseline year: hyperlipidemia (International Classification of Diseases, Ninth Edition [ICD-9], 272.0, 272.1), hypertension (401.0 to 401.9), atrial fibrillation (427.31), congestive heart failure (428.0 to 428.9, 429.3), or cardiovascular disease (410.xx to 414.xx, 427.4, 427.5).

Finally, we restricted our cohorts to those who did not enter a nursing home or hospice during the baseline year or in the 2-month trigger period before reaching the coverage gap spending threshold; these admissions indicate worsening health and might confound the relationship between exposure to drug costs and the outcomes of interest.

We used an algorithm that considered plan enrollment and beneficiaries’ out-of-pocket spending to categorize beneficiaries into 4 benefit groups, described previously. Briefly, Part D beneficiaries who did not receive a subsidy (nonsubsidy enrollees) were responsible for 100% of their drug costs in the coverage gap and were thus identified as exposed. If a beneficiary was in a Part D plan with generic drug coverage during the coverage gap but was responsible for 100% of branded drug costs, he was also classified as exposed. In sensitivity analyses, 19 beneficiaries with generic drug coverage were removed. The remaining 3 groups, Part D full subsidy beneficiaries, Part D partial subsidy beneficiaries and retirees, received financial assistance during the coverage gap and were considered unexposed. In accordance with Part D legislation, full-subsidy beneficiaries had per-prescription cost-sharing that was ≤$5 in 2006 or ≤$5.35 in 2007, even in the coverage gap. Partial subsidy beneficiaries’ cost-sharing was ≤15% for each prescription in the coverage gap. Finally, retirees shared drug costs with their former employers, and none of the retiree plans (none of which were Part D plans) had a coverage gap.

#### Propensity Score Matching

To balance covariate distributions between the exposed and unexposed, we constructed a propensity score (PS) assessing each beneficiary’s likelihood of receiving financial assistance after reaching the coverage gap spending threshold. Model predictors included age, sex, race, region of the United States, rural/urban residence, median household income from census block data, time (in days) from plan enrollment to reaching the gap spending threshold, and total Medicare Parts A and B spending in the baseline year. Diagnostic/health services covariates, assessed in the baseline year and in the 2 months before cohort entry, included diagnosis of dementia, cancer, chronic obstructive pulmonary disease/emphysema, renal failure, end-stage renal disease, depression, HIV/AIDS, diabetes, atrial fibrillation, hypercholesterolemia, hypertension, coronary artery disease, congestive heart failure, stroke, venous thromboembolism, myocardial infarction, and/or ACS with revascularization; Charlson comorbidity score, and number of office-based drug infusions, physician visits, and hospitalizations. Drug-related covariates, assessed in the 2 months before cohort entry, included number of unique drugs used and total (plan + beneficiary out-of-pocket) drug spending. Using a greedy matching algorithm, exposed beneficiaries were PS-matched to unexposed beneficiaries. Exposed patients who could not be matched were removed from analyses.

### Drug Use Outcomes

We considered 2 mutually exclusive drug use outcomes, discontinuation, and switching, and only 1 outcome was assigned. Any cardiovascular drug with available days’ supply at study entry was considered and followed until the first observed outcome. Drug X was discontinued if >30 days elapsed after study entry when no drug X was available and no further fills of drug X or another drug in the same class were made during the gap period. Therefore, follow-up for this outcome began at day 31 after study entry. In contrast, Drug...
X was switched if a beneficiary entered the study and switched from the generic to the brand version or vice versa or if the beneficiary stopped filling prescriptions for drug X but filled a new prescription for another drug within the same class within 30 days of exhausting his drug X supply. In sensitivity analyses, we considered discontinuations and switches with 15- and 45-day grace periods. We examined the use of drugs within the following classes: aldosterone antagonists, alpha blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, antiplatelet therapies, beta blockers, bile acid sequestrants, calcium channel blockers, digoxin, ezetimibe, loop diuretics, thiazide diuretics, niacin and other fibrates, potassium-sparking agents, statins, warfarin, and other medications. (Specific drugs are in the online-only supplemental Appendix.) If a beneficiary was taking a combination drug, each drug in the combination was counted as a unique drug in its respective class.

