RESEARCH ARTICLE

Effects of Medicare Part D coverage gap closure on utilization of branded and generic drugs

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Abstract

The Affordable Care Act included a provision to gradually eliminate the Medicare prescription drug coverage gap between 2011 and 2020, which substantially lower medication costs in the gap. Using 2007–2016 Medicare claims data, we estimate how filling the gap affects individuals' out-of-pocket spending and medication use, separately for branded and generic drugs. One important difficulty in estimating the policy impact is that around the same time, many blockbuster drugs commonly used by the Medicare population experienced patent expiration and began to see generic entry. Because generic entries affected different therapeutic classes at different times, we run difference-in-differences models by therapeutic category at the beneficiary-month level to isolate the effect of the gap closure from that of generic entry. Overall, we find that filling the gap substantially reduced out-of-pocket spending and increased the use of branded drugs, which had larger discount rates during the analysis period. Beneficiaries reaching the gap, at older ages, or with comorbidities experienced larger reduction in out-of-pocket spending. We show that without accounting for generic entry, the effect of filling the coverage gap on medication use is underestimated for branded drugs and overestimated for generic drugs.

KEYWORDS
coverage gap, generic entry, health insurance, Medicare Part D, prescription drugs

JEL CLASSIFICATION
I11, I12, I13

1 | INTRODUCTION

U.S. Medicare, the federal health insurance for the elderly and the disabled, began covering prescription drugs through its Part D program in 2006. Medicare Part D has a complex benefit structure. Initially, a typical benefit plan would have a small deductible, an initial coverage phase where beneficiaries were responsible for 25% of drug costs, a coverage gap where beneficiaries paid 100% of drug costs that kicked in after total drug spending reached the initial coverage limit ($2250 in 2006), and a catastrophic coverage phase where beneficiaries were responsible for just 5% of costs that kicked in after total drug spending exceeded the upper limit of the coverage gap ($5100 in 2006). The controversial coverage gap (also called the "doughnut hole") was originally created to lower the federal budget impact of the program.

The Part D cost-sharing structure has changed throughout the years. In particular, the Affordable Care Act (ACA) included a provision to gradually eliminate the coverage gap between 2011 and 2020. Over the 10-year period, this phased-in provision decreased the patient contribution percentage during the coverage gap phase from 100% down to 25% of medication costs (same as the initial coverage phase). As a result, total annual costs of purchasing medications have substantially decreased for beneficiaries who would have reached the coverage gap under the old policy. Importantly, the coverage gap discount rates were not the same for branded and generic drugs during our study period (Appendix Table A1). In the early years of the policy, branded drugs had higher discount rates and thus reduced relative prices to generic drugs, leading to substitution from generic to branded drugs. Therefore, we expect that the coverage gap closure would increase total medication use and use of branded drugs, whereas the effect on use of generic drugs depends on both own price elasticity and cross-price elasticity.

In this paper, we use the 2007–2016 Medicare administrative claims data to study the effects of the ACA provision to fill in the Part D coverage gap. We begin by estimating an event study difference-in-differences model that examines dynamic changes in out-of-pocket (OOP) spending and medication use between non-subsidized beneficiaries and a subset of beneficiaries who have remained exempt from the coverage gap and therefore have not been affected by the policy. We identify the drug type using the brand-generic code in the prescription drug event data and estimate the effects separately for branded and generic drugs to reflect the differences in discount rates. To fully understand the response to the coverage gap closure, we also estimate the policy effects on the probabilities of coverage gap entry and catastrophic coverage entry.

One major concern that could counteract the hypothesized relative increase in branded drugs used due to the larger discounts is what is often referred to as the "patent cliff." Around the same time during the coverage gap closure, several blockbuster drugs that are commonly used by the Medicare population experienced patent expiration and began to see generic entry. For example, patents expired for antipsychotic drugs such as Seroquel in 2012, as well as antidepressants such as Lexapro in 2012 and Cymbalta in 2013 (Appendix Table A3). Generic entry would lower drug spending for patients using a particular medication and may lead to substitution from branded to generic drugs within the same therapeutic category. Indeed, Bonakdar Tehrani and Cunningham (2017) estimate the early effects of filling the coverage gap using 2008–2013 Medical Expenditure Panel Survey data and find that utilization of branded drugs decreased significantly, whereas utilization of generic drugs increased after the implementation of the ACA gap provisions. Given that the coverage gap discounts were substantially larger for branded drugs than for generic drugs during their study period, it is possible that part of their results may be explained by the simultaneous nature of the patent cliff. Without considering the effect of generic entry, the results on both medication use and the composition of use could be biased.[1]

To isolate the effect of the coverage gap closure from that of patent expirations, we use monthly Medicare prescription drug event data to model initial generic entry. Because generic entries affected different therapeutic classes at different times, we control for the time points when a branded drug experienced generic entry within each therapeutic category and run difference-in-differences models by category at the beneficiary-month level. Comparing the estimates with and without these generic entry controls provides some evidence on to what extent the patent cliff may bias the effects of the coverage gap closure.

Overall, we find that filling the coverage gap substantially reduced individuals' OOP spending on branded drugs and increased the number of prescriptions filled for branded drugs. We do not find evidence that the gap closure increased the probabilities of reaching the coverage gap or the catastrophic coverage phase. Consistent with the policy design, those who fell in the gap, were in older age groups, or had coexisting chronic conditions received a larger reduction in the amount they paid for prescription drugs. We show that without accounting for generic entry, the effect of filling the coverage gap on medication use is underestimated for branded drugs and overestimated for generic drugs. The extent to which these impacts vary across therapeutic classes suggests higher substitutability in markets such as respiratory and antihyperlipidemic drugs, and lower substitutability among mental health drugs.

This paper has several contributions to the literature. First, we use more years of administrative data than prior research on the coverage gap closure and use a quasi-experimental approach to evaluate the dynamic impact of the policy. Our results provide important implications for understanding how changes in cost-sharing incentives affect the amount and the composition of medication use, which could be applied to other benefit designs that vary cost-sharing throughout the plan year, often used in private health insurance design. Second, we attempt to distinguish the impact of the coverage gap closure from the impact of generic entry and evaluate to what extent generic entry may affect the policy estimates. Third, we consider all the major therapeutic classes and assess the heterogeneous effects due to the coverage gap closure and generic entry. The focus on individual therapeutic classes allows us to better identify the impact of the policy and understand the heterogeneity in treatment responses.

2 | DATA AND DESCRIPTIVE ANALYSIS

2.1 | Sample construction

We use administrative data on a 5% random sample of U.S. Medicare beneficiaries from 2007 to 2016, which includes four years prior to and six years after the implementation of the ACA gap closure provisions. Specifically, the prescription drug event data contain individual-level information on consumer demographics (such as chronic conditions), Part D enrollment status, as well as each prescription drug filled, with details about the unique drug identifier (the National Drug Code, or NDC), the date of prescription filled, days of medication supplied, the amount that the beneficiary paid out of pocket, and total cost of the claim. We use the brand-generic code in the prescription drug event data to identify whether a drug is branded or generic.

