

The Effect of Public Insurance Design on Pharmaceutical Prices: Evidence from Medicare Part D*

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Abstract

The Affordable Care Act of 2010 closed an intentional coverage gap in the Medicare Part D benefit. Prior to closure, when beneficiaries entered the so-called “donut hole,” they became responsible for up to 100% of drug spending on the margin. The policy change greatly lowered cost-sharing for beneficiaries, in part by requiring drug manufacturers to cover 50% of all branded drug spending in the coverage gap. We study how beneficiaries responded to the insurance expansion and how drug prices evolved accordingly. In line with the motivation of the gap closure, beneficiaries no longer forgo prescriptions when entering the donut hole. Drug manufacturers correspondingly increased prices: Retail prices for branded drugs with greater exposure to the policy change differentially increased by 21%, driven by drugs without generic competition. Back-of-the-envelope calculations suggest that the gap closure represented a \$220 per capita transfer to beneficiaries, with the incidence of the transfer primarily born by the federal government. Drug manufacturers were able to substantially shift incidence through price increases.

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1 Introduction

Prescription drug spending has become an increasingly important component of health care spending in the United States, doubling from 5 percent of total spending in 1980 to more than 10 percent in 2018 (CBO 2022). With the introduction of Medicare Part D in 2006, the federal government has become a major payer of drug spending as the elderly population heavily relies on pharmaceuticals. While accounting for a declining share of prescriptions, brand-name drugs have repeatedly come under scrutiny due to soaring prices, increasing the financial pressure on the government.¹ In addition, beneficiaries frequently report struggling to afford their medication, leading to forgone prescriptions and detrimental knock-on effects on health. While the Part D market is tightly regulated, prices of prescription drugs have been determined by private, profit-maximizing players without direct involvement from the government. As the government seeks to ensure the financial viability of the program, a first-order question is how its design shapes market outcomes.

We study the effect of public insurance design on market outcomes, in particular pharmaceutical prices, in the context of a major redesign of the Part D benefit: the closing of the coverage gap. Medicare Part D was designed with an intentional coverage gap for individuals with high drug spending, the so-called “donut hole.” Once beneficiaries crossed a certain threshold in annual spending, they became responsible to cover up to 100% of prescription drug costs until their out-of-pocket spending qualified them for catastrophic coverage reinsurance. The sudden increase in marginal costs upon entering the gap caused many beneficiaries to forgo filling their prescriptions (Einav et al. 2015). The Affordable Care Act of 2010 stipulated the gradual closure of the donut hole until 2020, making insurers and drug companies responsible for covering up to 75% of drug spending. To finance this expansion, manufacturers of brand-name drugs had to cover 50% of the cost of claims filled in the gap starting 2011.

In this paper, we study how beneficiaries and manufacturers responded to the closing of the coverage gap. We hypothesize that manufacturers of brand-name drugs responded by raising prices because of two concurrent market forces: Beneficiaries increased demand following the insurance expansion, and manufacturers with market power passed on the required discount payments to beneficiaries and insurers downstream. We quantify the endogenous price response and its implications for the allocation of drug spending across payers. To study the beneficiary response, we leverage the institutional feature that roughly one third of beneficiaries receive the federal low-income subsidy and do not experience the coverage

¹The CBO estimates the average price of brand-name prescription drugs, accounting for manufacturer discounts, increased between 2009-2018 from \$149 to \$353 in Medicare Part D. The key drivers were higher launch prices of new drugs and rising prices of drugs already on the market (CBO 2022).

gap. Contrasting their spending behavior, we find that beneficiaries in 2018 are significantly more likely to fill an end-of-year prescription upon entering the gap compared to beneficiaries in 2010. To quantify the effect on pharmaceutical prices, we exploit variation in the exposure to the policy change across drugs and markets, measured as the share of revenue from claims filled in the gap. We find that, on average, high-exposure drugs differentially increased retail prices by up to 21% in years following the gap closure. Back-of-the-envelope calculations suggest that the insurance expansion represented a \$220 per capita transfer to beneficiaries. While the gap closure intended a direct transfer from manufacturers, we find that the expansion was primarily financed by the government as manufacturers could shift the incidence by increasing prices.

Medicare Part D is the federal prescription drug insurance program available to Medicare beneficiaries. Unlike traditional Medicare, Part D benefits are delivered by private insurance sponsors, which are largely funded by government subsidies and monthly premiums paid by their enrollees. Private plans have to follow the government-defined standard benefit or can provide more comprehensive coverage. As a political compromise to minimize financial costs, the government designed the standard benefit with an intentional coverage gap. Beneficiaries pay 25 cents per dollar of drug spending past the deductible until their annual spending reaches the initial coverage limit (\$2,830 in 2010). After that, beneficiaries are in the coverage gap and pay the full cost of each additional prescription. Only when their annual out-of-pocket spending reaches the out-of-pocket threshold (\$4,550 in 2010), they qualify for catastrophic coverage and the government pays the majority of drug spending. Private plans largely follow this provision and any additional coverage in the gap is oftentimes restricted to generic drugs. Notably, not all Part D enrollees are exposed to the different coverage phases. Recipients of the low-income subsidy (LIS) receive premium and cost-sharing assistance and pay only a small, fixed co-payment amount throughout. The remaining premium and out-of-pocket payments are paid for by the government.

The donut hole was a highly controversial aspect of the insurance design. Proponents argued that it kept drug expenditure under control and insurance premiums for Medicare Part D affordable. Opponents argued that it was a financial burden on the elderly with negative ramifications on medication adherence and health (Oliver et al. 2004).² Previous research documented substantial “bunching” around the start of the coverage gap, implying

²The design of Part D is often cited as a driving force behind the increase in prescription drug prices (U.S. Senate Committee on Finance 2018). Insurance plans bear little liability for spending past the initial coverage limit (i.e., spending in the coverage gap or the catastrophic coverage). Therefore, for expensive drugs that induce spending past plan liability, insurers have limited incentive to negotiate prices with drug manufacturers. The Inflation Reduction Act of 2022 will increase plan liability for spending in the catastrophic coverage in 2025.

that consumers forgo prescriptions to avoid entering the donut hole (Einav et al. 2015). This consumption response also affected life-saving medications, leading to substantial effects on mortality (Chandra et al. 2021).

After contentious debate, the Affordable Care Act (ACA) determined the closure of the donut hole and beneficiary cost-sharing in the gap gradually declined from 100% in 2010 to 25% in 2020. To finance this expansion, insurers and drug manufacturers became responsible for the remaining share of spending: Plans had to fully cover the outstanding cost for generic drugs, while manufacturers had to provide a 50% discount on claims for brand-name drugs starting 2011. Notably, the coverage gap only closed for beneficiaries who were previously exposed to it. For LIS beneficiaries, the gap remained open and the government continued to cover LIS spending in the gap. Thus, the manufacturer discount only applies to brand-name drugs filled by non-LIS beneficiaries in the gap. The pharmaceutical industry reluctantly accepted the discount requirement in return for the broader provisions by the ACA (Conti et al. 2020). However, when the Bipartisan Budget Act of 2018 accelerated the closing of the gap for brand-name drugs by increasing the manufacturer discount to 70%, the pharmaceutical industry launched one its biggest, yet unsuccessful, lobbying campaigns to overturn the change (Florko 2019).

Several institutional features warrant the need to study manufacturers' pricing response to the policy change. First, drug manufacturers face consumers who become less price-sensitive over time: LIS beneficiaries are insensitive to drug prices as the government is price-taker, and non-LIS beneficiaries are less exposed to prices as the donut hole closes. Second, prices are the outcome of negotiations between pharmacies and insurers, and manufacturers have great influence over acquisition costs in the branded drug market. The extent to which manufacturers can exercise market power and set prices changes over the drug life cycle, especially once patent protection expires and generic alternatives enter the market.

To study the beneficiary and price responses to the insurance contract redesign, we use detailed micro-level data on prescription drug purchases from a 20% random sample of Medicare beneficiaries from 2006 to 2018. For each purchase, we observe the identity of the drug, the retail price, and how the cost is split between payers. We supplement these data with information from the IBM MarketScan[®] Redbook and various resources from the Food and Drug Administration (FDA) to obtain additional drug-level characteristics such as brand status and patent expiration.

We begin our analysis with the demand response. We extend the descriptive analysis by Einav et al. (2015), who leverage the pre-ACA contract design, and zoom in on spending and purchasing behavior around the start of the coverage gap. Standard economic theory predicts that beneficiaries should bunch at the gap threshold as the marginal cost of prescription

drug consumption jumps discontinuously from 25 cents to 100 cents per dollar of spending. Replicating their results, we find substantial excess mass, or bunching, in the distribution of annual spending of non-LIS beneficiaries in years prior to the policy change. Yet, post-2011, beneficiary spending bunches less dramatically in line with the kink in cost-sharing disappearing. In addition, we find that beneficiaries respond less strongly to the donut hole by forgoing prescriptions. In 2010, beneficiaries were 9.6 percentage points less likely to fill a prescription at the end of the year as they approached the threshold. In contrast, they were only 3.2 percentage points less likely to fill an end-of-year prescription in 2018. We take this as direct evidence that the donut hole previously constrained drug consumption and that its closure led to an increase in demand.

Our main analysis focuses on the manufacturer response, particularly the effect on retail prices of brand-name drugs. We leverage an event study design that compares drugs differentially exposed to the policy change. The idea underlying our exposure metric is that both the demand increase and the discount requirement push manufacturers to raise prices more for drugs with a larger share of revenue from non-LIS spending in the gap. At the same time, revenue from LIS recipients is less relevant for the price response as demand of this consumer group is price-inelastic. For each drug sold in a Part D market in 2010, we measure the share of revenue from claims made by non-LIS beneficiaries in the gap relative to the market-wide revenue excluding spending directly financed by government subsidies. Thus, our exposure metric, which we term *gap share*, exploits variation in policy exposure both across drugs and across markets based on revenue in 2010.

Our baseline specification compares drugs with a *gap share* below versus above the first quartile—the latter generating four times more of their *variable* revenue from non-LIS claims in the gap, on average. We find a statistically significant effect for all post-closure years that is monotonically increasing over time: By 2018, retail prices of high-exposure drugs are 21% higher on average compared to low-exposure drugs. The trend and magnitude of the effect size is robust towards various alternative regression specifications. Notably, in the first years after the policy change, the effect is driven by drugs without generic competition and drugs that remain patent-protected beyond our sample period.

In the last section, we analyze the distributional implications of the gap closure. We provide model-free evidence on how spending was re-allocated between payers—that is, beneficiaries, government, insurers, and manufacturers—and contrast the mechanical effect of the benefit redesign with the effect of the price response of manufacturers. Our back-of-the-envelope calculations are in the style of a Laspeyres or Paasche price index: Holding prescription drug consumption fixed, either at the 2010 or 2018 level, we let beneficiaries progress through the standard benefit design before and after the gap closure, as well as

with and without endogenously adjusted prices. Overall, the policy change constitutes a \$180-220 per capita transfer to beneficiaries, on average. With prices fixed, this transfer would be primarily financed by drug manufacturers. However, allowing prices to respond, the incidence almost entirely shifts onto the government due to the spillover on LIS beneficiaries. While manufacturers have to provide discounts for non-LIS claims in the gap, they secure additional revenue from government-financed LIS spending by increasing prices.

Our analysis provides novel evidence on the equilibrium effect of the closure of the coverage gap and its distributional implications. Several caveats of our empirical approach need to be pointed out. First, our analysis of the manufacturer response is limited to drugs sold in Part D in 2010 and does not directly extend to launch prices of novel drugs. Second, while the gap discount operates in parallel to other price concessions that manufacturers directly pay to insurers, we cannot speak to the effects of the gap closure on post-sale rebates. Lastly, we do not explicitly model and account for the consumption response when estimating the distributional incidence of the gap closure. Instead, we provide an upper bound by fixing consumption at the 2010 level, and a lower bound by fixing it at the 2018 level.