Healthcare Outcomes

Our primary outcome was death from any cause. Additionally, we assessed rates of first hospitalization with a primary or secondary diagnosis code for ACS; congestive heart failure; and atrial fibrillation, as well as rates for 2 composite outcomes: (1) death or hospitalization for myocardial infarction or stroke; and (2) hospitalization for myocardial infarction or stroke. Definitions and codes are in the online-only supplemental Appendix.

Statistical Analysis

Beneficiaries’ baseline characteristics were cross-tabulated by benefit group and exposure status. After testing for effect measure modification by cohort year using a Wald test and finding none, we conducted pooled cohort analyses for all outcomes. Drug use analyses were at the individual drug level. For both PS-matched and hdPS-matched cohorts, we used Cox proportional hazards models25 to estimate the hazard of cardiovascular drug discontinuation and drug switching, for all drugs and within each class, and to estimate the hazards of death and each of the cardiovascular outcomes. For the drug use outcomes, subgroup analyses explored potential effect modification by branded/generic status. For the health outcomes, we explored potential effect modification among patients who had a hospitalization for a myocardial infarction, stroke, and/or ACS ≤90 days before study entry. These patients were at high risk for a second event. In drug use analyses, we used generalized estimating equation methods26 to account for multiple drugs within individuals. Both beneficiaries’ drug use and health outcomes could be assessed twice if he was eligible for both the Early and Established Part D cohorts, so pooled analyses employed generalized estimating equations as well. In all analyses, beneficiaries were censored on the date of a first outcome, death, reaching the catastrophic coverage spending threshold, or study year’s end. In the drug use analyses, we additionally censored beneficiaries who entered a nursing home or hospice or had a hospitalization >14 days because we could not ensure complete drug use data after 1 of these events. Additionally, we estimated rate differences using Poisson regression and multiplied these by the 11% prevalence of coverage gap exposure and average 3.6-month duration of the coverage gap (as described by the Centers for Medicare and Medicaid Services9) to obtain population attributable risks. The Human Subjects Committee at Brigham and Women’s Hospital approved this study. Data use agreements were in place with all data providers.

Results

Among all beneficiaries who reached the gap spending threshold, 39 470 were enrolled in Part D plans, and 3% of Part D enrollees received no financial assistance during the coverage gap (Table 1). At least 86% of beneficiaries had hypertension, and 33% had a diagnosis of congestive heart failure. A total of 4% to 6% of patients had only hypertension and/or hyperlipidemia. Only 6% of beneficiaries reached the catastrophic coverage period. Many characteristics were unbalanced across groups. More than 71% of full-subsidy beneficiaries were female, whereas 42% of retirees were. Of the 4014 exposed beneficiaries, 3980 (99%) could be PS-matched to unexposed beneficiaries. After multivariate PS matching, beneficiary characteristics were largely balanced across the exposed and unexposed groups (Table 2). In the hdPS-matched cohorts, 3787 (94%) of the exposed could be matched, and covariate balance between the groups was similar (data not shown).

Exposed beneficiaries were 1.57× (95% confidence interval [CI], 1.39 to 1.79) as likely to discontinue a cardiovascular drug on reaching the gap spending threshold as were
Table 1. Baseline Characteristics of All 122 255 Beneficiaries With a Cardiovascular Condition Who Reached the Coverage Gap Spending Threshold, by Exposure Status and Benefit Group