To address potential confounding effects caused by generic entry, we examine categories of drugs by therapeutic class to control for the time points when a branded drug experienced generic entry within each class. Therapeutic classes are defined according to the Uniform System of Classification (USC) level 2 category, which provides groupings of similar pharmaceutical products considered to compete in the same or similar markets (Ridley & Lee, 2020). We assign a drug to the appropriate therapeutic class by linking the drug's NDC number with the corresponding USC number. We then identify top 10 commonly prescribed therapeutic classes and their frequently prescribed branded drugs in the coverage gap in 2010, one year prior to filling the gap. Appendix Tables A2 and A3.1-10 report the complete lists of the identified therapeutic classes and branded drugs included in our analyses, respectively. These 10 therapeutic classes account for 81.3% of total number of prescriptions filled and 65.7% of total drug costs in the coverage gap in 2010 (Table A2). Lastly, we obtain the generic entry date from the *Food and Drug Administration Orange Book* using a drug's active ingredient (nonproprietary name). We parse out the effects of the coverage gap closure across these therapeutic classes after incorporating the impact of generic entry of these drugs.

Our main study outcomes are prescription drug utilization and OOP spending. We define our utilization outcome as the number of monthly (30-day equivalent) supply of prescription medications, which equals the number of days' supply of medication divided by 30 (e.g., 90 days' supply is counted as 3) (Zhang et al., 2009). OOP spending is the dollar amount that a beneficiary paid for prescription drugs without being reimbursed by a third party, including copayments, coinsurance, deductible, or other patient payment amounts. Both outcome measures are separately defined for branded and generic drugs and calculated in beneficiary-year units (for analyses in Section 3.1) and beneficiary-month units (for analyses in Section 3.3).

We create our baseline analysis sample from Medicare Part D enrollees between 2007 and 2016. We focus on individuals aged 65 years and older with a stand-alone prescription drug plan (PDP) for the full year. We restrict our sample to those who remained in the same PDP for the entire year over the course of each calendar year. Because the drug benefit cycle resets each January, people enrolled at different points of the year could have different likelihoods of entering the coverage gap. Those who enrolled in the beginning of the year would face a higher anticipated end-of-year drug price than those who enrolled later in the year (Aron-Dine et al., 2015; Einav et al., 2015; Kaplan & Zhang, 2017). To rule out the possibility that enrollment time may be endogenous, we do not consider individuals who enrolled in the middle of the year. Because end-of-life health needs and spending differ substantially from the overall Medicare population (Einav, Finkelstein, Mullainathan, 2018; Einav, Finkelstein, & Polyakova, 2018b), this sample restriction also excludes beneficiary-years of individuals who died during the year, but those beneficiaries may still contribute to the years before they died. We also exclude beneficiaries who were eligible for Medicare through disability because they were younger than 65, tended to be poorer, and were much more likely to be in worse health than other beneficiaries.

Importantly, the Low-Income Subsidy (LIS), established through Medicare Part D, aids beneficiaries with limited incomes and resources to supplement the premium and cost-sharing (including deductibles and cost-sharing during the coverage gap) associated with the Part D benefit.[2,3] Beneficiaries who receive the LIS face a simple and fixed copayment/coinsurance throughout the year. They are not subject to the initial coverage, coverage gap, or catastrophic coverage payment rules, and thus they do not face the change in cost-sharing at the coverage gap and can serve as a built-in comparison group.[4]

We define the treatment and control groups based on whether one had the LIS. The treatment group consists of those without any month of the LIS for the year, whereas the control group consists of those receiving the LIS for the entire year (i.e., those whose coverage did not vary during the year). Several studies have also used the LIS group as a comparison to identify causal effects of Medicare Part D (e.g., Ding et al., 2021; Joyce et al., 2013; Jung et al., 2017; Kaplan & Zhang, 2014; Kaplan & Zhang, 2017; Li et al., 2012; Zhang et al., 2012). We exclude beneficiaries who switched between the treatment and control groups during our study period (2007–2016). About four percent of the beneficiary-year observations were dropped due to switching between groups. Our analytic sample includes 7,598,597 beneficiary-year observations for 1,012,939 unique beneficiaries.

This study has been approved by the University of Southern California's Institutional Review Boards.

TABLE 1 Sample means by low-income subsidy (LIS) status and time period

| Variable	Pre-period: 2007–2010		Post-period: 2011–2016	
	No LIS	LIS	No LIS	LIS
Age	76.5	77.5	76.2	76.7
Age 65–74 (%)	45.9	41.7	49.1	46.5
Age 75–84 (%)	37.1	36.9	34.5	33.6
Age ≥ 85 (%)	17.0	21.4	16.3	19.9
White (%)	92.3	58.2	90.4	54.0
Black (%)	3.3	16.8	4.4	17.1
Hispanic (%)	2.4	15.1	2.3	16.9
Asian (%)	1.2	7.8	1.4	9.4
Other race/ethnicity (%)	0.8	2.1	1.5	2.6
Female (%)	65.7	72.2	61.6	69.0
No. of 21 high-priority conditions	2.2	2.9	2.1	3.0
Dual eligible (%)	0.0	85.1	0.0	87.9
Benefit phase				
Pre-gap (%)	73.7	48.9	84.0	54.5
In-gap (%)	22.9	32.0	13.0	25.0
Catastrophic (%)	3.5	19.1	3.0	20.5
Part D prescription drug—Annual supply counts				
Total	42.3	56.8	47.0	61.8
Branded	14.1	20.4	7.6	12.8
Generic	28.0	36.0	39.1	48.5
Part D prescription drug—Annual out-of-pocket spending				
Total	817.3	98.4	598.1	76.1
Branded	631.6	63.1	347.7	33.5
Generic	183.2	34.3	247.7	41.8
Part D prescription drug—Total annual spending				
Total	2069.8	3505.1	2482.8	4316.7
Branded	1552.4	2729.2	1803.3	3268.8
Generic	512.9	763.0	673.7	1034.5
Observations	1,747,516	912,972	3,830,514	1,107,595

Note: This table reports the means based on our baseline sample. The major restrictions from the full Medicare sample to the baseline sample are the exclusion of individuals under age 65, not in standalone prescription drug plans, and switching between study (LIS) groups. The sample consists of 7,598,597 beneficiary years that represent 1,012,939 unique beneficiaries.

2.2 | Descriptive statistics

Table 1 provides the descriptive statistics on key variables and outcomes by time period and LIS status. Comparing the demographic characteristics in the pre-policy period (2007–2010), the treatment (non-LIS) and control (LIS) groups were of similar age on average (76.5 and 77.5 years old, respectively). The control group had a slightly larger proportion of individuals aged 85 and over. The vast majority of the treatment group were White (92.3%), whereas the control group included relatively more minorities (e.g., Blacks: 16.8% and Hispanics: 15.1%). Compared to the treatment group, the control group also included more females (72.2% vs. 65.7%) and had slightly more chronic conditions on average (2.9 vs. 2.2).