1.1 Related literature

Our paper contributes to a large literature on Medicare Part D and the coverage gap. Leveraging the pre-ACA variation in cost-sharing, prior work has studied the demand response to the nonlinear price schedule (Einav et al. 2015; Kaplan and Zhang 2014; Kaplan and Zhang 2017; Abaluck et al. 2018; Dalton et al. 2020), its effect on insurance design (Einav et al. 2018), and the impact of cost-sharing on health outcomes (Li et al. 2012; Zhang et al. 2013; Chandra et al. 2021). These studies are the foundation of our analysis of the beneficiary response, which we extend to years after the gap closure. Several papers in the medical literature have examined the closing of the coverage gap, in particular the effect on prices and consumption of distinct, high-cost drugs (Dusetzina and Keating 2016; Olszewski et al. 2017; Erath and Dusetzina 2020; Gokhale et al. 2020). In line with our results, these papers conclude that affordability remains a concern due to rising retail prices. Complementary to our paper, Park and Look (2022) find that, based on survey data, annual out-of-pocket spending significantly decreased for non-LIS beneficiaries relative to LIS recipients following the gap closure. Beyond the coverage gap, our paper relates to a small literature that studies market distortions arising from the LIS subsidy (Decarolis 2015; Starc and Swanson 2021) and its optimal design to mitigate those (Decarolis et al. 2020). In our setting, the existence of LIS beneficiaries allows manufacturers to shift the incidence to the government by raising prices.

Lastly, our paper also relates to the literature on the equilibrium effects of insurance de-

sign (Morton 1997; Duggan and Scott Morton 2006; McWilliams et al. 2011; Blume-Kohout and Sood 2013; Yurukoglu et al. 2017). Duggan and Scott Morton (2010, 2011) document that the introduction of Medicare Part D and the use of drug formularies increased competition and reduced prices of brand-name drugs. We study a policy change that closed the controversial coverage gap five years after the program’s inception. The insurance expansion made drug manufacturers directly responsible for covering a large share of beneficiaries’ drug spending, leading to higher retail price and partly negating the intended goal of lowering out-of-pocket costs for consumers.

The rest of the paper proceeds as follows. Section 2 details the design of Medicare Part D and the gap closure policy. Section 3 presents our data and analysis sample. Section 4 discusses the beneficiary response to the policy change. Section 5 presents the manufacturer response. Section 6 provides a distributional analysis of the closing of the coverage gap. The last section concludes.

2 Setting

2.1 Medicare Part D

Medicare Part D, the voluntary federal prescription drug insurance available to Medicare beneficiaries, was established under the Medicare Modernization Act of 2003. Since its inception in 2006, Part D has grown in popularity and in 2018, the last year of our sample, 72% of Medicare beneficiaries were enrolled nationwide.

Generally, Part D benefits are provided by private insurance sponsors, either as stand-alone prescription drug plans (PDPs) to supplement traditional Medicare or as Medicare Advantage prescription drug plans (MA-PDs) which includes drug coverage and other Medicare-covered benefits. While MA-PD enrollment has dominated in recent years, 58% of Part D beneficiaries were enrolled in a stand-alone plan in 2018. Importantly, PDPs and the prescription drug component of MA-PDs are subject to the same regulatory framework upheld by the Centers for Medicare and Medicaid Services (CMS).

In our analysis, we abstract away from the added complexity of providing both medical and prescription drug coverage and focus on beneficiaries enrolled in PDPs.³ The average beneficiary in 2018 could choose from 23 PDPs, offered in their geographic market, and enroll at an average monthly premium of \$43. Across the 34 PDP markets, sponsors offered a total

³Starc and Town (2020) study the differences in insurance design between both plan types and find that MA-PDs internalize the medical care offsets from more generous prescription drug coverage. Important for our setting is their finding that retail prices are not systematically different between plans for a given drug.

of 782 stand-alone plans.⁴ However, enrollment is concentrated, with three plan sponsors covering 67% of all PDP enrollees in 2018 (KFF 2017, 2018, 2023).

About one in three enrollees qualifies for the Part D low-income subsidy (LIS) and receives premium and cost-sharing assistance from the federal government. LIS beneficiaries include recipients of Supplemental Security Income and individuals dual eligible for Medicare and Medicaid, who qualify automatically and receive the full subsidy level. LIS recipients can select any plan offered in their area, but may be required to pay a portion of their plan’s monthly premium if benefits exceed the standard Part D benefit package.

2.2 Standard benefit design

With the introduction of Part D, CMS established a standard benefit design that serves as a minimum requirement for the coverage provided by commercial plans. The standard design has four coverage phases: (i) deductible, (ii) initial coverage, (iii) coverage gap, and (iv) catastrophic coverage. Beneficiaries progress through these phases as they accumulate drug spending over the course of a year. Figure 1 illustrates the standard design in 2010 as a function of total drug spending and total out-of-pocket spending. After paying the deductible amount, beneficiaries enter initial coverage and pay 25% of each dollar spent, with the remainder covered by the insurance plan. As annual spending crosses the initial coverage limit, beneficiaries enter the coverage gap and become responsible (again) for 100% of drug costs. This insurance gap lasts until beneficiaries reach the out-of-pocket threshold, after which they enter catastrophic coverage. In this last phase, 80% of spending is covered by the federal government and approximately 15% is paid by the plan.⁵ Commercial plans must provide benefits that are either actuarially equivalent to the standard design or more generous, featuring a lower deductible or lower cost-sharing in the initial coverage or gap phase.

Notably, LIS recipients are not exposed to the different coverage phases. Instead, they pay little to no cost-sharing across the entire benefit schedule as out-of-pocket costs are covered by the federal government.⁶ Thus, the low-income subsidy creates two consumer segments in the Part D market: non-LIS beneficiaries, who experience a sharp increase in cost-sharing as they enter the coverage gap, and LIS beneficiaries, whose spending in the

⁴A PDP typically operates in one of 34 service areas and is open for enrollment to all Medicare-eligible beneficiaries who reside in that market. A plan service area spans a single state or a group of small adjacent states.

⁵Key benefit parameters, including the deductible amount, initial coverage limit, and out-of-pocket threshold, are updated annually based on the percentage increase in average spending for Part D drugs.

⁶In 2010, beneficiaries receiving the full LIS subsidy paid no deductible, at most \$2.50 for generic drugs and \$6.30 for brand-name drugs. Partial subsidy recipients had a \$63 deductible and a 15% coinsurance rate up to the out-of-pocket threshold.

gap is almost entirely covered by the government.

2.3 Gap closing and manufacturer discount program

The Affordable Care Act (ACA) of 2010 stipulated the gradual closing of the coverage gap in the standard benefit design. Panel (A) in Figure 2 illustrates the standard design for 2011. Within one year, the effective coinsurance rate for non-LIS beneficiaries in the gap dropped from 100% to almost 50%. To finance this expansion, manufacturers of brand-name drugs became responsible for covering 50% of branded drug spending in the gap. Notably, the ACA retained the original benefit design for LIS recipients, with no liability for plans or manufacturers in the coverage gap. Instead, costs arising in the gap remained to be borne almost entirely by the federal government.

Table 1 details how cost-sharing in the gap evolved for non-LIS beneficiaries from 2010 to 2020. For generic drugs, the coinsurance rate decreased by 7 percentage points each year. This decline was offset by a one-to-one increase in the share paid by insurance plans.⁷ For brand-name drugs, the reform demanded an immediate drop in patient cost-sharing from 100% to 50% in 2011, and an additional, slower decline in subsequent years.⁸ The remaining share was primarily levied on drug manufacturers: Starting 2011, manufacturers had to cover 50% of branded drug spending by non-LIS beneficiaries in the coverage gap. Following the Bipartisan Budget Act of 2018, this share further increased to 70% in 2019, reducing plans' liability to 5%. To facilitate beneficiary progression from the coverage gap to the catastrophic phase, manufacturer discounts are treated as though they were out-of-pocket spending.

As part of the reform, CMS created the *Medicare Coverage Gap Discount Program*, which commits manufacturers to providing the price discount in the coverage gap. The discount requirement applies to all drugs approved under a New Drug Application (NDA) or a Biologics License Application (BLA)—broadly, all drugs with (former) patent protection or marketing exclusivity that are sold under a proprietary trademark-protected name.

To enforce participation, a manufacturer's drugs may only be covered by Part D if they sign the agreement annually. By participating, manufacturers agree to pay 50% of the retail price of claims filled by non-LIS beneficiaries in the gap.⁹ In practice, insurance plans pay

⁷The category of generic drugs includes authorized generic drugs, biosimilars, and compounded drugs.

⁸Already in 2010, non-LIS beneficiaries received \$200 discount when reaching the coverage gap.

⁹The retail price is negotiated by the pharmacy and insurer, and comprises the ingredient cost and dispensing fee. Only the ingredient cost is subject to the manufacturer discount requirement. For claims that "straddle" the coverage gap and another coverage phase, the discount only applies to the portion of the negotiated price that falls at or above the initial coverage limit and below the annual out-of-pocket threshold. If a Part D plan offers coverage in the gap, the discount applies to the remaining cost after supplemental coverage has been applied. If the coverage completely eliminates the gap, no discount is available.

the manufacturer discount upfront at the point-of-sale and report these payments to CMS together with their claims records. CMS coordinates the collection of discount payments and sends out invoices to manufacturers which directly reimburse the plans. Importantly, the discount program runs in parallel to other agreements between insurers and manufacturers, such as price concessions via post-sale rebates (CMS 2010).

2.4 Pharmaceutical pricing in Part D

At the core of pharmaceutical pricing in Part D is the vertical relationship between drug manufacturers, retail pharmacies, insurers, and beneficiaries. Throughout our study period, the government was price-taker and did not interfere with price negotiations.¹⁰ Thus, next to policy exposure, we expect a manufacturer’s pricing response to depend on its level of market power, in particular whether a brand-name drug faces generic competition.

Drug supply chain. Figure 3 shows a simplified version of the drug supply chain. At the top, manufacturers set a list price for each drug. Wholesalers, which are price-takers in the branded-drug market, purchase drugs at list price minus a negotiated discount, and pass on a similar price to pharmacies downstream. Thus, manufacturers have great influence over acquisition costs for pharmacies (Sood et al. 2017; Seeley 2022). Final retail prices are negotiated by pharmacies and insurers.

Patent protection and generic competition. The extent to which a manufacturer enjoys market power depends on the stage of the drug life cycle. During the period of patent protection or marketing exclusivity, the manufacturer enjoys market power and only faces competition from other drugs in the same therapeutic class (Perloff et al. 2006). As both terms expire, generic alternatives enter the market, leading to significant price drops at the molecule level. However, empirical evidence suggests that the price of the brand-name version changes little, and may even rise, after generic entry (Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1997; Frank et al. 2021). This phenomenon can arise in a segmented market with both price-elastic and inelastic consumers (Frank and Salkever 1992). As price-sensitive consumers switch to the generic alternative, the residual demand curve becomes steeper, allowing for a higher price for the branded drug. Both features are present in our setting: Starting 2011, a series of top-selling drugs, such as the cholesterol lowering Lipitor, went off-patent and saw generic entry (DeRuiter and Holston 2012). In addition, the consumer population is highly segmented as LIS beneficiaries face little out-of-

¹⁰Following the passage of the Inflation Reduction Act in 2022, the federal government selected the first ten drugs covered under Part D for price negotiations, which will be effective 2026.

pocket costs.

Insurers, drug formularies, and rebates. Insurers employ two mechanisms to constrain retail prices of brand-name drugs. First, they selectively contract with pharmacies forming so-called preferred pharmacy networks. Second, they use drug formularies which restrict coverage to a selected list of drugs and place them on different cost-sharing tiers.¹¹ Coverage and tier placement of a drug depend on the negotiated retail price and post-sale rebate that the manufacturer directly pays the insurer (or the third-party administrator acting on behalf of the insurer, so-called pharmacy benefit managers).¹²

Previous research documented that both mechanisms can exert significant price pressure and steer consumers to lower-cost drugs.¹³ However, the rebate system has been criticized for undermining insurers' incentives to constrain spending on brand-name drugs. While insurers are increasingly successful at negotiating rebates, these price concessions are rarely passed on to consumers of high-rebate drugs. Instead, rebates are re-channeled to reduce plan premiums and, potentially, to increase profits (CMS 2017b). Consumers' out-of-pocket costs are often directly tied to the point-of-sale price, which does not reflect rebate payments (Kakani et al. 2020). MedPAC (2020) argued that the coverage gap reform may have exacerbated this problem: Insurers may prefer to cover the branded version over the generic alternative, as they pay only 5% of branded spending in the gap and receive post-sale rebates. Manufacturers may prefer higher retail prices (and rebates), passing on the gap discount to non-LIS beneficiaries and moving them faster into the catastrophic phase where prices are no

¹¹In Part D, two statutes govern the design of formularies: First, plans must cover at least two chemically distinct drugs from each of about 150 drug classes. In addition, each plan must cover all drugs belonging to the protected classes of immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. The reference guidelines for the drug classification system used by Part D plans is designed by the United States Pharmacopeia (USP). Second, the average coinsurance rate provided in the initial coverage phase may not exceed 25%. This requirement does not restrict tier-specific cost-sharing to 25%. Instead, CMS defines the maximum allowable copay or coinsurance rate for each tier. For instance, in 2014, thresholds for the initial coverage phase were \$45 or 25% for drugs on the preferred brand tier, and \$95 or 50% for drugs on the non-preferred brand tier. See regulatory details in the Code of Federal Regulations, 42 CFR Part 423. Since the inception of Part D, there has been a trend toward using more cost-sharing tiers, with the majority of plans in 2014 using a five-tier benefit design (KFF 2013).