<table>
<thead>
<tr>
<th>Region</th>
<th>Unexposed to Gap in Coverage</th>
<th>Exposed to Gap in Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Retired With Full Coverage</td>
<td>Partial Subsidy Beneficiaries</td>
</tr>
<tr>
<td></td>
<td>Female sex</td>
<td>Female sex</td>
</tr>
<tr>
<td></td>
<td>N (%) or Mean±SD</td>
<td>N (%) or Mean±SD</td>
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<tr>
<td>Northea h</td>
<td>10 664 (23)</td>
<td>12 448 (26)</td>
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<tr>
<td></td>
<td>6333 (37)</td>
<td>7148 (37)</td>
</tr>
<tr>
<td></td>
<td>1024 (45)</td>
<td>1082 (45)</td>
</tr>
<tr>
<td></td>
<td>14 696 (38)</td>
<td>16 018 (38)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>White</td>
<td>43 559 (94)</td>
<td>43 559 (94)</td>
</tr>
<tr>
<td></td>
<td>11 656 (68)</td>
<td>11 656 (68)</td>
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<tr>
<td></td>
<td>2073 (92)</td>
<td>2073 (92)</td>
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<tr>
<td></td>
<td>2362 (94)</td>
<td>2362 (94)</td>
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<td></td>
<td>34 051 (74)</td>
<td>34 051 (74)</td>
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<td></td>
<td>8368 (49)</td>
<td>8368 (49)</td>
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<tr>
<td></td>
<td>9 034 (40)</td>
<td>9 034 (40)</td>
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<tr>
<td></td>
<td>14 870 (68)</td>
<td>14 870 (68)</td>
</tr>
<tr>
<td>Other</td>
<td>665 (1)</td>
<td>665 (1)</td>
</tr>
<tr>
<td></td>
<td>2195 (13)</td>
<td>2195 (13)</td>
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<tr>
<td></td>
<td>69 (3)</td>
<td>69 (3)</td>
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<td></td>
<td>22 (1)</td>
<td>22 (1)</td>
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<tr>
<td></td>
<td>517 (1)</td>
<td>517 (1)</td>
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<tr>
<td></td>
<td>1603 (12)</td>
<td>1603 (12)</td>
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<tr>
<td></td>
<td>165 (13)</td>
<td>165 (13)</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>Median household income in zip code of residence ($)</td>
<td>15 669 (54)</td>
<td>15 669 (54)</td>
</tr>
<tr>
<td></td>
<td>54 058 (15 002)</td>
<td>54 058 (15 002)</td>
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<tr>
<td></td>
<td>18 921 (38 506)</td>
<td>18 921 (38 506)</td>
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<tr>
<td></td>
<td>20 354 (52 565)</td>
<td>20 354 (52 565)</td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis of atrial fibrillation*</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>1.0</td>
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<tr>
<td></td>
<td>0.7</td>
<td>0.7</td>
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<tr>
<td></td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Diagnosis of congestive heart failure*</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Diagnosis of coronary artery disease*</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Diagnosis of hypertension*</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Diagnosis of hypertension or hypercholesterolemia ONLY*</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>1.0</td>
</tr>
</tbody>
</table>

*Assessed in the 12 mo of the baseline year; †Assessed in the 2 mo prior to reaching the coverage gap spending threshold. IQR indicates interquartile range.

unexposed beneficiaries (Table 3). On the absolute scale, exposure was associated with discontinuation of an additional 13.76 (10.99 to 16.54) drugs/100 person-years. The effect was not modified by the drug’s generic/branded status. Within most specific drug classes, exposed beneficiaries were more likely to discontinue use: beta blockers (hazard ratio [HR], 1.68; 95% CI, 1.28 to 2.20; risk difference [RD], 10.71; 95% CI, 5.18 to 16.24 drugs/100 person-years) and statins (HR, 2.16; 95% CI, 1.72 to 2.71, RD, 25.85; 95% CI, 18.38 to 33.32 drugs/100 person-years) than were unexposed beneficiaries. At the population level, ~2.9 million Part D beneficiaries discontinued an additional 117 991 (94 239 to
141 830) drugs during an average 3.6 months of coverage gap exposure (data not shown).