Regarding the prescription drug outcomes, descriptive results show an increase in average supply counts between pre-policy period (2007–2010) and post-policy period (2011–2016), mainly attributed to a substantial increase in generic drugs used. Prior to 2011, beneficiaries in the treatment (control) group received an average of 42.3 (56.8) 30-day supplies of medications each year, of which about one-third were branded drugs and two-thirds were generic drugs. After 2011, the total and generic supply counts increased, but the branded supply counts decreased for both groups. On the other hand, OOP spending on overall prescription drugs declined substantially for the treatment group (from $817.3 per person per year in the pre-period to $598.1

A. Out-of-Pocket (OOP) Spending
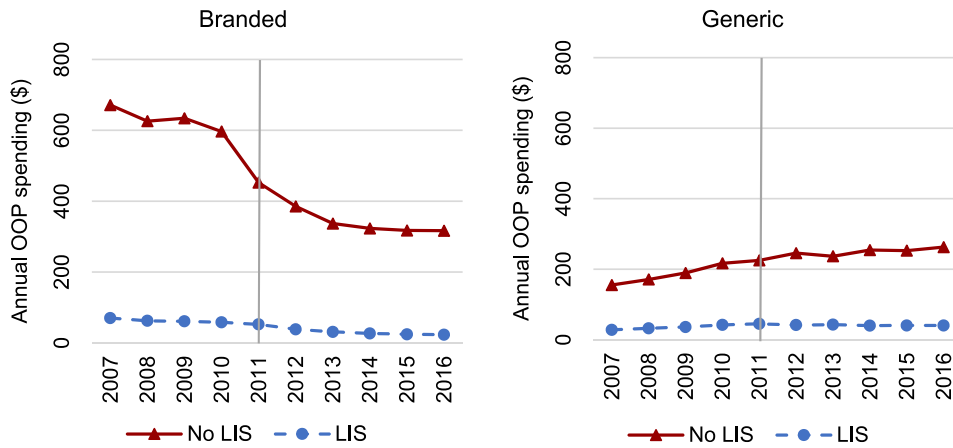
B. Supply Counts
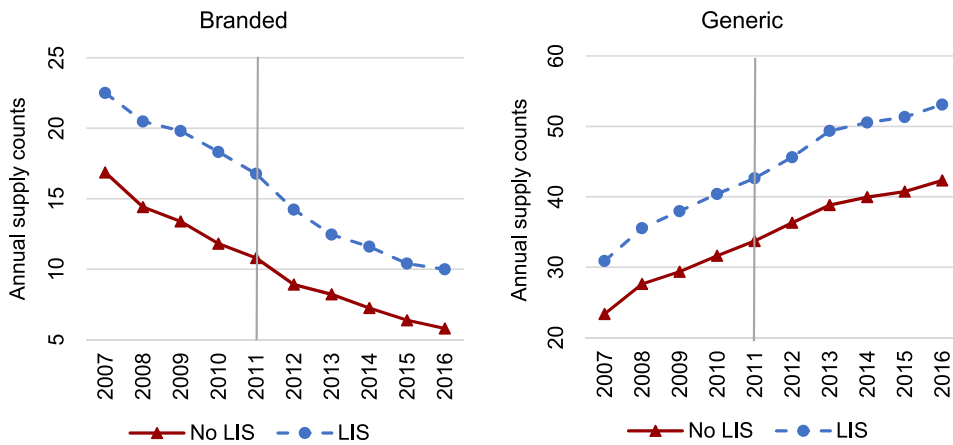
FIGURE 1   Trends in Mean Prescription Drug Outcomes by Low-Income-Subsidy (LIS) Status, 2007–2016. These figures compare unadjusted trends in annual supply counts and OOP spending on prescription drugs, separately for branded and generic drugs, between the treatment (non-LIS) and control (LIS) groups [Colour figure can be viewed at wileyonlinelibrary.com]

in the post-period). In comparison, the control group spent significantly less out of pocket in both periods, and the amount did not change much ($98.4 in the pre-period and $76.1 in the post-period), as expected. Appendix Tables A4 provide more detailed summary statistics by therapeutic class, LIS status, and time period.

Figure 1 shows unadjusted trends in annual supply counts and OOP spending on prescription drugs, separately for the treatment (non-LIS) and control (LIS) groups, and for branded and generic drugs. Prior to 2011, the trends in OOP spending were relatively flat for both groups, but these changed after 2011 when the coverage gap provision went into effect (Panel A). Total OOP spending of the treatment group substantially decreased by 16% (from $811.6 to $678.0) in 2011, whereas OOP spending of the control group remained stable across the treatment years. This change was largely associated with the reduction in OOP spending on branded drugs, which decreased by 24% (from $593.1 to $450.7 in 2011; Panel A). Similarly, branded and generic supply counts were trending in a similar fashion between the two groups prior to 2011, but the group differences in supply counts of branded drugs shrank slightly afterward (Panel B).

3 | EMPIRICAL STRATEGY

3.1 | Event study difference-in-differences approach

We examine the dynamic effects of the gradual phase-in of policy changes using an event study difference-in-differences model. The regression model is as follows:

$$Y_{it} = \beta_0 + \sum_t \beta_t nonLIS_i \cdot Year_t + \delta nonLIS_i + \sum_t \lambda_t Year_t + X'_{it}\gamma + \varepsilon_{it}, \quad (1)$$

where Y_{it} represents the main prescription drug outcomes, supply counts and OOP spending, for individual i in year t. Both outcomes are measured at the beneficiary-year level and separately defined for branded and generic drugs. $nonLIS_i$ is an indicator that equals one if individual i is not a recipient of the LIS; that is, they are subject to the coverage gap and therefore our treatment group. $Year_t$ is a set of year dummies. X_{it} is the vector of covariates controlling for other differences between the treatment and control groups that may affect the outcomes. X_{it} consists of age, age squared, sex, race/ethnicity, dual eligibility status, and a wide range of diagnosed chronic conditions: indicators for 21 high-priority chronic conditions defined by the Centers for Medicare and Medicaid Services (CMS) and six other disabling mental disorders.[5]

The key variables of interest are the non-LIS (treatment group) indicator interacted with the series of year dummies ($nonLIS_i \cdot Year_t$). The coefficients on these interaction terms (the β_t's) measure the effects of the coverage gap closure on the outcomes in each year relative to the reference year 2010, one year prior to the policy implementation, between the treatment and control groups. If there were no other changes that affected the outcomes, the coefficients indicating pre-policy years (2007–2009) will be zero. The coefficients indicating post-policy years (2011–2016) will tell us how the policy effects evolve over time relative to 2010. Because the post-policy period in our analyses covers the initial six years of the policy when the coverage gap discount for branded drugs was larger than that for generic drugs (Appendix Table A1), we expect the effects of the coverage gap closure on branded drugs to be larger. δ controls for time-invariant and unobserved group differences to ensure that identification does not come from level differences between the treatment and control groups. λ_t controls for the year fixed effects. Standard errors are clustered at the individual level to account for serial correlation of the error terms given the structure of the data.