¹²The Anti-Kickback Statute prohibits the use of manufacturer price concessions directly advertised to beneficiaries, such as copay coupons, in government health insurance programs.

¹³Starc and Swanson (2021) find that plans with more restrictive pharmacy networks pay lower retail prices, but that LIS beneficiaries undermine potential cost-savings as they are not exposed to the variation in out-of-pocket prices across preferred versus non-preferred pharmacies. Duggan and Scott Morton (2010, 2011) show that the inception of Part D significantly slowed down the growth in prescription drug spending, mainly due to the price pressure created by formulary competition and tiered cost-sharing. Recently, Hwang et al. (2019) show that drugs in protected classes that face no formulary competition saw substantial price growth over the past decade. Olssen and Demirel (n.d.) estimate post-sale rebates for two branded statins, Lipitor and Crestor, in Part D in 2010 and illustrate their effect on tier placement and consumer spending.

longer discounted. These incentives may have contributed to the stark increase in spending for prescriptions filled in the catastrophic phase, from less than 18% in 2010 to 42% in 2018, compromising the financial viability of the insurance program (KFF 2023).

As data on post-sale rebates is confidential, little is known about the levels and trends of these price concessions. Appendix B summarizes the existing empirical evidence on manufacturer rebates and discusses why these findings are not applicable to our setting. Overall, it is difficult to assess how the coverage gap closure affected incentives to rebate drug prices: On the one hand, manufacturers have to provide an additional discount in the coverage gap and may prefer to reduce other price concessions. On the other hand, insurers may demand higher rebates as they have to cover at least a small portion of gap spending. Generally, we expect rebates to be more relevant for branded drugs with generic alternatives, for off-patent drugs, and for drugs facing more competition in the same therapeutic group. We explicitly account for these features when studying manufacturers' pricing response to the gap closure.

2.5 Part D financing

Medicare Part D is financed by a combination of general revenues (71% in 2018), beneficiary premiums (17%), and state contributions (12%) (Board of Trustees 2019). Plan premiums are determined by a competitive bidding process: Each year, Part D sponsors submit a standardized bid that reflects total plan costs and accounts for all direct and indirect remuneration, such as manufacturer rebates, that decrease the costs incurred by the sponsor.¹⁴ CMS calculates the national average premium as 25.5% of the national average bid amount adjusted for reinsurance. The individual plan premium is the national average premium plus the difference between the plan bid and the national average bid. Starting 2011, higher-income beneficiaries had to pay a larger share of standard Part D costs, ranging from 35% to 85%, depending on income.

Thus, each plan receives monthly risk-adjusted direct subsidies, prospective reinsurance payments, and prospective low-income cost-sharing subsidies from Medicare, as well as premiums from beneficiaries and premium subsidies from Medicare on behalf of low-income beneficiaries. At the end of the year, the prospective reinsurance and low-income cost-sharing subsidy payments are reconciled to match the plan's actual experience. During this process, if actual experience differs from the plan's bid beyond specified risk corridors, Medicare shares in the plan's gain or loss. In 2018, Part D plans received, on average per enrollee, \$301 in direct subsidy, \$923 in reinsurance, and \$2,219 per LIS beneficiary.

¹⁴Manufacturer discounts received as part of the *Medicare Coverage Gap Discount Program* are not considered direct or indirect remuneration because they do not decrease the drug costs incurred by the sponsor. Therefore, they do not enter the bid calculation (CMS 2017).

3 Data

This section describes the construction of our sample of Part D beneficiaries and the implementation of the gap closure by Part D plans. Our analysis of the beneficiary response in Section 4 directly draws on this sample. For the analysis of the manufacturer response, we construct a derivative sample of brand-name prescription drugs described in Section 5.

3.1 Sample of Part D beneficiaries

Our main data source is a 20 percent random sample of the population enrolled in Medicare from 2006 through 2018. For each beneficiary enrolled in Part D, we observe basic demographic information, as well as detailed, claim-level data on prescription drugs purchases.

Our sample comprises all beneficiaries enrolled in a Part D standalone prescription drug plan (PDP). We measure a beneficiary’s plan enrollment and LIS status in December of a given year, and make no restrictions based on age or basis of eligibility.¹⁵ For each beneficiary, we observe all prescription drug purchases covered by the insurance plan. For each claim, we observe the 11-digit National Drug Code (NDC), the retail price of the drug, as well as the amount paid out-of-pocket, the amount covered by the plan, and the amount reimbursed through LIS.¹⁶ Starting in 2012, we also observe the amount of the manufacturer discount for claims filled by non-LIS beneficiaries in the coverage gap. We combine these claims data with NDC-level information from the IBM MarketScan[®] Redbook, which allows us to categorize prescription drugs into brand-name versus generic.¹⁷ More details about the sample construction can be found in Appendix A.

The final sample covers about 8.2 million beneficiaries and 48 million beneficiary-years, with close to 1.9 billion prescription drug claims for more than 74k unique NDCs. Table 2 presents basic demographics for our sample. In 2010, beneficiaries were 69 years old on average, 61% were female, and 73% were Medicare-eligible based on the old-age threshold of 65. Half of beneficiaries received cost-sharing assistance through LIS and 41% were dual-eligible for Medicare and Medicaid. Among non-LIS, 23% of beneficiaries entered the coverage gap at some point in 2010. Between 2006-2018, the total number of beneficiaries in our sample increases by almost 30%, while the share receiving LIS decreases from 50 to 36%. In line with the patent cliff in 2011 and 2012, the share of non-LIS beneficiaries entering the coverage

¹⁵We exclude beneficiaries enrolled in Medicare Advantage prescription drug plans. In addition, we drop small geographic markets of the US territories due to small sample size.

¹⁶The NDC code describes the manufacturer or drug labeler, the product, and the packaging of the product.

¹⁷IBM MarketScan[®] is a health analytics company that provides life science research databases. We successfully match 94.9% of NDCs in Part D to the Redbook, or 99.9% when weighted by Part D spending.

gap decreases slightly over time. However, in 2018, still 16% of non-LIS beneficiaries entered the coverage gap at some point in the year.

Table 3 shows trends in average plan enrollment, separately for three beneficiary groups: (a) non-LIS who consume before the coverage gap, (b) non-LIS who enter the gap, and (c) LIS who are not exposed to the different coverage phases. We report the average monthly premium paid by beneficiaries in the respective group, the average deductible and initial coverage amounts, and the percent of beneficiaries with additional gap coverage for brand-name or generic drugs.¹⁸ On average, non-LIS who enter the gap enroll in more generous plans compared to the other groups. They pay a higher monthly premium, face a lower deductible and prefer plans with additional gap coverage. LIS recipients tend to enroll in less generous plans and pay a premium close to zero. Consistently across groups, premiums paid by beneficiaries either stagnate or slightly decrease over time, while the average deductible amounts increase. This trend could reflect a change in the characteristics of plans offered in the market or a compositional change of beneficiaries in Part D. Notably, all beneficiary groups face the same initial coverage limit which corresponds to the level in the standard benefit plan. Thus, there is essentially no variation across plans in the spending threshold that marks the start of the coverage gap.

3.2 Implementation of gap closure

As most Part D plans deviate from the standard benefit design, we assess empirically the extent to which PDPs followed the statutory changes in the plan design and how cost-sharing for non-LIS beneficiaries in the gap evolved.

Separately for brand-name and generic drugs, Figure 4 illustrates how spending in the coverage gap is divided up between beneficiaries, plans, and manufacturers, and how these shares evolved over time. We construct these empirical cost-sharing rates for each non-LIS beneficiary who entered the gap in a given year, and plot the average across beneficiaries.¹⁹ Overall, PDPs closely tracked the proposed policy change and provided cost-sharing rates similar to the standard plan, especially for brand-name drugs: In 2010, the average non-LIS beneficiary paid 92% of brand-name spending out-of-pocket. This percentage dropped to 48% in 2011. In subsequent years, any additional gap cost-sharing that PDPs may provide seems

¹⁸All dollar amounts are inflation-adjusted. We adapt CMS’ approach to update the threshold amounts of the standard benefit plan and use the September Consumer Price Index for All Urban Consumers (CPI-U; for all items; not seasonally adjusted). We use September 2010 as reference period.

¹⁹For this exercise, we restrict our sample to non-LIS beneficiaries who remain in the same plan and hold the same LIS status throughout the year. We exclusively use claims that start and end in the coverage phase (i.e., we drop “straddle” claims) and exclude beneficiaries with spending in the bottom and top percentile of the gap spending distribution of a given year.

ineffective.²⁰ Overall, plans tend to provide more generous coverage for generic drugs—beneficiaries paid 84% out of pocket in 2010—but the additional coverage fades out and converges to the standard design.

This exercise provides an intuitive summary of the implementation of the policy change but abstracts away from other plan features that may have changed following the closing of the coverage gap. For example, we do not account for potential changes in the design of drug formularies (e.g., changes in the identity of drugs covered or in the tier placement) or changes in the types of drugs consumed by beneficiaries in the gap.²¹ We leave the analysis of an insurer response to future work.

4 Beneficiary response

In this section, we study how the closure of the coverage gap affected beneficiaries’ spending behavior. This analysis extends the descriptive evidence in Einav et al. (2015), who document that the increase in cost-sharing at the start of the donut hole causes consumers to postpone or forgo drug consumption. We investigate whether the policy change was successful at mitigating this problem.

4.1 Trends in average drug spending

First, we summarize trends in average drug spending in Table 4. Again, we separately look at the three groups of (a) non-LIS who consume before the coverage gap, (b) non-LIS who enter the gap, and (c) LIS who are not exposed to the different coverage phases. For each group, we report the average annual amount of drug spending, out-of-pocket spending, and purchased days’ supply, as well as the average percentage that is accounted for by brand-name drugs.²²

Consistently across groups, beneficiaries consume more drugs overall over time, but purchase fewer brand-name drugs. For example, in 2006, 52% of annual days’ supply for the average non-LIS who entered the gap came from branded drugs. This share dropped to 19% in 2018. Yet, we find diverging trends in drug spending across the groups: For the average non-LIS before the gap, annual spending decreased from \$1,065 in 2006 to \$636 in 2018,

²⁰For example, in 2014, more than 20% of non-LIS beneficiaries who entered the gap were enrolled in a PDP with some additional gap coverage for brand-name drugs (see Table 3). However, we find that these beneficiaries paid 45% of drug spending out-of-pocket, on average, which is close to the 47.5% cost-sharing rate in the standard plan design.

²¹For instance, Bignon et al. (2023) show that the number of cost-sharing tiers for generic drugs in Part D plans substantially increased between 2013-2017. However, the authors do not link this phenomenon to the closing of the coverage gap.

²²Again, all dollar amounts are inflation-adjusted.

attributable to a decrease in spending on brand-name drugs from 75% to 37%. On the contrary, for the average non-LIS who enters the gap, annual spending more than doubled, from \$4,233 in 2006 to \$10,288 in 2018, and the share of spending from branded drugs remained consistently above 80%. Thus, the increase in spending is driven by rising prices of new and existing brand-name drugs. Notably, beneficiaries' out-of-pocket spending remained fairly constant over time.²³

In line with the dramatic rise in annual spending, non-LIS beneficiaries who enter the gap do so earlier in a given year and are more likely to move on to the catastrophic phase. In 2006, 11% of non-LIS beneficiaries in the gap eventually entered the catastrophic phase. In 2018, this share increased to 25%.

4.2 Bunching at the kink

Next, we zoom in on beneficiaries' consumption behavior around the cost-sharing kink. To build intuition for our analysis, we return to the standard benefit design. Prior to the ACA, when beneficiaries entered the donut hole, they became responsible for 100% of drug spending on the margin. As illustrated in Figure 2, the ACA gradually removed the wedge in marginal costs of filling a prescription between the initial coverage phase and the gap. Moving into the donut hole, the out-of-pocket price increased, on average, by 75 cents for every \$1 spent before the ACA, by 29 cents in 2011, and by 11 cents in 2018.