Although they discontinued drugs more often, exposed beneficiaries were no more or less likely to switch a cardiovascular drug (HR, 1.04; 95% CI, 0.88 to 1.23; RD, 0.24; 95% CI, −0.92 to 1.41) than were unexposed beneficiaries, an effect that was not modified by the drug’s generic/branded status or drug class (Table 4). In both the discontinuation and switching analyses, sensitivity analyses with grace periods of 15 and 45 days, analyses that excluded beneficiaries with generic drug coverage during the gap, and analyses with hdPS-matched cohorts produced analogous results (data not shown).

In PS-matched analyses, the exposed were no more likely to die (HR, 1.23; 95% CI, 0.89 to 1.71; RD, 1.05; 95% CI,
greater risk of all-cause mortality or hospitalization for cardiovascular outcomes during the gap period. Although increased cardiovascular drug discontinuations are regrettable, the impact of these increased discontinuations on health outcomes is not clear.

Some policymakers have argued that sensitizing Part D consumers to drug costs through mechanisms like the coverage gap would encourage beneficiaries to use only essential and lower-priced medications. Although theoretically plausible, patients’ actions have been quite different: Researchers have observed increased rates of drug discontinuation and adherence across both essential and potentially unnecessary drugs but have not observed higher rates of switching to generic drugs during the coverage gap. The current study further tests the consumer cost-sensitization hypothesis by examining whether beneficiaries with underlying cardiovascular conditions might be more likely to use medications judiciously, given their health status and the likelihood of adverse events if they discontinue drug use. Instead of observing different behaviors, we found that sudden exposure to 100% of drug costs in the gap still led to abrupt discontinuation of essential cardiovascular medications among those with cardiovascular conditions. Beneficia-

### Discussion

Among Medicare beneficiaries with cardiovascular conditions, reaching the Part D coverage gap spending threshold and receiving no financial assistance to pay for drugs was associated with a 57% increased risk of cardiovascular drug discontinuation (an additional 14 drugs discontinued per 100 person-years) but no greater risk of drug-switching. Results were similar across drug classes and generic/branded status. Beneficiaries without financial assistance in the gap had no

### Table 3. Risk of Drug Discontinuation, Hazard Ratios, and Rate Differences Among PS-Matched Pooled Cohort Beneficiaries Who Reached the Coverage Gap Spending Threshold and Did Not (Exposed) or Did (Unexposed) Receive Financial Assistance to Pay for Drugs, for All Drugs, and for Each Drug Class