3.2 | The "patent cliff"

A major concern is that the policy period coincided with the expiration of patents for some blockbuster drugs widely used by the Medicare population, which shifted medication use from branded to generic drugs (Aitken et al., 2016). In fact, the makeup of major therapeutic drugs had undergone a transition from predominantly branded to predominantly generic medications over our study period (Appendix Tables A3). Because generic drugs are considered therapeutically equivalent to their original counterparts yet much cheaper,[6] generic entry could lead to an increase in generic share of total prescriptions over time. This is consistent with the pattern shown in Panel B of Figure 1. Given that Bonakdar Tehrani and Cunningham (2017) counterintuitively find that closing the coverage gap led to larger increases in utilization of generic drugs, which saw smaller price decreases than branded drugs, it is possible that they are in part identifying the impact of the patent cliff, rather than the isolating effect of the coverage gap closure.

3.3 | Isolate policy impact from generic entry

We attempt to isolate the impact of the coverage gap closure from the impact of generic entry and evaluate to what extent generic entry may affect the policy estimates. Unlike previous specification at the beneficiary-year level, we perform the analyses at the beneficiary-month level to more accurately track initial generic entries and further examine the behavioral response on medication use by therapeutic class. We rank the top 10 leading therapeutic classes by total days' supply of branded drugs used in the coverage gap in the year prior to the gap closure (Appendix Table A2). We then sort out the most frequently prescribed branded drugs within each therapeutic class and document the information on generic entry (Appendix Tables A3).

We control for the time at which the generic version of each of the identified branded drugs first became available using indicator variables that switch on when the generic entered the market.[7] We calculate the outcome measures in individual-month units and separately estimate the following equation for each of the top 10 therapeutic classes:

$$Y_{imt} = \beta_0 + \beta_1 Post_t \cdot nonLIS_i + \beta_3 nonLIS_i + \sum_d \theta_d Gen_{dmt} \cdot nonLIS_i + \sum_d \rho_d Gen_{dmt} + X'_{it}\gamma + \sum_t \lambda_t Year_t + \delta_m + \varepsilon_{imt}, \quad (2)$$

where Y_{imt} denotes the two prescription drug outcomes of a therapeutic class for individual i in month m and year t, conditional on use of medications in that class. In addition, we also estimate the impact on medication use at the extensive margin with the dependent variable being an indicator for any use of medication in each therapeutic class. $Post_t$ is an indicator equal to one in 2011 or after and zero otherwise. Gen_{dmt} denotes a vector of generic entry indicators which equal one if a common branded drug d in the therapeutic class had generic versions available in month m and year t for the whole month.[8] We include the interaction

terms between generic entry indicators and the LIS status indicator to address that generic entry may affect the treatment and control groups differently. δ_m denotes a vector of calendar month dummies (i.e., January, February, etc.) to adjust for seasonal trends. The model also includes year fixed effects and a set of control variables (X_{it}), same as Equation (1).[9]

4 | RESULTS

4.1 | Event study results

The dynamic effects of the coverage gap closure can be characterized by the coefficients β_t in Equation (1) and are presented graphically in Figure 2. Panel A shows that OOP spending on branded drugs substantially decreased after the coverage gap began to close, with the largest reduction in the first year of the intervention (−$135.8 in 2011). This is consistent with the discount scheme shown in Appendix Table A1. Meanwhile, OOP spending on generic drugs steadily and slightly increased, reflecting an increase in generic drug costs over time.

Panel B shows that total supply counts of prescription drugs increased gradually following the ACA coverage gap provisions, and the effects were more evident in the first two years of policy implementation. Consistent with our expectations, the results on supply counts show a much stronger and positive effect on branded drugs, compared to a small and negative effect on generic drugs. From 2011 to 2013, the effect on supply counts of branded drugs continued to increase and remained fairly stable afterward. The largest increase in supply counts of branded drugs occurred between 2012 and 2013, over a year after the
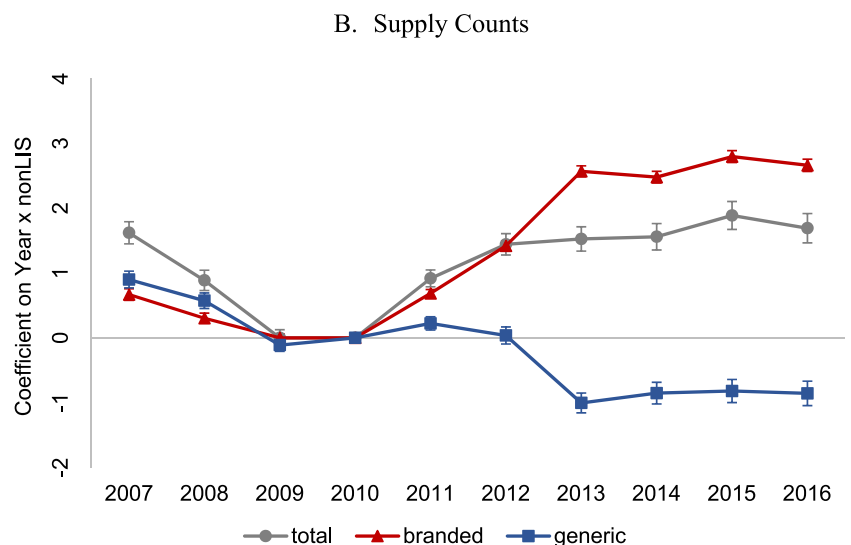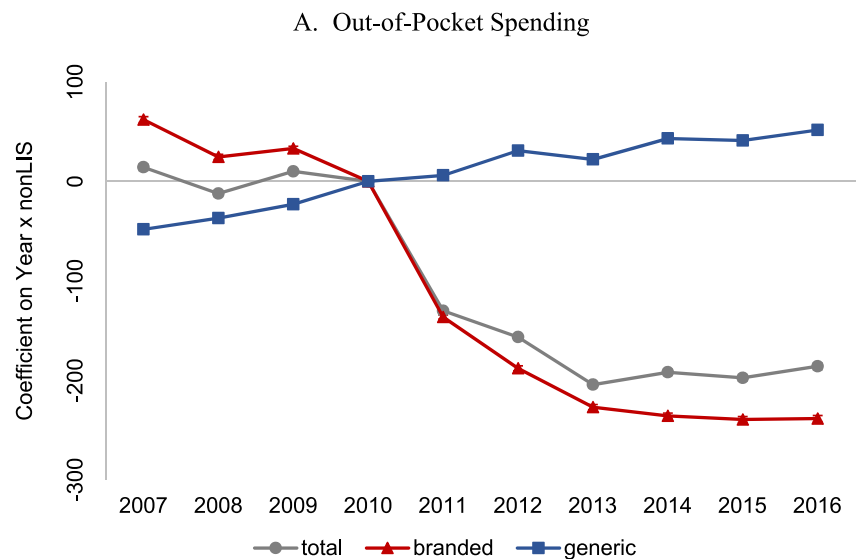
FIGURE 2 Event Study Estimates of the Effect of Coverage Gap Closure. These figures report the coefficients on nonLIS*Year using Equation (1), along with respective 95% confidence bounds (although some are hard to see due to their small sizes, especially for Panel A). The sample includes all aged Medicare beneficiaries who enrolled in a stand-alone Part D plan for the entire year and did not switch between study groups. Covariates include age, age squared, race/ethnicity, gender, dual eligibility status, indicators of chronic conditions, and year fixed effects. The level of observation is per person per year [Colour figure can be viewed at wileyonlinelibrary.com]

largest discount was provided. One possible explanation is that the behavioral response to such complex policy changes may not be realized immediately, suggesting a "learning" effect about the presence of the gap closure by individuals, providers, or pharmacists (Einav et al., 2015).