Standard economic theory suggests that as long as preferences for prescription drugs are well behaved and smoothly distributed in the population, we should observe beneficiaries bunching at this convex kink point of their budget set.²⁴ Beneficiaries consume until the marginal cost of filling a prescription equals the marginal benefit of filling a prescription. The jump in marginal costs then induces bunching of beneficiaries whose marginal benefit of filling a prescription lie in between the old and new marginal costs. Beneficiaries whose marginal benefit no longer exceeds the marginal cost in the gap who will stop or slow down consumption, leading to bunching at the start of the gap. The magnitude of the bunching should reduce with the ACA policy change as the kink in cost-sharing becomes less drastic.

For beneficiaries in our sample, Figure 5 presents histograms of total annual prescription drug spending between 2008 and 2018. The response to the pre-ACA cost-sharing kink is apparent: There is a noticeable spike in the distribution of annual spending of non-LIS

²³For non-LIS beneficiaries who enter the gap, average annual out-of-pocket spending increased somewhat between 2006-2010, dropped in 2011 with the closing of the gap, and started to rise again in subsequent years, reaching a similar level in 2016 as it did in 2006.

²⁴In practice, beneficiaries are instead expected to cluster in a narrow area around the coverage gap threshold due to real-world frictions such as the lumpiness of drug purchases and uncertainty about future health shocks (Saez 2010).

beneficiaries around the coverage gap threshold. As a placebo test, we confirm that we do not see a similar response to the kink for LIS recipients, who do not experience the coverage gap due to government subsidies and therefore should not bunch around the threshold. Furthermore, the response to the kink diminishes over time and is greatly moderated by 2018.

To quantify the amount of excess mass around the coverage gap threshold, we follow Chetty et al. (2011) and approximate the counterfactual distribution of annual spending in the absence of the kink. Specifically, we fit a cubic polynomial to the empirical spending distribution in Figure 5, using beneficiaries with spending between \$1,000 and \$10,000 and omitting those with spending within \$200 around the coverage gap threshold.²⁵ Figure 6 presents estimates of the excess mass around the threshold for each year from 2006 until 2018. In line with the policy change, we find a sharp decrease in the amount of excess mass for non-LIS beneficiaries in 2011 that continues to decline gradually. Excess mass around the coverage gap threshold was 3.2% in 2008 but only 0.6% in 2018. Again, for LIS beneficiaries, we find no evidence for excess mass around the threshold of the donut hole.

4.3 Timing of purchases

The bunching around the kink presumably reflects beneficiaries forgoing or postponing prescriptions that they would otherwise have filled. To study this aspect more closely, we look at beneficiaries' propensity to fill a prescription as they approach the coverage gap.

Absent a price response, standard economic theory suggests that the share of beneficiaries with a drug purchase in a given month should monotonically increase with the level of annual spending (Einav et al. 2015). This is in fact the case for LIS recipients, who experience minimal cost-sharing. As Figure 8 depicts, the share of LIS beneficiaries with a prescription drug purchase in December is monotonically increasing in the level of spending. In contrast, we find a slowdown in the probability of end-of-year purchases for non-LIS beneficiaries both as they approach the coverage gap and while they are in the gap.²⁶ Similar to Section 4.2, we fit a cubic polynomial to the conditional probability distribution function using beneficiaries with spending between \$1,000 and \$10,000 and omitting those with spending within \$200 around the kink.²⁷ In 2008, non-LIS beneficiaries with annual spending near the kink are 9.6 percentage points less likely to fill any prescription in December (Figure 8). The slowdown becomes less prevalent post-policy and, in 2018, non-LIS beneficiaries close to the kink are

²⁵We estimate the excess mass for spending within \$200 of the coverage gap threshold.

²⁶We do not find a similar slowdown in the probability of beginning-of-year purchases for non-LIS beneficiaries (Figure 7). This is unsurprising as beneficiaries are unlikely to have approached the coverage gap yet at the beginning of the year.

²⁷We estimate the missing mass for purchases within \$200 of the coverage gap threshold.

only 3.7 percentage points less likely to fill any prescription in December.

Overall, we find that reaching the coverage gap has a more modest impact on slowing down the drug consumption of non-LIS beneficiaries, suggesting an increase in beneficiary demand for prescription drugs. While this effect is unsurprising, and indeed the intended goal of the policy change, it warrants the need to analyze manufacturers' response: As the coverage gap no longer restrains drug purchases and beneficiaries become less price-sensitive, manufacturers may increase drug prices.

5 Manufacturer response

In this section, we investigate the effect of the gap closure on retail prices by exploiting variation in policy exposure across brand-name drugs and markets. Intuitively, manufacturers that generate a higher share of revenue from claims in the gap are more exposed to the policy change as they face a higher demand increase and higher discount payments in future years. We link this variation to trends in retail prices of brand-name drugs sold in Part D in 2010.²⁸ We begin by describing the construction of our analysis sample.

5.1 Variable construction

Defining drugs. To be able to track brand-name drugs over time, we need a consistent definition of a prescription drug. Specifically, we cannot measure prices at the NDC level as these codes change frequently and multiple codes may describe the same drug product.²⁹ Instead, we rely on information from the IBM MarketScan[®] Redbook and combine NDCs that describe pharmaceutically equivalent products with the same brand status and trade name. Following the definition by the FDA, drug products are pharmaceutically equivalent if they contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration. For example, we group together 24 NDC codes that describe a 40mg oral tablet of brand-name Lipitor with the active ingredient atorvastatin calcium. In this case, we combine products from 12 different manufacturers, or drug labelers, offered in 7 different package sizes.

²⁸By focusing on drugs already on the market in 2010, our analysis does not speak to the effect on launch prices of new drugs.

²⁹Under federal regulation, the manufacturer has to update the product-specific portion of the code when one of the following changes: the proprietary name of the product, any active ingredient or its strength, the dosage form, the status of the product (e.g., whether it is a prescription or over-the-counter drug), the intended use, or any distinguishing characteristics such as size, shape, or color. In addition, the manufacturer has to update the packaging-specific portion of the code when there is any change to the package size or type. Source: [21 CFR 207.35](#).

We augment these data with information from the FDA on drug approval and patent expiration. In particular, we combine the Part D claims data with the National Drug Code Directory, which links NDCs to their drug application number. This number allows us to link NDCs to the DrugsFDA and Orange Book databases, which list the date a drug was first approved and when its patent or marketing exclusivity expires.³⁰

Constructing average retail prices. In our analysis, we focus on the average retail price per days' supply of a brand-name drug in a given market and year. The retail price is the total cost of a prescription drug event and comprises the ingredient cost and dispensing fee. Specifically, it is the price paid by the insurer and beneficiary to the pharmacy at the point of sale. By measuring prices at the market-year level, we capture the market-wide response of manufacturers, pharmacies, and insurers, but abstract away from intra-market price variation across plans.

To limit measurement error from non-standard claims, we exclude prescriptions filled at out-of-network pharmacies and drop drugs with less than ten claims for the most common package size in a market and year.³¹ Although the latter restriction drops many infrequently purchased drugs, we retain more than 98% of all claims and revenue for brand-name drugs. For the remaining drugs, we take the five most common package sizes to compute the average price per days' supply across all claims in the same market and year.

Measuring policy exposure. Our research design exploits variation in the exposure to the closing of the coverage gap. We measure exposure as drug j 's revenue from non-LIS beneficiaries in the gap relative to the *variable* revenue in market m in 2010,

$$\text{gap share}_{jm|2010} = \frac{\text{non-LIS gap spending}_{jm|2010}}{\text{total spending}_{jm|2010} - \text{government spending}_{jm|2010}} \quad (1)$$

The numerator is the total cost of claims by non-LIS beneficiaries in the gap in 2010.³² The denominator is market-wide spending minus the total cost of government subsidies, which comprises LIS cost-sharing subsidies and non-LIS reinsurance in the catastrophic phase. We

³⁰Since drugs may be protected by multiple patents, we use the last year of patent or market exclusivity expiration.

³¹Approximately 98% of all claims for brand-name drugs are filled at in-network pharmacies. We do not impose the in-network restriction when constructing the policy exposure measures (see next paragraph). The median brand-name drug in our data is prescribed in three different package sizes, or numbers of days' supply, in a market and year. The most common package size is prescribed in more than 80% of filled claims.

³²Specifically, we add up the total cost of non-LIS claims that end up in the coverage gap. This comprises claims that start in the deductible phase, the initial coverage phase, or the coverage gap. We do *not* count claims that start in the coverage gap and end in the catastrophic phase.

subtract government subsidies as recipients of cost-sharing assistance are much less sensitive to price. Intuitively, we regard government-financed spending as “guaranteed” revenue, while the manufacturer chooses a price to maximize revenue from price-sensitive consumers.³³

Analysis sample. Our sample comprises 2,452 brand-name drugs (40,652 drug-markets) that were sold in Part D in 2010. These drugs account for 76% of total Part D spending in 2010 and 27% of total days’ supply.³⁴ Table 5 shows drug-level summary statistics in 2010. Retail prices are heavily right-skewed, with a mean of \$35 per days’ supply and a median of \$6.5, which is why we use log-prices in the event study.

Table 6 compares drugs with a *gap share* below versus above the 25th percentile, in line with our empirical strategy. Several noticeable differences arise: First, high-exposure drugs are cheaper, costing \$18 per days’ supply on average compared to \$68 for low-exposure drugs. Second, 66% of high-exposure drugs treat primarily chronic conditions, compared to 43% of low-exposure drugs. Thus, while the daily dosage may be cheaper, beneficiaries consume high-exposure drugs more consistently. We detect no substantial differences in dosage form or route of administration. While the vast majority of drugs are patent-protected in 2010, a larger share of low-exposure drugs loses protection before 2018. Despite this difference, both groups have the same approval year and patent expiration year, on average, and roughly 70% of drugs have a generic alternative available ever.³⁵

Figure 9 shows a histogram of the policy exposure metric (at the drug-market level) and Table 7 summarizes key moments of the distribution. The *gap share* captures two sources of identifying variation. First, consistently across markets, there are drugs more versus less commonly consumed by non-LIS beneficiaries in the coverage gap. Second, the composition of the beneficiary population differs across markets with high versus low shares of non-LIS beneficiaries. In an Abowd-Kramarz-Margolis-style variance decomposition, we find that drug fixed effects explain 68% of variation in the *gap share*, while market fixed effects explain about 8%. Thus, our empirical strategy mainly leverages variation in policy

³³In addition, we want to avoid that government-financed revenue “deflates” our exposure measure. For example, suppose that 80% of drug revenue comes from LIS beneficiaries and 20% from non-LIS beneficiaries. As LIS beneficiaries pay close to zero cost-sharing, they are essentially sheltered from variation in the retail price.

³⁴As illustrated in Table A2 in Appendix D, drugs in our analysis sample accounted for 99% of brand-name spending, days’ supply, and number of claims in Part D in 2010. With the entry of new, high-priced drugs, the share of spending accounted for by our sample declines (46% of brand-name spending in 2018). Yet, these drugs remain central to Part D beneficiaries and capture 60% of total brand-name days’ supply and claims in 2018.

³⁵We define a brand-name drug as having a generic alternative if we ever observe a NDC in the Part D claims data that is labeled as generic and pharmaceutically equivalent to the brand-name product in the IBM MarketScan® Redbook.

exposure across drugs rather than across markets.³⁶ Furthermore, we find that our exposure measure is highly correlated over time in pre-closure years, implying that it predicts the relative revenue impact in years following the policy reform.³⁷

Due to market entry after 2006 and exit before 2018, our drug-market-year panel is unbalanced. See Appendix C for a discussion.

5.2 Event study

Our empirical strategy leverages differential exposure to the gap closure across drugs. In our baseline specification, we dichotomize the exposure measure and compare drug-markets with a *gap share* below versus above the 25th percentile.³⁸ We estimate the following event study,

$$p_{jmt} = \sum_t \beta^t \times \delta_t \times \mathbb{1} \{ \text{gap share}_{j|m|2010} > Q_1 \} + \lambda_{jm} + \tau_{mt} + \eta_{e(j)t} + \varepsilon_{jmt} \quad (2)$$

Here, p_{jmt} is the log-average price per days' supply for drug j in market m in year t . We interact the exposure indicator with a series of year fixed effects, δ_t , normalized to 2010. The parameters of interest, β^t , capture the average difference in log prices of high- versus low-exposure drugs in year t . We include drug-market fixed effects, λ_{jm} , to capture differences in relative market size between drugs and to control for other time-invariant characteristics. Market-year fixed effects, τ_{mt} , capture changes in insurer or pharmacy competition and their average effect on retail prices. We also allow time trends to vary by patent expiration year e , $\eta_{e(j)t}$, to account for varying pricing incentives over the drug life cycle.³⁹ Thus, identification comes from deviations in market-level trends in retail prices between drugs with the same patent expiration year but different policy exposure. In addition, we rely on the assumption of parallel trends in the absence of the policy change, which we can assess empirically in pre-policy years. In the estimation, we weight observations by their respective drug-market spending in 2010. Standard errors are clustered at the drug-market level.