<table>
<thead>
<tr>
<th></th>
<th>Exposed</th>
<th>Unexposed</th>
<th>HR (95% CI)*</th>
<th>Rate Difference (95% CI) per 100 Person-Years*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N beneficiaries</strong></td>
<td>3980</td>
<td>3980</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td><strong>N cardiovascular drugs</strong></td>
<td>11 226</td>
<td>11 122</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Discontinuation of a cardiovascular drug†</td>
<td>940 (8)</td>
<td>766 (7)</td>
<td>1.57 (1.39–1.79)</td>
<td>13.76 (10.99–16.54)</td>
</tr>
<tr>
<td>Discontinuation of a generic cardiovascular drug</td>
<td>551 (8)</td>
<td>501 (7)</td>
<td>1.40 (1.21–1.63)</td>
<td>9.88 (6.55–13.22)</td>
</tr>
<tr>
<td>Discontinuation of a branded cardiovascular drug</td>
<td>389 (10)</td>
<td>265 (7)</td>
<td>1.89 (1.58–2.27)</td>
<td>20.98 (16.03–25.94)</td>
</tr>
<tr>
<td><strong>Alpha blockers</strong></td>
<td>13 (7)</td>
<td>22 (10)</td>
<td>0.96 (0.48–1.93)</td>
<td>−1.47 (−2.18 to −1.83)</td>
</tr>
<tr>
<td><strong>ACE inhibitors</strong></td>
<td>93 (8)</td>
<td>68 (6)</td>
<td>1.83 (1.33–2.52)</td>
<td>15.84 (7.40–24.28)</td>
</tr>
<tr>
<td><strong>ARBs</strong></td>
<td>69 (10)</td>
<td>36 (6)</td>
<td>2.33 (1.55–3.49)</td>
<td>25.83 (14.07–37.58)</td>
</tr>
<tr>
<td><strong>Antiplatelet drugs</strong></td>
<td>73 (6)</td>
<td>61 (7)</td>
<td>1.42 (1.01–2.00)</td>
<td>10.27 (−0.20–20.74)</td>
</tr>
<tr>
<td><strong>Beta blockers</strong></td>
<td>122 (6)</td>
<td>91 (5)</td>
<td>1.68 (1.28–2.20)</td>
<td>10.71 (5.18–16.24)</td>
</tr>
<tr>
<td><strong>Calcium channel blockers (CCBs)</strong></td>
<td>83 (6)</td>
<td>76 (7)</td>
<td>1.35 (0.99–1.84)</td>
<td>9.56 (0.76–18.35)</td>
</tr>
<tr>
<td><strong>Digoxin</strong></td>
<td>17 (5)</td>
<td>23 (7)</td>
<td>1.06 (0.67–2.00)</td>
<td>0.83 (−13.28 to 14.93)</td>
</tr>
<tr>
<td><strong>Ezetimibe</strong></td>
<td>55 (9)</td>
<td>35 (6)</td>
<td>1.97 (1.29–3.01)</td>
<td>20.64 (8.33–32.94)</td>
</tr>
<tr>
<td><strong>Loop diuretics</strong></td>
<td>54 (7)</td>
<td>76 (10)</td>
<td>0.97 (0.68–1.37)</td>
<td>−0.76 (−10.84 to 9.32)</td>
</tr>
<tr>
<td><strong>Niacin</strong></td>
<td>23 (6)</td>
<td>22 (7)</td>
<td>1.33 (0.75–2.37)</td>
<td>11.45 (−4.08 to 26.99)</td>
</tr>
<tr>
<td><strong>Potassium-sparing agents/aldosterone antagonists</strong></td>
<td>29 (12)</td>
<td>24 (10)</td>
<td>1.48 (0.84–2.62)</td>
<td>18.71 (−5.14 to 42.57)</td>
</tr>
<tr>
<td><strong>Statins</strong></td>
<td>195 (11)</td>
<td>125 (7)</td>
<td>2.16 (1.72–2.71)</td>
<td>25.85 (18.38–33.32)</td>
</tr>
<tr>
<td><strong>Generic statins</strong></td>
<td>60 (10)</td>
<td>39 (7)</td>
<td>1.85 (1.22–2.78)</td>
<td>21.73 (8.63–34.82)</td>
</tr>
<tr>
<td><strong>Branded statins</strong></td>
<td>135 (11)</td>
<td>86 (6)</td>
<td>2.32 (1.72–3.04)</td>
<td>27.74 (18.63–38.86)</td>
</tr>
<tr>
<td><strong>Thiazides</strong></td>
<td>73 (10)</td>
<td>52 (8)</td>
<td>1.49 (1.04–2.14)</td>
<td>17.44 (4.86–30.02)</td>
</tr>
<tr>
<td><strong>Warfarin</strong></td>
<td>37 (8)</td>
<td>48 (10)</td>
<td>1.09 (0.71–1.69)</td>
<td>2.81 (−12.12–17.74)</td>
</tr>
</tbody>
</table>

*HR indicates hazard ratio; CI, confidence interval.
†Drug X was discontinued if ≥30 d elapsed during the coverage gap when no drug X was available and no further fills of drug X or a drug in the same class were made during the coverage gap period.
Our health outcome results are inconsistent with a growing body of literature regarding the consequences of stopping or reducing adherence to drugs in response to benefit caps, gaps in coverage, and high deductibles. Medicare Advantage beneficiaries, whose plans employed an annual drug cap, reduced their drug use and experienced 13% higher rates of drug discontinuation during the gap, confirming results of prior studies.

Our cohort entry, as these admissions are markers of worsening health and likely confounders. The PS-matched analyses controlled for over 40 possible confounders assessed both before and after drug plan selection. Results from the hdPS-matched analyses, which empirically identified 400 additional potential confounders to improve residual confounding control, remained consistent with the PS-matched results, with the exception of hospitalization for ACS. For this outcome, the hdPS results confirmed a null association in contrast with borderline significant PS-matched analyses.