Our event study results show that the effects in the pre-policy period were relatively minor but cannot completely reject no other changes that affected the outcomes prior to the gap closure, even after controlling for observed differences. While beneficiaries who receive the LIS did not face changes in OOP costs associated with the coverage gap, they could be different from those who did not receive the LIS in unobserved ways.

We explore the sensitivity of the above results to changes in our empirical specification. As shown in Appendix Figures A1-A2, our results continue to hold when we further control for state fixed effects and state and year fixed effects. We also conduct a sensitivity analysis including oral drugs only because the dispensing of drugs which are non-standard packaged or administered as inhaled or injected drugs may have different patterns of use, and these drugs are difficult to measure by monthly supply counts. As shown in Appendix Figures A3, the results are very similar to our main findings.

4.2 | Heterogeneous effects from event study results

The ACA coverage gap provisions contributed to a larger reduction in costs of prescription drugs for certain Part D beneficiaries, such as those who reached the coverage gap or had more chronic conditions, which should result in larger policy effects. To examine the heterogeneity of the effects, we perform a stratified analysis by (1) benefit phase: pre-gap, in-gap, and catastrophic coverage[10]; (2) number of chronic conditions: no or one condition versus two or more chronic conditions; (3) age group: 65–74, 75–84, and greater or equal to 85 years old. We repeat the analysis using Equation (1) for each group to estimate the heterogeneous effects of the coverage gap closure on OOP spending and supply counts.

The estimated effects on OOP spending are consistent with what we expect, as shown in Appendix Figure A4. The reduction of OOP spending on branded drugs were considerably larger among beneficiaries who entered the catastrophic coverage phase, followed by those in the coverage gap and those in the initial coverage phase (Panel A). Beneficiaries with comorbid chronic conditions (Panel B) or in an older age group (Panel C) received a larger discount on branded drugs. In contrast, the effects on OOP spending on generic drugs did not differ much for all these three comparisons.

The estimated effects on supply counts of branded and generic drugs (Appendix Figure A5) show that the coverage gap closure led to a small but statistically significant increase in branded drugs used and nearly no change in generic drugs used for those in the coverage gap (Panel A). On the other hand, it led to a statistically significant decrease in both branded and generic drugs used for those who entered the catastrophic coverage phase. The effects on drug use among beneficiaries in the pre-gap phase were negligible. Among patients with comorbid chronic conditions, the effects on branded drugs used statistically significantly increased after 2011, whereas the effects on generic drugs used significantly decreased across years (Panel B). When stratifying by age group, we find that the increase in branded drugs used was attributed to younger beneficiaries, suggesting that they were more elastic to price changes due to the coverage gap closure.

4.3 | Results with controls for generic entry

Table 2 reports the difference-in-differences estimates (β_1) using Equation (2) that show the effects of the coverage gap closure on the use of prescription drugs for separate therapeutic classes, with controls for generic entry. The results on the extensive margin (Column 1) show that closing the gap increased the likelihood of monthly drug use in all top 10 classes except for ophthalmic drugs, with the magnitude ranging from 0.2 to 1.6 percentage points. The statistically significant positive estimates on the extensive margin provide evidence that new users were more likely to initiate branded drugs in response to the in-gap discount than for existing users to switch to branded drugs. Conditional on use, the coverage gap closure led to a statistically significant increase in total supply counts for all top 10 classes (Column 2). For most therapeutic classes, closing the coverage gap increased supply counts of both branded drugs and generic drugs.[11]

Table 3 shows the effects of the coverage gap closure on monthly OOP spending for separate therapeutic classes, controlling for generic entry. As expected, the coverage gap closure led to significantly lower total OOP spending across these classes (except for ophthalmic drugs; Column 1), which was mainly due to a reduction in OOP spending on branded drugs (Column 2). Converted in annual terms, total OOP spending decreased by $53 for psychotherapeutic, $158 for respiratory, $35 for antihyperlipidemic, $14 for diabetes, $430 for neurological, $32 for vascular, $176 for hemostatic, $108 for gastrointestinal, and $81 for genitourinary therapeutics.

TABLE 2 DID estimates of the effect of coverage gap closure on monthly supply counts by therapeutic class, with controls for generic entry

	Coefficient on nonLIS*Post			
		Intensive margin: Supply counts		
	Extensive margin: Drug use (0/1)	Total	Branded	Generic
Therapeutic class	(1)	(2)	(3)	(4)
Psychotherapeutic	0.010*** (0.001)	0.087*** (0.004)	−0.005 (0.003)	0.091*** (0.004)
Respiratory	0.008*** (0.001)	0.116*** (0.009)	0.093*** (0.009)	0.023*** (0.005)
Antihyperlipidemic	0.006*** (0.001)	0.113*** (0.002)	−0.008** (0.003)	0.121*** (0.003)
Diabetes	0.009*** (0.001)	0.127*** (0.005)	0.028*** (0.004)	0.096*** (0.004)
Neurological/Neuromuscular	0.005*** (0.001)	0.082*** (0.004)	0.050*** (0.004)	0.031*** (0.005)
Vascular	0.004*** (0.001)	0.082*** (0.003)	0.023*** (0.002)	0.059*** (0.003)
Hemostatic	0.009*** (0.001)	0.056*** (0.004)	0.071*** (0.003)	−0.015*** (0.004)
Gastrointestinal	0.016*** (0.001)	0.097*** (0.003)	0.001 (0.003)	0.097*** (0.003)
Genitourinary	0.002*** (0.001)	0.067*** (0.004)	0.037*** (0.004)	0.030*** (0.004)
Ophthalmic	0.001 (0.001)	0.045*** (0.006)	0.009 (0.006)	0.037*** (0.005)

Note: This table reports the coefficients on nonLIS*Post using Equation (2). Column (1): Regressions are estimated as linear probability models with the outcome being an indicator for any use of medication in each therapeutic class (extensive margin). Columns (2)-(4): Outcome is monthly (30-day) supply counts conditional on use of medications in each class (intensive margin). Regressions include generic entry time controls and the interaction terms between generic entry indicators and the LIS status indicator. Covariates include age, age squared, race/ethnicity, gender, dual eligibility status, indicators of chronic conditions, as well as state and year fixed effects. The sample includes all aged Medicare beneficiaries who enrolled in a stand-alone Part D plan for the entire year and did not switch between study groups. The level of observation is per person per month. Robust standard errors clustered at individual level in parentheses.