³⁶To decompose the variance of the exposure measure, we first regress the gap share on full sets of drug fixed effects and market fixed effects. We compute the variance of estimated drug (market) fixed effects across all 2010 drug-markets and divide it by the variance of the gap share.

³⁷To estimate the serial correlation of the exposure measure, we construct the *gap share* for each drug-market for years $t = 2006, \dots, 2010$ and estimate the following AR(1) model, $\text{gap share}_{jmt} = \alpha + \rho \text{gap share}_{jmt-1} + \varepsilon_{jmt}$. We estimate an autocorrelation coefficient of $\hat{\rho} = 0.6688$ (0.0121).

³⁸Drug-markets at the 25th percentile make 4.32% of their *variable* revenue from non-LIS beneficiaries in the coverage gap. See Table 7. All numbers are weighted by drug-market specific spending in 2010.

³⁹For roughly 24% of brand-name drugs in our analysis sample, we fail to identify a patent expiration year. These drugs account for less than 5% of brand-name spending in 2010. We assign these drugs to one of two “placeholder” categories, depending on whether we linked them to an NDA, so that we do not lose these observations in the estimation.

Figure 10 illustrates the regression results. We find a positive and statistically significant effect on retail prices of high-exposure drugs for all years following the gap closure. Notably, the effect size is monotonically increasing over time: Compared to low-exposure drugs, prices of high-exposure drugs were 2% higher in 2011 and 21% higher in 2018, on average. The relative increase in retail prices starts to stabilize in 2016, suggesting that manufacturers of high-exposure drugs increased retail prices over the course of several years following the gap closure. Importantly, we detect no meaningful difference in prices in the years leading up to the policy change. To put this result into context: The average *gap share* in the two exposure groups differs by 9 percentage points (10.8% versus 1.9%), implying that high-exposure drugs made roughly four times more of their “variable” revenue from non-LIS beneficiaries in the gap. Notably, to the extent that low-exposure drugs were still impacted by the gap closure and responded by raising prices, our estimates understate manufacturers’ pricing response.⁴⁰

We implement several robustness checks, summarized in Table 8. First, we add therapeutic group-year fixed effects to allow aggregate price trends to differ across therapeutic groups (column 2).⁴¹ Next, we estimate the baseline specification on a balanced panel of drug-market-years and on the subset of drugs successfully linked to a New Drug Application number (columns 3 and 4). Lastly, we implement our baseline specification with a simplified exposure measure that does not subtract government-financed spending from total spending in 2010 (column 5). Our estimation results are robust to these alterations: Across specifications, we find that prices of high-exposure drugs are between 19-21% higher in 2018, on average, compared to low-exposure drugs.

Role of generic competition and patent protection. We investigate the role of generic competition in manufacturers’ response to the gap closure. For that, we separately estimate Equation (2) for drugs with and without generic competition. Columns (6) and (7) in Table 8 report the results. Across years, we find that the effect on prices was roughly 40% higher for drugs without generic competition. This difference is especially pronounced in the first years of the policy change. In 2013, for example, prices were 9% higher for high-exposure drugs without a generic, compared to 5% for high-exposure drugs with a generic.

We repeat this analysis for the subset of drugs with observed patent expiration year

⁴⁰For example, when defining drug-markets with a *gap share* above 1% as high-exposure, we estimate a difference in retail prices of 24% in 2018. While this approach guarantees a cleaner “control group”, i.e., drug-markets with close to zero policy exposure, it means we compare more extreme and less comparable drugs with one another.

⁴¹Drugs in our analysis sample belong to one of 26 therapeutic groups. With respect to 2010 branded spending, the top three therapeutic groups are central nervous system agents (e.g., analgesics, anticonvulsants), cardiovascular agents (e.g., antihypertensives, beta-blockers), and hormones & synthetic substitutes (e.g., estrogens, antidiabetic agents).

(Table 8, columns 8 and 9). In particular, we estimate the event study for drugs that lose patent protection between 2011 and 2018, and for drugs that remain protected beyond our study period.⁴² Again, we find a stronger effect on prices of patent-protected drugs in early years of the policy change.

Our results suggest that manufacturers increased prices more for high-exposure drugs that faced *less* competition. Under patent protection and without generic competition, manufacturers enjoy more market power and can pass through a higher share of the discount requirement by raising retail prices. In addition, without close therapeutic substitutes, these manufacturers also face a higher demand increase as beneficiaries’ cost-sharing in the gap decreases. Both mechanisms lead to higher retail prices in equilibrium.

Heterogeneity by exposure intensity. To study heterogeneity by policy exposure, we augment Equation (2) by separate indicator variables for drug-markets in the second, third, or fourth quartile of the *gap share* distribution.⁴³ By splitting the *gap share* into quartiles, we allow the effect on retail prices to be non-linear in exposure.⁴⁴ We estimate this specification separately for drugs with and without generic alternative.

Figure 11 illustrates the results. We find a clear trend for drugs without generic competition: Consistently, the effect on prices is increasing across exposure quartiles, suggesting that manufacturers raised prices more if they were more reliant on revenue from non-LIS beneficiaries in the gap. For 2018, prices are 16% higher for drugs in the second quartile, relative to drugs in the first quartile, 21% higher for drugs in the third quartile, and 24% higher for drugs in the fourth quartile. While this trend holds qualitatively, point estimates are not statistically different across quartiles in most post-policy years. Overall, the results suggest that the effect on retail prices is concave in exposure: On average, drugs in the second quartile made 6.6% of their variable revenue from non-LIS in the gap, compared to 16.2% in the fourth quartile. For drugs with generic alternative, we detect the same trend in early post-policy years. Starting 2016, the differences across quartiles dissipate, presumably reflecting more stringent competition.

⁴²Drugs that lose patent protection in 2010 or earlier account for less than 2% of brand-name spending in 2010. Therefore, we refrain from running separate estimation for this subset of drugs.

⁴³Table 7 summarizes the cutoff *gap share* values.

⁴⁴Figure A1 in Appendix E shows the event study results with a linear effect in the exposure measure. A one-unit increase in the *gap share* yields a 1.4% higher retail price in 2018 for drugs without a generic, and a 1.1% higher price for drugs with a generic.

6 Distributional implications

So far, we have documented two effects of the policy change: Non-LIS beneficiaries no longer forgo prescription drugs upon reaching the coverage gap, and manufacturers responded by increasing retail prices. To bring these pieces together, we investigate the distributional implications of the closing of the coverage gap and ask which payer—beneficiaries, government, insurer, or manufacturer—gained or lost from the insurance expansion. We provide two pieces of model-free evidence on the distributional incidence. First, we illustrate how drug spending was reallocated between payers mechanically by the redesign of the coverage gap. Second, we isolate the effect of the endogenous price response of manufacturers.

In particular, we conduct a back-of-the-envelope calculation to assess the distributional incidence of closing the coverage gap. For each beneficiary i , we calculate the following,

$$\Delta Incidence_i^k = C_k^{2018} \left(\sum_j p_{ij}^{2010} \times (1 + \beta_{jm}) \times Q_{ij}^{2010} \right) - C_k^{2010} \left(\sum_j p_{ij}^{2010} \times Q_{ij}^{2010} \right) \quad (3)$$

and

$$\Delta Incidence_i^k = C_k^{2018} \left(\sum_j p_{ij}^{2018} \times Q_{ij}^{2018} \right) - C_k^{2010} \left(\sum_j p_{ij}^{2018} \times (1 + \beta_{jm})^{-1} \times Q_{ij}^{2018} \right) \quad (4)$$

where $C_k^t(\cdot)$ is the cost-sharing function for payer k (i.e., beneficiary, government, insurer, or manufacturer) implied by the standard design in year t , p_{ij}^t is the retail price of drug j experienced by beneficiary i in year t , and Q_{ij}^t is the quantity of drug j consumed by beneficiary i in year t . The variable β_{jm} captures the drug-market-specific price response by manufacturers as estimated in Equation (2) in Section 5.

That is, we calculate the difference in payments by payers (i.e., beneficiaries, the government, insurers, and manufacturers) due to the change in cost-sharing from the closure of the coverage gap, accounting for manufacturer price increases in response to the policy change. We only change the cost-sharing for each coverage phase—we do not change when the coverage phases begin. For instance, absent a price increase, beneficiary out-of-pocket payments should decrease under the standard design in year 2018 relative to the standard design in year 2010, since cost-sharing was more generous to beneficiaries in 2018. This distributional analysis is a first-order approximation as we hold beneficiary behavior fixed. In reality, beneficiaries may adjust their prescription consumption to new drug prices and cost-sharing. We conduct the distributional analysis using both prices and quantities before the ACA policy change in 2010 (in the style of a Lapreyes price index), and prices and

quantities after the ACA policy change in 2018 (in the style of a Paasche price index).

Figure 12 and Figure 13 presents the results of our back-of-the-envelope calculations. We find that the closure of the gap represents a per capita transfer of \$220 to beneficiaries that is approximately financed three quarters by the government and one quarter by firms (i.e., insurers and manufacturers). The endogenous price response by manufacturer is quantitatively important. A naive estimate ignoring price responses by manufacturers greatly overestimates the incidence born by firms and underestimates the incidence born by the government. A naive estimate would conclude instead that the government fiscally benefited from the change in the standard benefit design. Figure 14 decomposes the distributional results by whether beneficiaries receive low income subsidies. The decomposition highlights the importance of considering endogenous price responses. Increasing drug prices have spillover effects for beneficiaries that receive low income subsidies, despite the policy change not directly impacting them. Drug manufacturers are able to shift the incidence of discount payments onto the federal government via this channel.

7 Conclusion

Our paper studies the general equilibrium effects of the closure of the Medicare Part D coverage gap. We use the 2010 Affordable Care Act policy change as a quasi-experimental shock to study beneficiary and drug manufacturer responses to changes in the standard benefit design. First, we find that beneficiaries increase demand in response to lower cost-sharing. Prior literature has documented that the increase in cost-sharing at the start of the donut hole caused consumers to forgo drug consumption, and the policy change was successful at mitigating this problem. In 2008, beneficiaries were 9.6 percentage points less likely to fill an end-of-year prescription as they approached the threshold. In 2018, individuals were only 3.7 percentage points less likely to fill an end-of-year prescription in 2018.

Second, drug manufacturers increased retail prices in response to the ACA policy change. The coverage gap was closed with an implicit tax on manufacturers with the creation of the manufacturer discount program. Therefore, we would ex-ante expect manufacturers to pass through discounts via raising prices, and price increases should be greater for drugs with a larger share of revenue coming from spending in the coverage gap. We find that branded drugs with a greater exposure to the policy change—measured by the share of non-government revenue in 2010 coming from spending in the coverage gap—experienced 20% higher price increases.

Finally, we conduct a back-of-the-envelope calculation to determine the distributional incidence of the Medicare Part D donut hole. We find that the closure of the gap represents

a per capita transfer of \$220 to beneficiaries. This transfer was financed three quarters by the government and one quarter by firms (i.e., insurers and manufacturers).

Understanding the effect of public insurance design on pharmaceutical prices continues to be critical to policy as the Part D benefit design is an ongoing topic on the political agenda. For instance, under the Trump administration, the Centers for Medicare & Medicaid Services accelerated the closure of the coverage gap in 2019 by increasing the manufacturer discount to 70%. Most recently, as part of the Inflation Reduction Act of 2022, the Biden administration abolished manufacturer discounts, and completely overhauled the Part D benefit design.