Still, we cannot rule out unmeasured confounding, owing to the limitations of the PS- and hdPS-matching techniques. An imbalance in the use of healthcare services not covered by Medicare (and therefore not recorded in our data) might result in unmeasured confounding. We did not directly examine the association between cardiovascular drug discontinuation and adverse health outcomes. Evidence suggests that other drugs are stopped as well, and, in our study, patients filled 6 to 9 prescriptions before study entry. Thus, a cardiovascular drug-specific analysis would give an incomplete picture of which drug discontinuations were associated with adverse outcomes. Finally, although it would be possible to study
Table 5. Risk of Health Outcomes, Hazard Ratios, and Rate Differences Among Pooled Cohort Beneficiaries Who Reached the Coverage Gap Spending Threshold and Did Not (Exposed) or Did (Unexposed) Receive Financial Assistance to Pay for Drugs

<table>
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</thead>
<tbody>
<tr>
<td>N beneficiaries</td>
<td>3980</td>
<td>3980</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
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<td>...</td>
</tr>
<tr>
<td>Total person years</td>
<td>1297.10</td>
<td>1440.41</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
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</tr>
<tr>
<td>Death from any cause</td>
<td>73 (2)</td>
<td>66 (2)</td>
<td>1.23 (0.89–1.71)</td>
<td>1.26</td>
<td>(0.90–1.77)</td>
<td>1.05 (0.65 to 2.75)</td>
<td>1.24</td>
<td>(0.51 to 2.99)</td>
<td></td>
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</tr>
<tr>
<td>Hospitalization with a primary or secondary diagnosis of:*</td>
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</tr>
<tr>
<td>Acute coronary syndrome with revascularization</td>
<td>48 (1)</td>
<td>34 (1)</td>
<td>1.55 (1.00–2.41)</td>
<td>1.30</td>
<td>(0.86–1.96)</td>
<td>1.58 (0.20–2.97)</td>
<td>1.07</td>
<td>(0.42 to 2.55)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Congestive heart failure</td>
<td>100 (3)</td>
<td>120 (3)</td>
<td>0.99 (0.75–1.30)</td>
<td>0.80</td>
<td>(0.61–1.05)</td>
<td>0.21 (2.03 to 2.45)</td>
<td>-1.96</td>
<td>(4.35–0.43)</td>
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<tr>
<td>Atrial fibrillation</td>
<td>67 (2)</td>
<td>69 (2)</td>
<td>1.08 (0.77–1.50)</td>
<td>0.94</td>
<td>(0.67–1.31)</td>
<td>0.70 (1.07 to 2.46)</td>
<td>-0.09</td>
<td>(1.95 to 1.78)</td>
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<tr>
<td>Composite outcomes:</td>
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</tr>
<tr>
<td>Death or hospitalization with a primary or secondary diagnosis of myocardial infarction or stroke</td>
<td>93 (2)</td>
<td>89 (2)</td>
<td>1.20 (0.89–1.61)</td>
<td>1.16</td>
<td>(0.87–1.55)</td>
<td>1.28 (0.73–3.29)</td>
<td>1.08</td>
<td>(1.03–3.18)</td>
<td></td>
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</tr>
<tr>
<td>Hospitalization with a primary or secondary diagnosis of myocardial infarction or stroke</td>
<td>41 (1)</td>
<td>48 (1)</td>
<td>0.93 (0.61–1.42)</td>
<td>0.97</td>
<td>(0.64–1.47)</td>
<td>0.02 (0.40 to 1.43)</td>
<td>0.10</td>
<td>(1.37 to 1.57)</td>
<td></td>
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</tr>
</tbody>
</table>

*For specific codes for each health outcome, please see the online-only supplemental Appendix.

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The authors thank Joyce Lii for exceptional programming assistance.