***$p < 0.01$, **$p < 0.05$.

TABLE 3 DID estimates of the effect of coverage gap closure on monthly out-of-pocket spending by therapeutic class, with controls for generic entry

| | Coefficient on nonLIS*Post | | |
| | Total | Branded | Generic |
Therapeutic class	(1)	(2)	(3)
Psychotherapeutic	−4.434*** (0.138)	−5.218*** (0.137)	0.784*** (0.044)
Respiratory	−13.171*** (0.568)	−13.206*** (0.568)	0.035 (0.079)
Antihyperlipidemic	−2.916*** (0.074)	−3.736*** (0.077)	0.820*** (0.016)
Diabetes	−1.127*** (0.175)	−1.121*** (0.174)	−0.243*** (0.025)
Neurological/Neuromuscular	−35.845*** (0.417)	−38.979*** (0.413)	3.134*** (0.144)
Vascular	−2.640*** (0.074)	−1.917*** (0.067)	−0.724*** (0.034)
Hemostatic	−14.672*** (0.264)	−14.450*** (0.251)	−0.222* (0.095)
Gastrointestinal	−8.980*** (0.174)	−8.657*** (0.173)	−0.323*** (0.061)
Genitourinary	−6.733*** (0.192)	−5.249*** (0.184)	−1.485*** (0.076)
Ophthalmic	8.924*** (0.219)	4.580*** (0.218)	4.344*** (0.074)

Note: This table reports the coefficients on nonLIS*Post using Equation (2). Outcome is monthly OOP spending conditional on use of medications in each therapeutic class. Regressions include generic entry time controls and the interaction terms between generic entry indicators and the LIS status indicator. Covariates include age, age squared, race/ethnicity, gender, dual eligibility status, indicators of chronic conditions, as well as state and year fixed effects. The sample includes all aged Medicare beneficiaries who enrolled in a stand-alone Part D plan for the entire year and did not switch between study groups. The level of observation is per person per month. Robust standard errors clustered at individual level in parentheses.

***$p < 0.01$, *$p < 0.10$.

4.4 | Effects on the probabilities of entering coverage gap and catastrophic coverage phase

As the coverage gap is filled in, forward-looking and rational beneficiaries may increase their drug spending prior to the gap because the expected cost of entering the gap substantially decreases (Ellis, 1986; Jung et al., 2014; Keeler et al., 1977). Therefore, the coverage gap closure could potentially alter the likelihood of being in different phases of the benefit. To address

this, we further estimate the effects of the coverage gap closure on the probabilities of being in initial phase, coverage gap, and catastrophic coverage phase using a difference-in-differences approach. The marginal effects are estimated from a multinomial logit model predicting the end-of-year coverage phase.[12]

Despite the reduction in OOP costs in the gap due to the ACA provision, the probability of being in the initial coverage phase slightly increased by 1.9 percentage points, and the probability of reaching the coverage gap slightly decreased by 1.7 percentage points (Appendix Table A6). The estimated effect on the likelihood of reaching the catastrophic coverage phase is close to zero (Appendix Table A6). Our results suggest that filling the coverage gap did not lead to more new entrants into the coverage gap phase or the catastrophic coverage phase.

5 | THE ROLE OF GENERIC ENTRY ON THE EFFECTS OF COVERAGE GAP CLOSURE

Figure 3 compares the results with and without controlling for generic entry in Equation (2). Without the generic entry controls, the effects of the coverage gap closure on total medication use tend to be upward biased for all the major therapeutic categories considered, besides respiratory drugs. In addition, the policy effects on utilization are underestimated for branded drugs and overestimated for generic drugs for most of these therapeutics, with psychotherapeutic and hemostatic drugs being the only exceptions. Furthermore, the policy effects on OOP spending on generic drugs are unanimously overestimated without controlling for generic entry, yet the results of the comparisons for total and branded OOP spending are mixed. Comparing the coefficients between models with and without generic entry controls using a Hausman test suggests statistically significant differences (*p*-value <0.01), as shown in Appendix Tables A7-A8. These findings are generally consistent with our theoretical predictions (Appendix B) and highlight the importance of accounting for generic entry when evaluating this policy.

Notably, the extent to which generic entry affects the policy estimates varies across therapeutic classes. Theoretically, the extent of response to emerging price differentials depends on the possibility of substitution across drugs and molecules within a class, which can be referred to as the degree of cross-molecular substitutability (Branstetter et al., 2016). Within some therapeutic classes, it is relatively easier to substitute between molecules because tolerability and effectiveness are relatively similar. In such therapeutic markets, physicians would generally consent to switching drugs if it saves patients money. On the other hand, drugs with lower cross-molecular substitutability may include psychotherapeutic drugs and neurologic drugs, where patients may be less likely to switch.

While most of the frequently prescribed branded drugs used to treat mental disorders experienced generic entry during our study period (Appendix Table A3.1), the lower prices available to consumers did not appear to induce them to use more of these drugs or replace branded drugs with generic drugs.[13] Our findings resonate with prior literature, which suggests that mental health drugs theoretically have lower cross-molecular substitutability (Branstetter et al., 2014) and often present more challenges to patients who wish to switch to cheaper drugs for several reasons (Branstetter et al., 2016). These include the fact that the effectiveness of these drugs is highly variable, and patients are more closely matched to a molecule that works for them, the need to titrate the dose of a new drug over several weeks, higher rates of withdrawal side effects, and drug toxicity associated with using more than one drug at the same time (e.g., serotonin syndrome). Thus, providers are often reticent to switch medications without close monitoring. This is not the case for other commonly prescribed therapeutic classes such as antihyperlipidemic drugs, which have similar effectiveness to each other and high tolerability (Aitken et al., 2008). Among drugs with a high level of cross-molecular substitutability (such as respiratory, antihyperlipidemic, gastrointestinal, and genitourinary drugs), our results are consistent with the fact that generic entry could lead to switching from branded to generic drugs and lower drug spending for patients using such medications.