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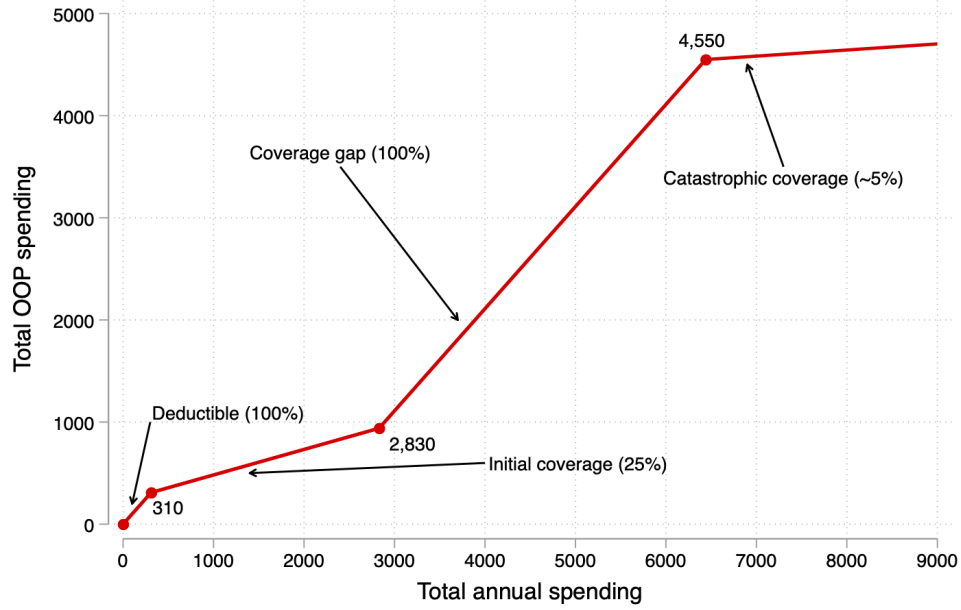
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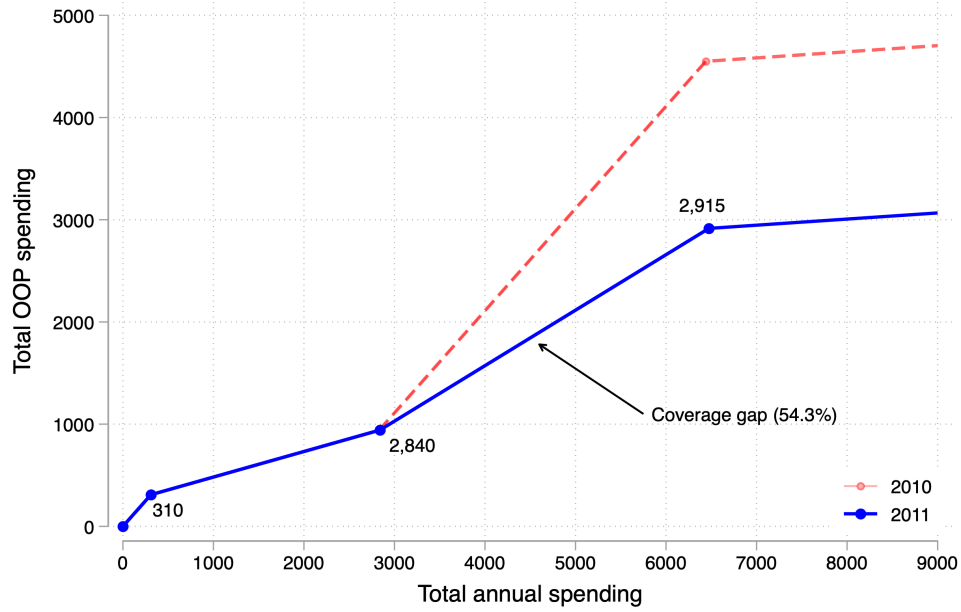
Figure 1: Government-defined standard benefit design in 2010



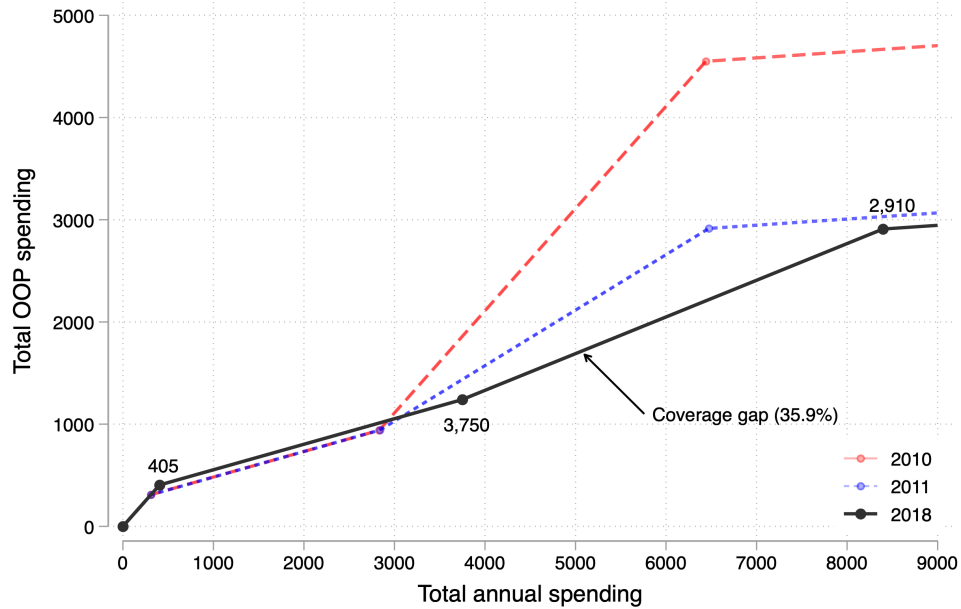
Note: Figure shows the beneficiary's coinsurance rate in the government-defined standard benefit plan in 2010. The plan has four coverage phases (deductible, initial coverage, coverage gap, catastrophic coverage), which are a function of the beneficiary's annual total drug spending (x-axis) and annual out-of-pocket (OOP) spending (y-axis). The beneficiary starts out in the deductible phase with a coinsurance rate of 100% until its (OOP) spending reaches \$310. In the initial coverage phase, which lasts until the initial coverage limit of \$2,830 in total spending, the beneficiary faces a coinsurance rate of 25%. In the coverage gap, which lasts until the OOP threshold of \$4,550 in OOP spending, the coinsurance is, again, 100%. Afterwards, the beneficiary is in the catastrophic phase and pays approximately 5% of drug spending out-of-pocket. Drug benefits reset at the beginning of each year. Only non-LIS beneficiaries are exposed to the different coverage phases. For LIS beneficiaries, the government covers the vast majority of beneficiary contributions, including 100% of spending in the coverage gap.

Figure 2: Gap closure in government-defined standard benefit design

(A) 2010 vs 2011

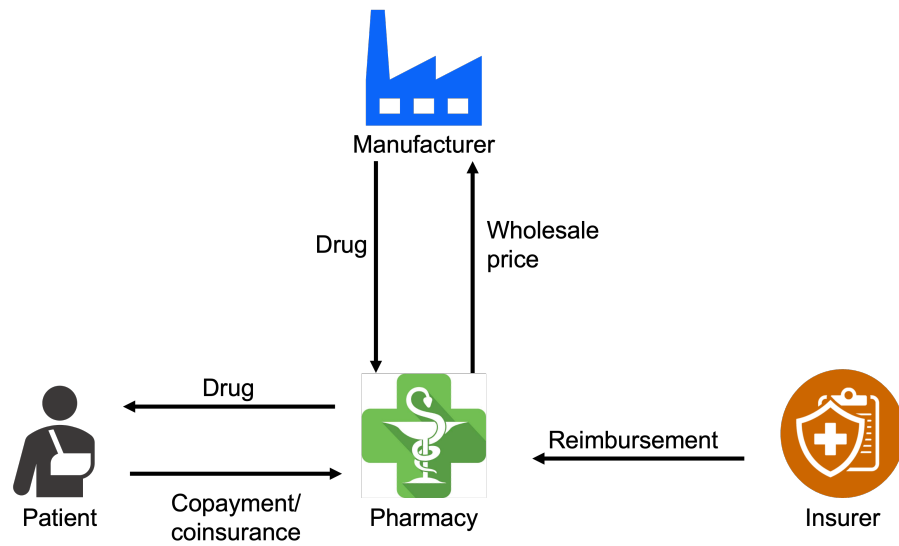


(B) 2010 vs 2011 vs 2018



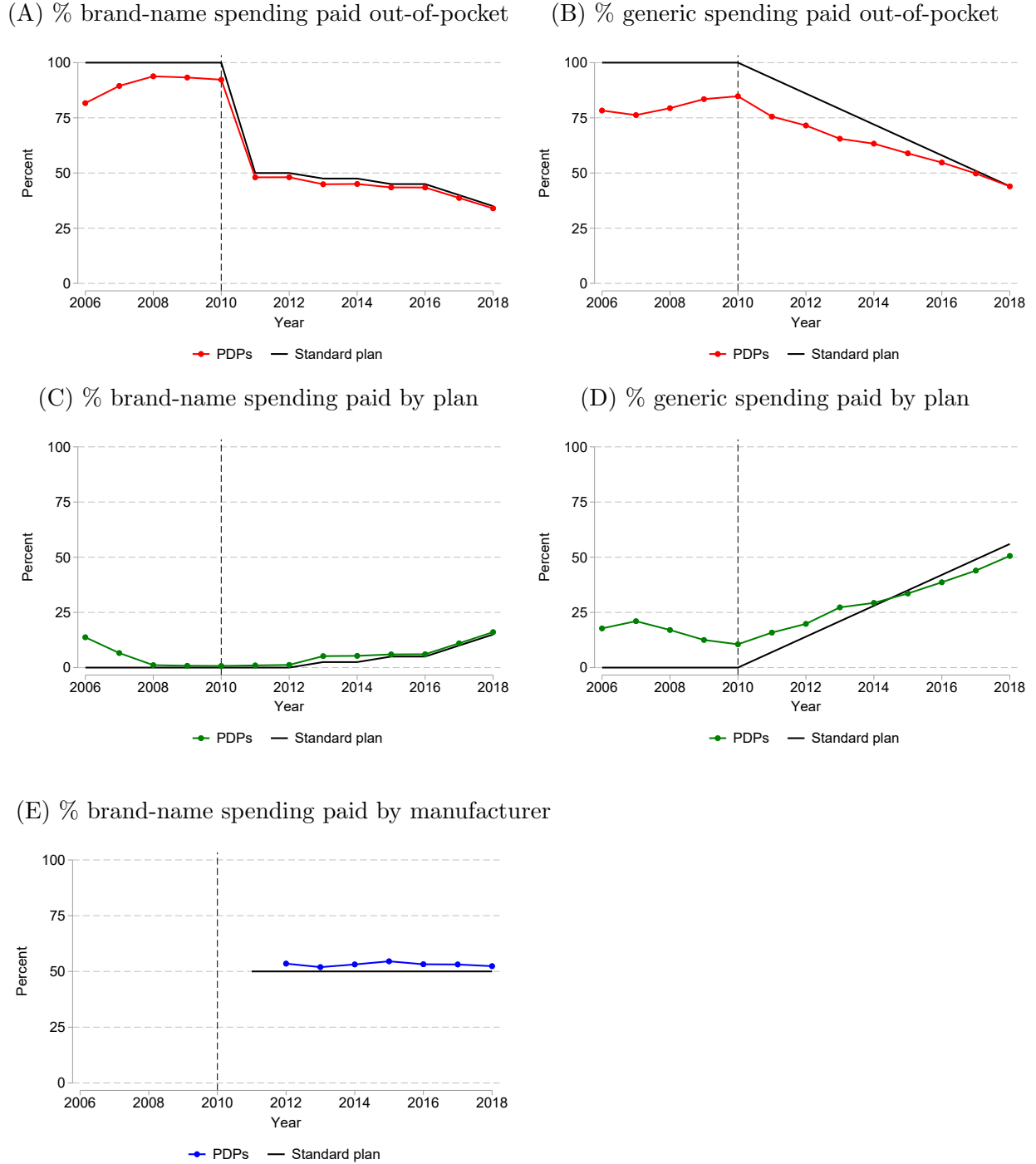
Note: Figure shows the beneficiary's coinsurance rate in the government-defined standard benefit plan in 2010, 2011, and 2018. In 2011, i.e., the first year of the gap closure, coinsurance rate in the gap is 50% for brand-name drugs and 93% for generic drugs. In 2018, i.e., the last year of our data, coinsurance rate in the gap is 35% for brand-name drugs and 44% for generic drugs. We plot a coinsurance rate assuming that the beneficiary consumes 90% branded and 10% generic drugs in the gap. This approach follows the measure used by CMS to estimate total spending at the out-of-pocket threshold (CMS, 2013). Thresholds (nodes) are updated annually based on the Consumer Price Index for All Urban Consumers and the annual percentage increase in average expenditures for Part D Drugs per eligible beneficiary.