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References


Beneficiaries With Cardiovascular Disease and the Part D Coverage Gap
Jennifer M. Polinski, William H. Shrank, Robert J. Glynn, Haiden A. Huskamp, M. Christopher Roebuck and Sebastian Schneeweiss

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**Appendix Table 1.** Beneficiary classification algorithm

<table>
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<tr>
<th></th>
<th>Deductible</th>
<th>Initial coverage period</th>
<th>Coverage gap period</th>
<th>Catastrophic coverage period</th>
<th>Exposure status in spending threshold analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full subsidy beneficiaries</strong> [Income ≤ $7,500 (single) or $12,000 (married) in 2006; income ≤ $7,620 (single) or $12,190 (married) in 2007]</td>
<td>$0</td>
<td>Co-insurance ≤ $5 in 2006, ≤ $5.35 in 2007</td>
<td>Co-insurance ≤ $5 in 2006, ≤ $5.35 in 2007</td>
<td>$0</td>
<td>Unexposed: receive financial assistance to pay for drugs during the coverage gap</td>
</tr>
<tr>
<td><strong>Partial subsidy beneficiaries</strong> [Income ≤ $11,500 (single) or $23,000 (married) in 2006; income ≤ $11,710 (single) or $23,410 (married) in 2007]</td>
<td>Plan-dependent; $50 in 2006; $53 in 2007 in defined standard plan.</td>
<td>Plan-dependent; Co-insurance ≤ 15%</td>
<td>Plan-dependent; Co-insurance ≤ 15%</td>
<td>≤ $2 generic/$5 brand in 2006; ≤ $2.15 generic/$5.35 brand in 2007</td>
<td>Unexposed: receive financial assistance to pay for drugs during the coverage gap</td>
</tr>
<tr>
<td><strong>Non-subsidy enrollees</strong> [Do not receive any subsidy]</td>
<td>Part D plan-dependent; defined standard was $250 in 2006; $265 in 2007</td>
<td>Part D plan-dependent; defined standard was 25% co-insurance in both 2006 and 2007</td>
<td>100% of drug costs (unless plan was enhanced alternative)</td>
<td>The greater of 5% or $2 generic/$5 brand in 2006; the greater of 5% or $2.15 generic/$5.35 brand</td>
<td>Exposed: do not receive any financial assistance during the coverage gap</td>
</tr>
<tr>
<td><strong>Retirees</strong> [not enrolled in a Part D plan]</td>
<td>Cost-sharing throughout the benefit is plan-dependent. Because we have no identifier for retiree plan nor information about the cost-sharing structure, we cannot categorize these plans</td>
<td></td>
<td></td>
<td></td>
<td>Unexposed: receive financial assistance to pay for drugs during the coverage gap</td>
</tr>
</tbody>
</table>
## Appendix Table 2. Definitions and codes for covariates and outcomes of interest