Another factor that may affect the differential policy effects across therapeutic classes is the inclusion of protected classes in Medicare Part D. For these classes, plans are required to cover all or substantially all drugs on the formulary, and previous research has suggested that this gives market power to manufacturers and leads to high prices (Duggan & Scott Morton, 2010; Hwang et al., 2019; Yarbrough, 2020). Since psychotherapeutic drugs and neurologic drugs both include protected classes, the theoretical effect of the policy may be muted. For example, patients may continue to prefer generics due to a maintained price differential. Thus, the protected class theory predicts that psychotherapeutic drugs and neurologic drugs will see a smaller policy impact, while the cross-molecular substitutability theory predicts that these same classes will see a larger policy impact.
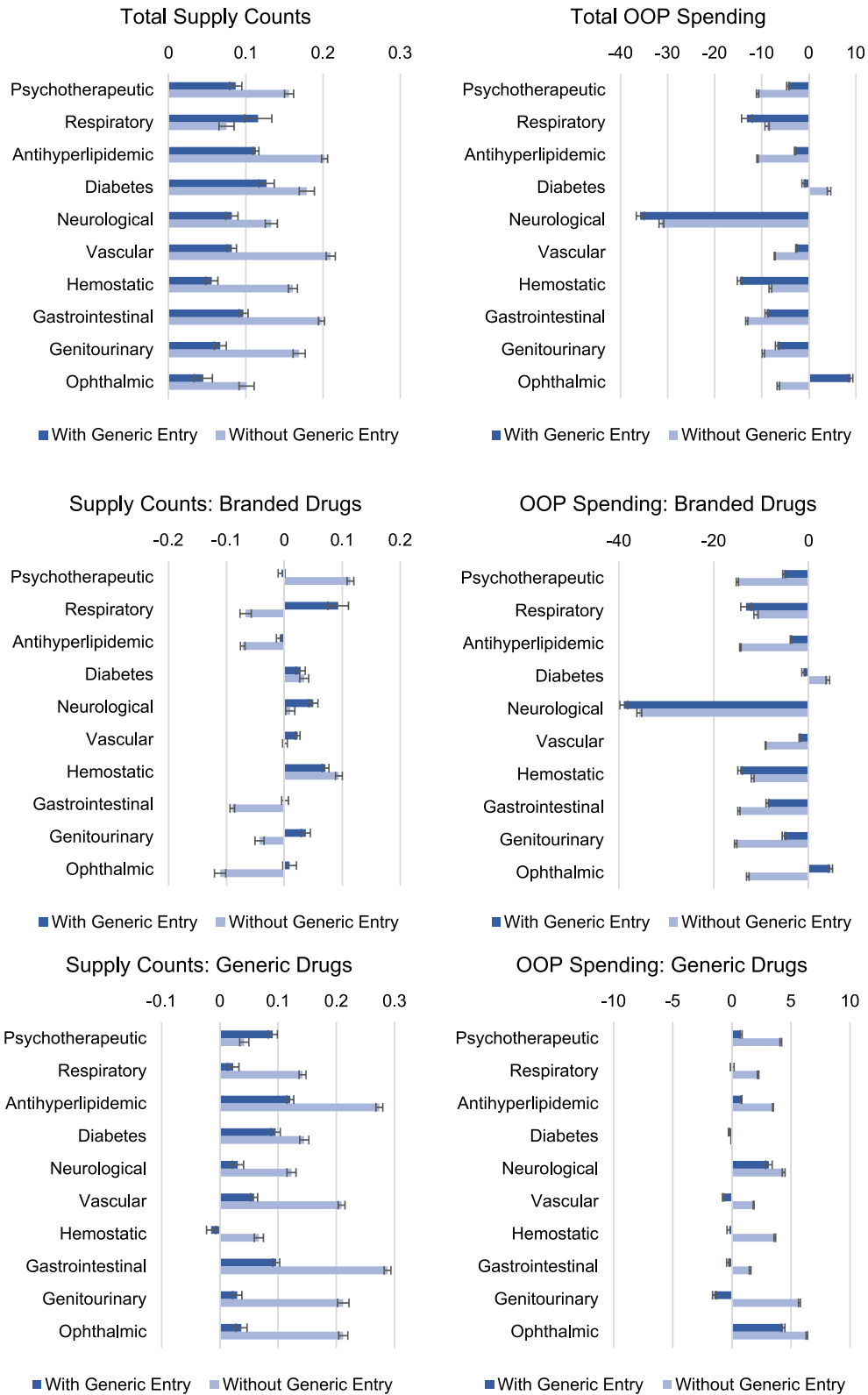
FIGURE 3 DID Estimates of the Effect of Coverage Gap Closure: With versus Without Generic Entry Time Controls. These figures display the coefficients on nonLIS*Post using Equation (2). The level of observation is per person per month. The sample includes all aged Medicare beneficiaries who enrolled in a stand-alone Part D plan for the entire year and did not switch between study groups. The dependent variables are monthly (30-day) supply counts (left) and OOP spending (right) conditional on use of medications in each therapeutic class. Covariates include age, age squared, race/ethnicity, gender, dual eligibility status, indicators of chronic conditions, as well as state and year fixed effects. Details of these estimates are presented in Appendix Tables A7-A8 [Colour figure can be viewed at wileyonlinelibrary.com]

6 | POTENTIAL ISSUES AND MECHANISMS

6.1 | Comparability of Low-Income Subsidy with non-LIS groups

A potential limitation of our analyses is the comparability of the control group. While beneficiaries who received the LIS did not face any changes in OOP costs associated with the coverage gap, they could be different from those who did not receive the LIS in unobserved ways that potentially violate the parallel trends assumption. Visual inspection of the pre-policy trends (Figure 1) and the event study estimates (Figure 2) suggest that there were no major differences in the trajectory of OOP spending and utilization of prescription drugs between groups prior to 2011. We attempt to control for observed differences between the treatment and control groups, as well as other time varying factors such as generic entry controls interacted with group indicators, but we cannot rule out all potential violations to the parallel trend assumption.

6.2 | Potential concern due to patent extension tactics

Generic entry dates may be endogenous to medication use and price because of pay-for-delay or other patent extension tactics (e.g., filing patents for manufacturing processes, evergreening) to preserve monopoly power (Federal Trade Commission, 2010; Hemphill Kraus, 2012). Manufacturers are more likely to engage in these tactics if potential profits are high enough.

We cannot directly estimate how pharmaceutical manufacturers respond to the coverage gap closure, and its impact on profitability of branded drugs is theoretically unclear. It could make branded drugs less profitable if brand manufacturers were charging the profit maximizing price, and now they are forced to offer a 50% discount in the coverage gap. In this case, manufacturers would be less likely to engage in these tactics, and thus generic entry dates may be systematically earlier due to the coverage gap closure, which would further bias our estimates toward an increase in generic use and a decrease in brand use. However, the coverage gap closure could make branded drugs more profitable if it effectively allows brand manufacturers to price discriminate. In addition, generic manufacturers may also forestall generic entry in anticipation of the coverage gap closure and the implied reduction in demand price sensitivity. These manufacturers' responses would introduce an upward bias in our estimates on brand use and a downward bias on generic use.

6.3 | Drug plan selections and offerings

Individuals who anticipate using more medications may be more likely to buy enhanced plans that provide benefits in addition to basic plans. Many enhanced plans offer some additional coverage during the coverage gap for generic drugs, while a few offer additional coverage for selected branded drugs. With the elimination of the coverage gap, these benefits become less valuable so beneficiaries might be less likely to choose them. On the other hand, an additional change in 2011 required enhanced plans to have meaningfully lower monthly OOP costs compared to basic plans offered by the same issuer, potentially making enhanced plans more valuable relative to basic plans.

We recognize that consumers' plan selections and insurers' plan offerings could be important mechanisms to affect medication use. If non-LIS beneficiaries were less likely to enroll in enhanced plans post gap closure, this would attenuate the effects of reduction in drug costs toward zero. However, in 2013, 94% of beneficiaries enrolled in plans that offered no additional coverage in the gap—the exact same percentage as in 2006 (Hoadley et al., 2013).

6.4 | The role of prescribers

For the effects to be seen, physicians' prescribing of drugs should be responsive to the coverage gap closure. There are several mechanisms for this to occur. First, patients could demand lower-cost drugs from their physicians. Second, pharmacists could contact prescribers on behalf of patients who are looking for less expensive medications. Third, physicians could learn over time which drugs are less expensive. Fourth, insurers could require more use of less expensive medications through step therapy or other mechanisms. Therefore, the effects should be viewed as a combined response from all the key players in health care.