Figure 3: Drug supply chain



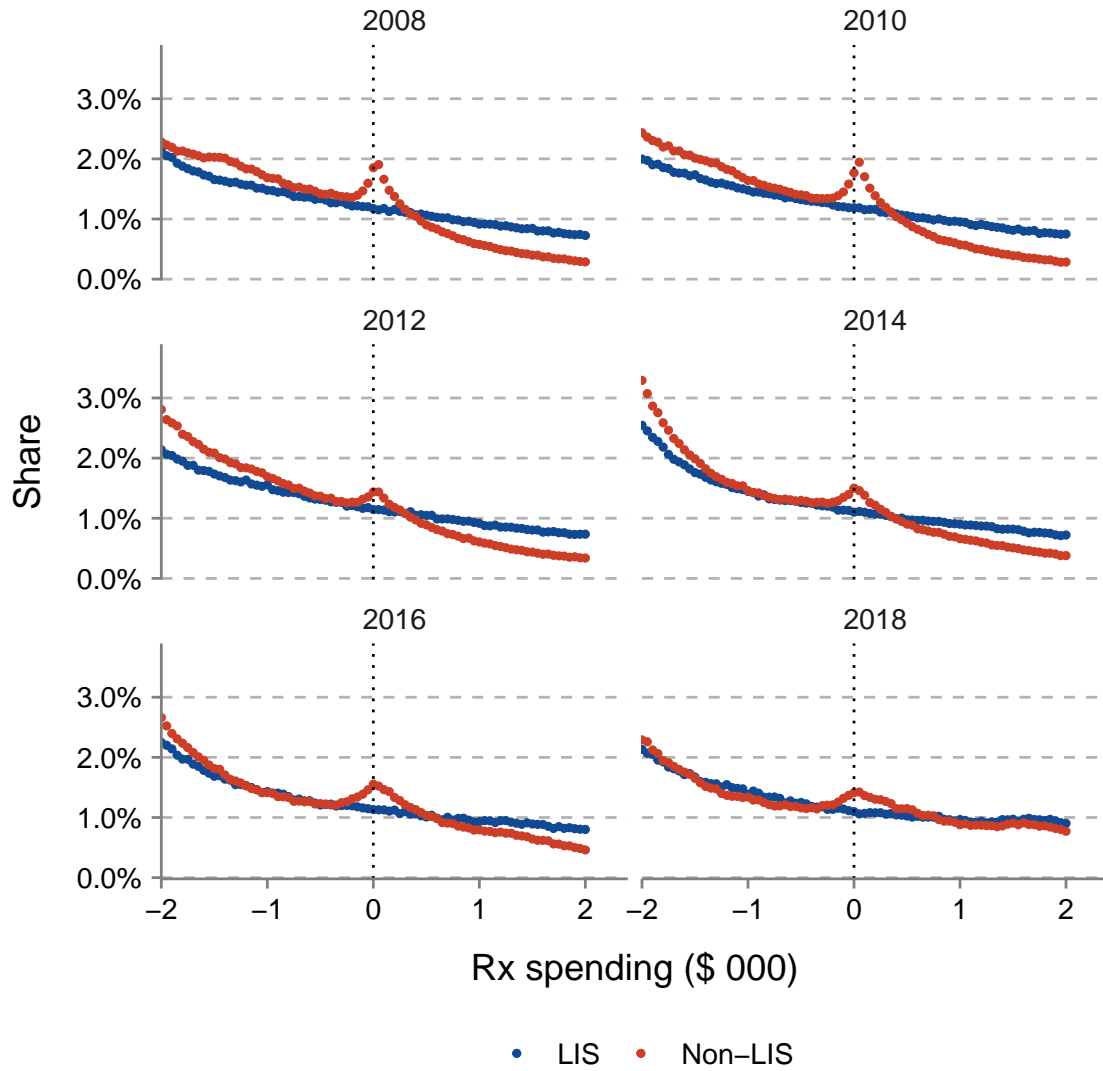
Note: This illustration is based on an industry report by the Drug Channels Institute ([2020](#)).

Figure 4: Non-LIS cost-sharing in the coverage gap



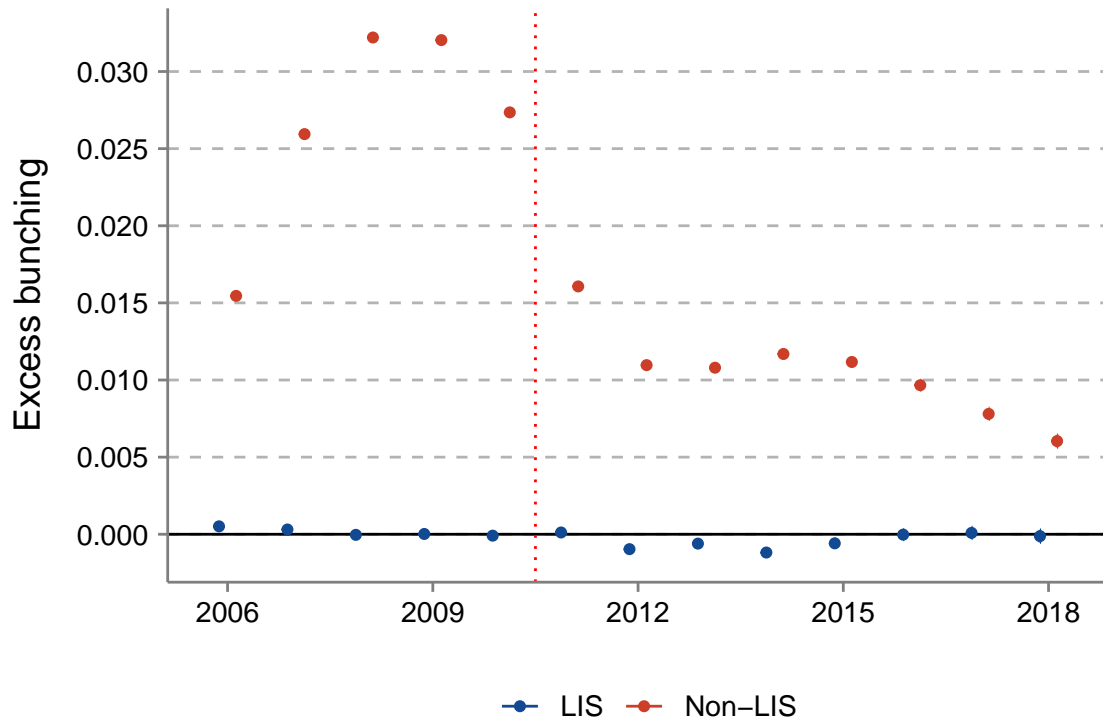
Note: Figure shows how cost-sharing in the coverage gap evolved over time for non-LIS beneficiaries, on average. We compare the empirical gap cost-sharing in Part D standalone plans (“PDPs”) to the standard plan design (“Standard plan”). We measure gap cost-sharing for non-LIS empirically: For a given year, we take all beneficiaries who enter the gap at some point in the year. We take beneficiaries who hold the non-LIS status and remain enrolled in the same plan throughout the year. For each beneficiary, we add up total drug spending, out-of-pocket spending, plan, and manufacturer contributions for claims made entirely in the gap (that is, claims that start and end in the gap). We drop beneficiaries in the bottom and top percentile of the gap spending distribution of a given year. For each beneficiary, we compute the empirical cost-sharing by dividing the total out-of-pocket spending, plan and manufacturer contributions by total drug spending in the gap. The figures plot the average cost-sharing rates across beneficiaries.

Figure 5: Prescription drug spending around the kink



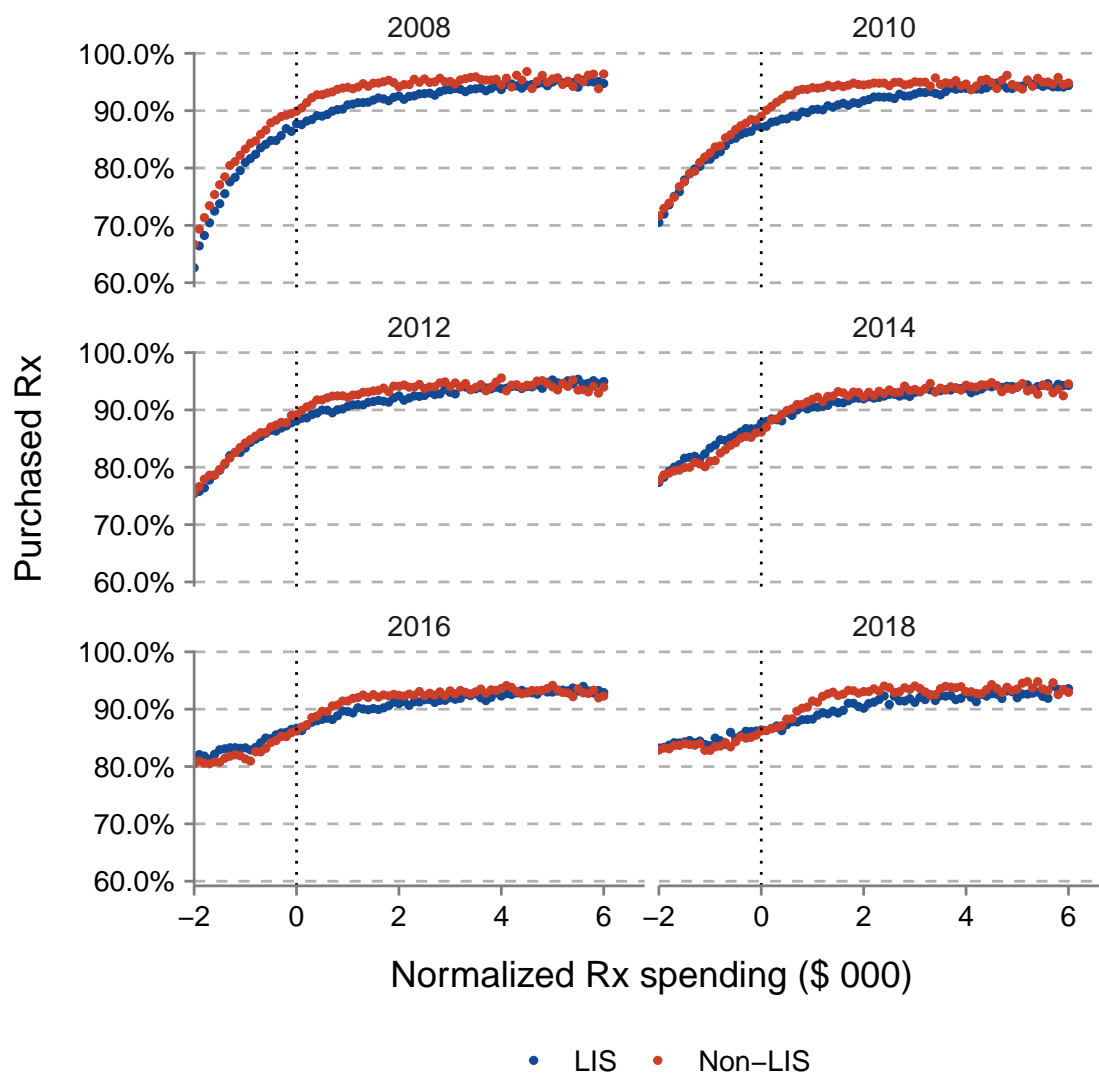
Note: This figure presents the empirical distribution of annual beneficiary spending (in \$1,000) from 2008 to 2018. Annual beneficiary spending, in \$1,000, is normalized relative to the coverage gap threshold. Separate empirical distributions are presented for low-income subsidy (LIS) beneficiaries and non-LIS beneficiaries.