<table>
<thead>
<tr>
<th>Diseases assessed as covariates</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>ICD-9 250.0-250.9</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>ICD-9 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.71, 410.81, 410.91; DRG 121, 122, 123</td>
</tr>
<tr>
<td>Hypertension</td>
<td>ICD-9 401.xx, 402.xx, 403.xx, 404.xx, 405.xx</td>
</tr>
<tr>
<td>Dementia</td>
<td>ICD-9 290.0x – 290.9x, 294.1x, 294.9x, 330.x, 331.x</td>
</tr>
<tr>
<td>Diabetes</td>
<td>ICD-9 250.xx</td>
</tr>
<tr>
<td>Cancer</td>
<td>ICD-9 140.x-208.x; 230.x-239.x</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease or emphysema</td>
<td>ICD-9 490.0x-491.9x, 492.xx, 494.0x-494.9x, 496.0x-496.9x</td>
</tr>
<tr>
<td>Renal failure</td>
<td>ICD-9 403.xx – 404.xx</td>
</tr>
<tr>
<td>End stage renal disease</td>
<td>ICD-9 585.6</td>
</tr>
<tr>
<td>Depression</td>
<td>ICD-9 296.2x, 296.3x, 309.0x, 309.1x, 311.xx</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>ICD-9 042.xx, 079.53</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>ICD-9 272.0, 272.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiovascular outcomes</th>
<th>Definition (inpatient ICD-9/DRG diagnosis in primary or secondary position)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute coronary syndrome (ACS)</td>
<td>410.xx (except where the 5th digit is 2) with length of stay &gt;= 3 and &lt;= 180 days, 411.xx</td>
</tr>
<tr>
<td>Myocardial infarction (MI)</td>
<td>ICD-9 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.71, 410.81, 410.91; DRG 121, 122, 123</td>
</tr>
<tr>
<td>Stroke</td>
<td>ICD-9 433.x1, 434.x1, 436.xx, 437.1x, 437.9x; 430, 431, 432.x, 800.2, 800.3, 800.7, 800.8, 801.2, 801.3, 801.7, 801.8, 803.2, 803.3, 803.7, 803.8, 804.2, 804.3, 804.7, 804.8, 852.x, 853.x</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>428.xx</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>427.31</td>
</tr>
<tr>
<td>Venous thromboembolism</td>
<td>451.11, 451.18, 451.2, 451.81, 451.9, 453.1, 453.2, 453.8, 453.9, 415.1</td>
</tr>
<tr>
<td>Revascularization</td>
<td>PTCA: CPT-4: 92982 - 92984, 92995, 92997; ICD-9 procedure: 00.66, 36.03, 36.09; DRG: 112, 555</td>
</tr>
<tr>
<td></td>
<td>Stent: CPT-4: 92980, 92981; ICD-9 procedure: 36.06, 36.07; DRG: 556, 557,558</td>
</tr>
<tr>
<td></td>
<td>CABG surgery: CPT-4: 33510 – 33545; ICD-9 procedure: 36.1x, 36.2x; DRG: 106, 107, 109, 547, 548, 549, 550</td>
</tr>
<tr>
<td></td>
<td>Systemic Thrombolysis: CPT-4: 92975-92977; ICD-9 procedure: 99.29, 99.10</td>
</tr>
<tr>
<td>Procedure Type</td>
<td>CPT-4 Codes</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------</td>
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<tr>
<td><strong>Intracoronary Thrombolysis</strong></td>
<td>CPT-4: 92975; ICD-9 procedure: 36.02, 36.04, 36.05</td>
</tr>
<tr>
<td><strong>Angiography</strong></td>
<td>CPT-4: 92978, 92979, 93508, 93510, 93511, 93539, 93540, 93543, 93545, 93556; ICD-9 procedure: 37.22, 37.23, 88.5x</td>
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Appendix Table 3. Evaluated drug classes/individual drugs

<table>
<thead>
<tr>
<th>Cardiovascular drug classes/individual drugs</th>
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<tbody>
<tr>
<td>• Warfarin</td>
</tr>
<tr>
<td>• Statins</td>
</tr>
<tr>
<td>• Niacin and fibrates</td>
</tr>
<tr>
<td>• Bile acid sequestrants</td>
</tr>
<tr>
<td>• ACE Inhibitors</td>
</tr>
<tr>
<td>• Loop diuretics</td>
</tr>
<tr>
<td>• Angiotensin receptor blockers</td>
</tr>
<tr>
<td>• Aldosterone antagonists</td>
</tr>
<tr>
<td>• Beta-blockers</td>
</tr>
<tr>
<td>• Digoxin</td>
</tr>
<tr>
<td>• Anti-platelet drugs</td>
</tr>
<tr>
<td>• Thiazide diuretics</td>
</tr>
<tr>
<td>• Calcium channel blockers</td>
</tr>
<tr>
<td>• Potassium-sparing agents</td>
</tr>
<tr>
<td>• Alpha blockers</td>
</tr>
<tr>
<td>• Diazoxide</td>
</tr>
<tr>
<td>• Metyrosine</td>
</tr>
<tr>
<td>• Reserpine/mannitol hexanitrate</td>
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<tr>
<td>• Acetazolamide</td>
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