7 | CONCLUSION

This paper empirically examines how the closure of Medicare Part D coverage gap affected beneficiaries' medication use and OOP costs. Using the Medicare administrative data from 2007 to 2016, we adopt a quasi-experimental approach with the exogenous change in benefit design to estimate the dynamic effects of filling the coverage gap. To address the issue that the policy period coincided with many patent expirations and increased generic penetration, we examine individual therapeutic classes to better isolate the impact of the coverage gap closure from that of generic entry.

Overall, filling the coverage gap significantly decreased patients' OOP spending, mainly due to a substantial reduction in OOP spending on branded drugs. We provide evidence that the coverage gap closure contributed to a larger reduction in OOP spending and increased use of branded drugs for beneficiaries who fell in the coverage gap or had more chronic conditions. This was in line with the intent of the ACA coverage gap provisions, which was to reduce the financial burden associated with prescription drugs. We also find that the policy increased utilization of branded drugs due to the large discounts on branded drugs during the coverage gap phase in the initial years of the policy. Bonakdar Tehrani and Cunningham (2017) similarly find that the coverage gap closure led to reduced OOP spending, but they only find a significant difference in prescription drug utilization when limiting the sample to those entering the coverage gap, and only for generic drugs. Our results are more consistent with expectations given that the policy mostly affected the price of branded drugs rather than generic drugs in the early treatment years. After further controlling for generic entry, we find that substitution away from generic drugs due to the coverage gap closure was even larger. Other possible differences between our study and theirs include the fact that we use direct Medicare claims data rather than survey data yielding, among other things, a sample that is more than 400 times larger, and the fact that we use a different control group (the LIS group rather than the near-elderly).

We show that without accounting for generic entry, the policy impact on medication use is likely to be underestimated for branded drugs and overestimated for generic drugs. However, the extent to which generic entry affects the policy estimates varies across therapeutic classes because of different levels of cross-molecular substitution and available generic entries. For some therapeutic classes (e.g., psychotherapeutic, vascular, hemostatic, gastrointestinal, genitourinary, ophthalmic, as shown in Figure 3), the estimates on total drugs used from the model with generic entry controls are less than half of those without generic entry controls. These differences in the estimates between models with and without generic entry are economically meaningful given that the policy impact on medication use is modest.

In summary, we view this study as an important step in better understanding changes in the amount and composition of medication use under common benefit designs. We demonstrate that the design of prescription drug benefits that reflects the heterogeneity in treatment response is essential to produce effective utilization outcomes. Current leading proposals include the House of Representatives plan which caps Part D OOP costs to $2000 and lowers the cost of certain branded drugs through negotiation, and the Senate Finance Committee bill, which caps OOP costs to $3100 by eliminating cost-sharing in the catastrophic phase. As bipartisan efforts continue to reform Medicare Part D, it will be important to consider the various impacts of benefit design changes on patient spending and utilization.

CONFLICT OF INTEREST
None for all authors.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the US Centers for Medicare and Medicaid Services. Restrictions apply to the availability of these data, which were used under license for this study.

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ENDNOTES

[1] Appendix B summarizes the expected effects of the coverage gap closure and generic entry on medication use and OOP spending and illustrates how estimating the policy effects without accounting for generic entry would bias the results.

[2] There are two categories of the LIS: full and partial subsidy. An individual is eligible for the full subsidy if she/he (1) is deemed automatically eligible based on qualification for other Federal programs (full Medicaid benefits, Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI), Supplemental Security Income (SSI)) or (2) applies and has family income at or below 135% FPL and resources less than $9,230 (individuals, 2019) or $14,600 (couples, 2019). An individual is eligible for the partial subsidy if she/he applies and has family income below 150% FPL and resources less than $14,390 (individuals, 2019) or $28,720 (couples, 2019).

[3] The full subsidy includes: (1) 100% premium subsidy, (2) elimination of the deductible, (3) fixed copayment ($1.25 for generic, $3.80 for brand for those below 100% FPL; $3.40 for generic, $8.50 for brand for 100%–135% FPL, 2019) up to the OOP threshold, (4) elimination of the coverage gap, (5) elimination of cost-sharing above the OOP threshold, and (6) waiver of late enrollment penalty (LEP). The partial subsidy includes: (1) 25%–75% premium subsidy, (2) reduction to the deductible ($85, 2019), (3) 15% coinsurance up to the OOP threshold, (4) elimination of the coverage gap, (5) fixed copayment above the OOP threshold ($3.40 for generic, $8.50 for brand, 2019), and (6) waiver of LEP.

[4] We consider both full and partial LIS recipients because both were not exposed to the coverage gap closure.

[5] These include acute myocardial infarction, Alzheimer's disease, Alzheimer's disease and related disorders or senile dementia, atrial fibrillation, cataract, chronic kidney disease, chronic obstructive pulmonary disease, heart failure, diabetes, glaucoma, hip/pelvic fracture, ischemic heart disease, depression, osteoporosis, rheumatoid arthritis/osteoarthritis, stroke/transient ischemic attack, prostate cancer, colorectal cancer, breast cancer, lung cancer, endometrial cancer, anxiety, bipolar, depressive disorders, schizophrenia, schizophrenia and other psychotic disorder, ADHD.

[6] Branstetter et al. (2016) show that the average discount factor offered by generic entry is about 38% of the branded price in the quarter of entry, and the average drug price decreased by 20% after generic entry. Strikingly, the incumbent pharmaceutical firm increased branded price by 23% for the molecule where there was entry as the remaining brand consumers have more inelastic demand.

[7] Note that the first generic entrant may have duopoly power on price with the original branded provider initially. Based on FDA regulation, the first entrant is awarded 180 days of exclusivity. Once this exclusivity period ends, any generic producer can enter the market. Thus, the price may subsequently decrease. Branstetter et al. (2016) show significant additional entry (on average 17 subsequent generic entrants) and rapid price declines following the acceleration of generic entry. Here, we only capture the influence of the first entry.

[8] For instance, Seroquel had its first-time generic entry on March 27, 2012, and thus the generic entry indicator for Seroquel equals zero before March 2012 and turns one from April 2012.

[9] The effect of $Post_t$ drops out of the regression because of the inclusion of the year fixed effects.

[10] The benefit phase is defined by the status on the last day of the year: (1) pre-gap: spending less than the initial coverage limit; (2) in-gap: spending between the coverage limit and the catastrophic amount; (3) catastrophic coverage: spending more than the catastrophic amount.

[11] The only few exceptions are no or small negative effects on branded psychotherapeutic and antihyperlipidemic drugs (Column 3) and generic hemostatic drugs (Column 4).

[12] We thank an anonymous Reviewer for suggesting this exercise.

[13] Psychotherapeutic drugs appear to have an opposite pattern when we compare the estimates with generic entry controls to those without generic entry controls. As shown in Figure 3, after controlling for generic entry, we find a decrease in the estimated policy effect on branded drugs and an increase in the estimated policy effect on generic drugs.

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