Figure 6: Excess bunching



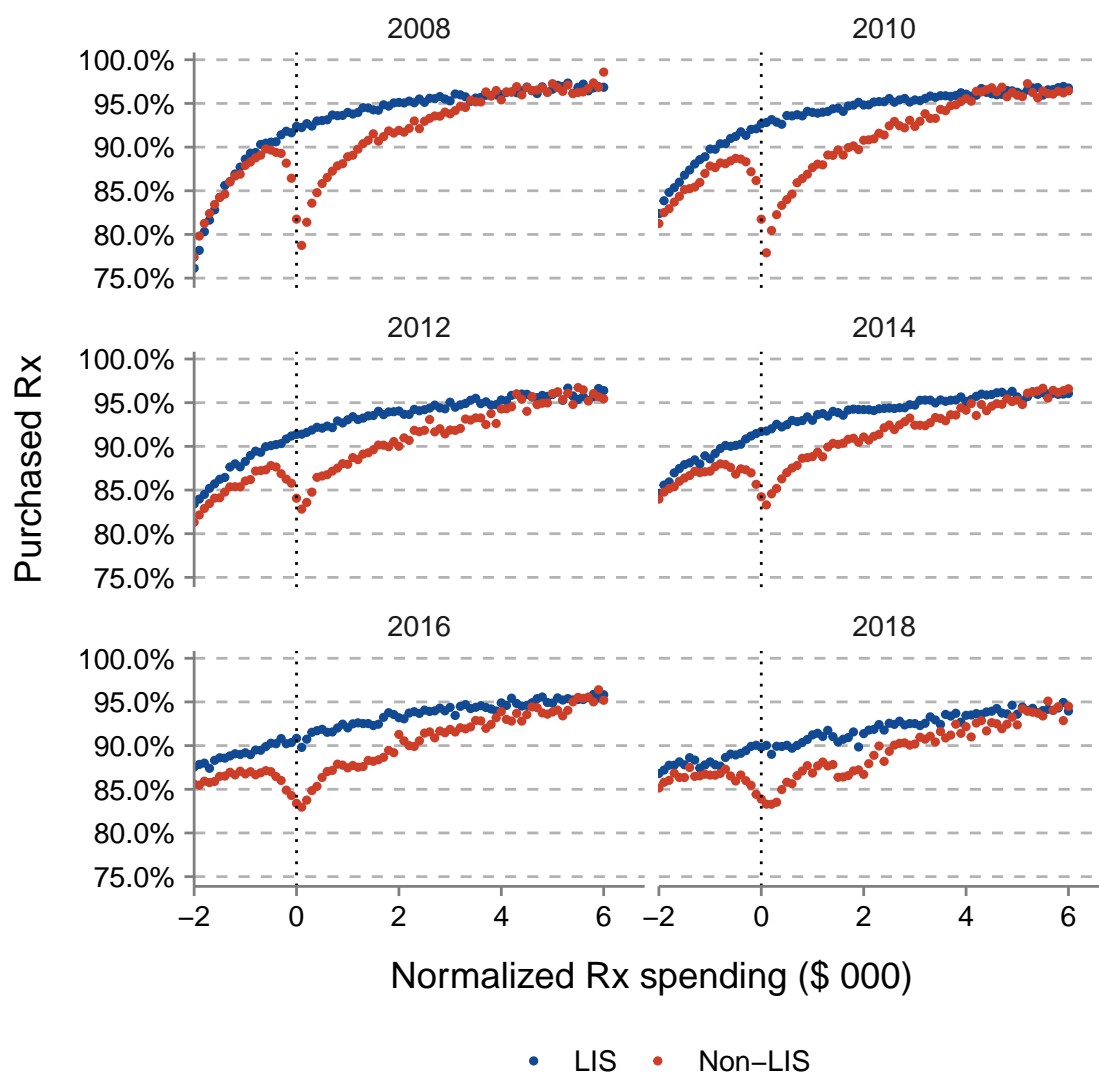
Note: This figure presents the estimated excess mass around the coverage gap threshold (i.e., within \$100 of the threshold) from 2006 to 2018. To quantify the amount of excess mass, we fit a cubic approximation to the empirical distribution function (shown in Figure 5), using only beneficiaries whose spending are between \$1,000 and \$10,000 and not near the coverage gap threshold (at least \$200 away from the threshold).

Figure 7: Propensity of prescription drug purchase in January as function of drug spending



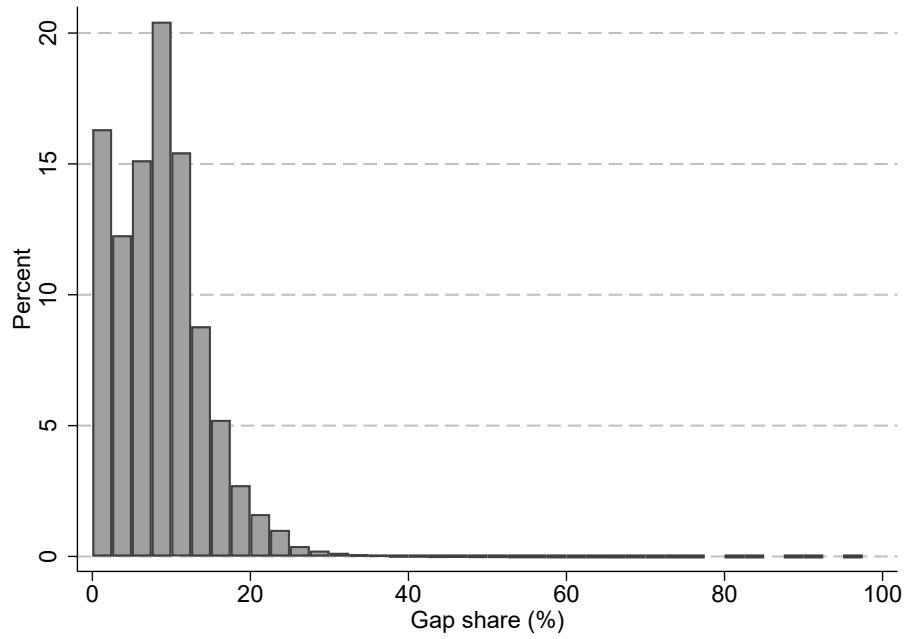
Note: This figure presents the beneficiary-level propensity of any prescription drug purchase in January as a function of annual beneficiary spending (in \$1,000) from 2008 to 2018. Annual beneficiary spending is normalized relative to the coverage gap threshold. Separate propensities are presented for low-income subsidy (LIS) beneficiaries and non-LIS beneficiaries.

Figure 8: Propensity of prescription drug purchase in December as function of drug spending



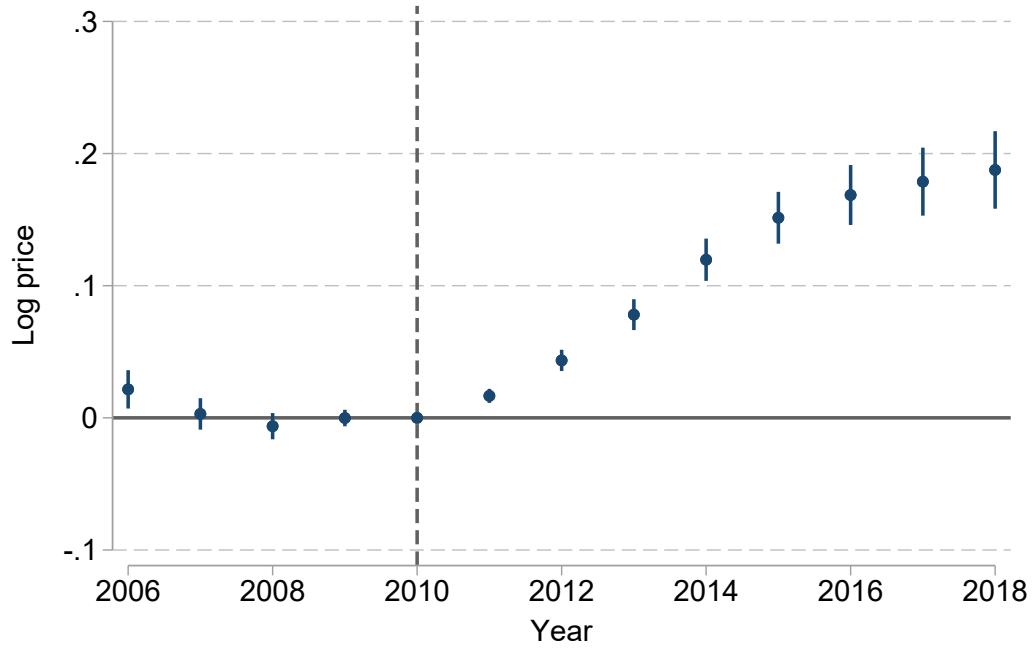
Note: This figure presents the beneficiary-level propensity of any prescription drug purchase in December as a function of annual beneficiary spending (in \$1,000) from 2008 to 2018. Annual beneficiary spending is normalized relative to the coverage gap threshold. Separate propensities are presented for low-income subsidy (LIS) beneficiaries and non-LIS beneficiaries.

Figure 9: Distribution of drug-market exposure measure



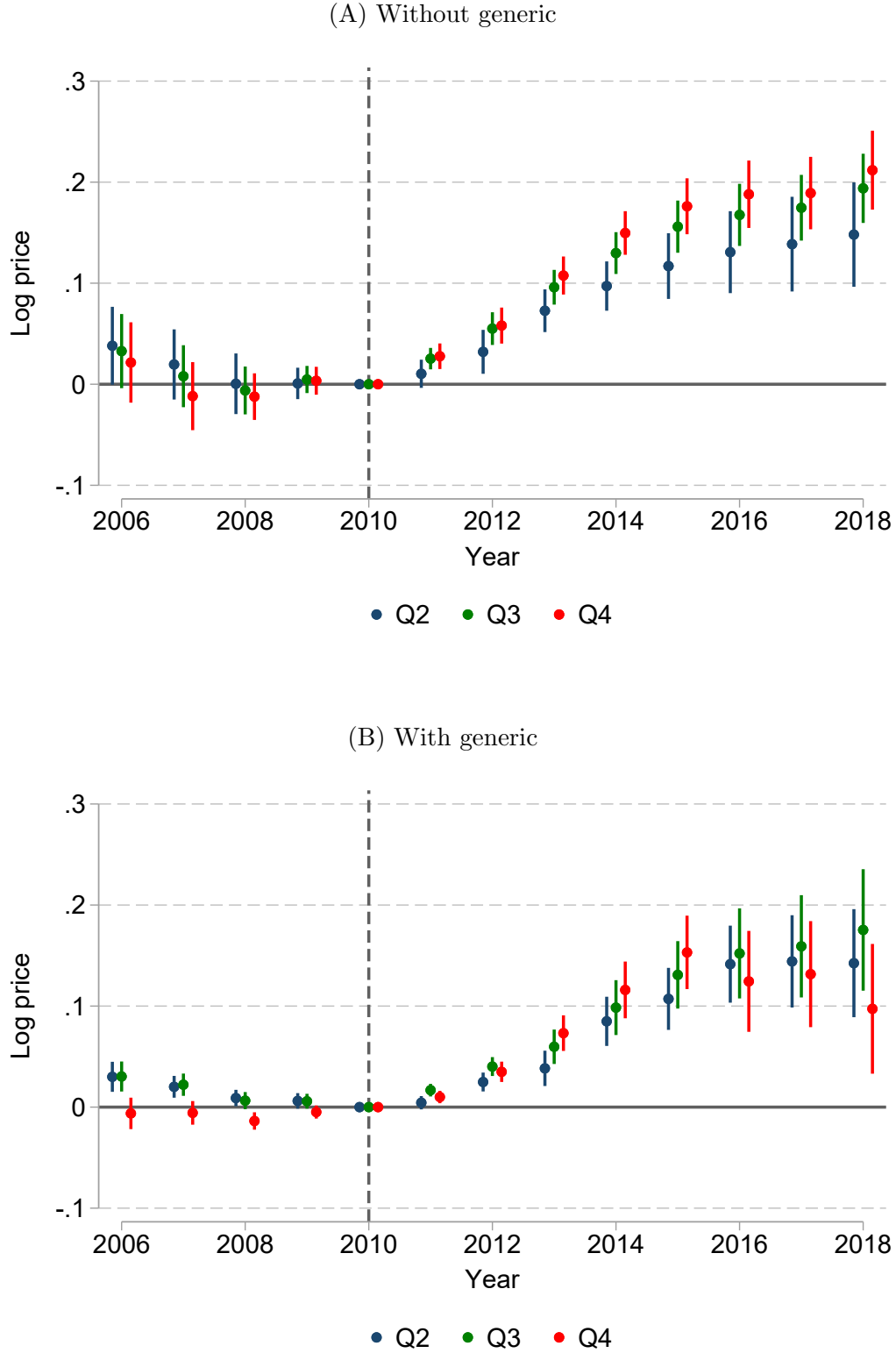
Note: Histograms show the distribution of the policy exposure measure “gap share” across drug-markets in our analysis sample. The exposure measure is the share of variable revenue from non-LIS beneficiaries in the coverage gap of a drug-market in 2010. Variable revenue is the total spending of drug j in market m , minus government-financed spending from LIS subsidy and reinsurance in the catastrophic phase.

Figure 10: Event study, baseline specification



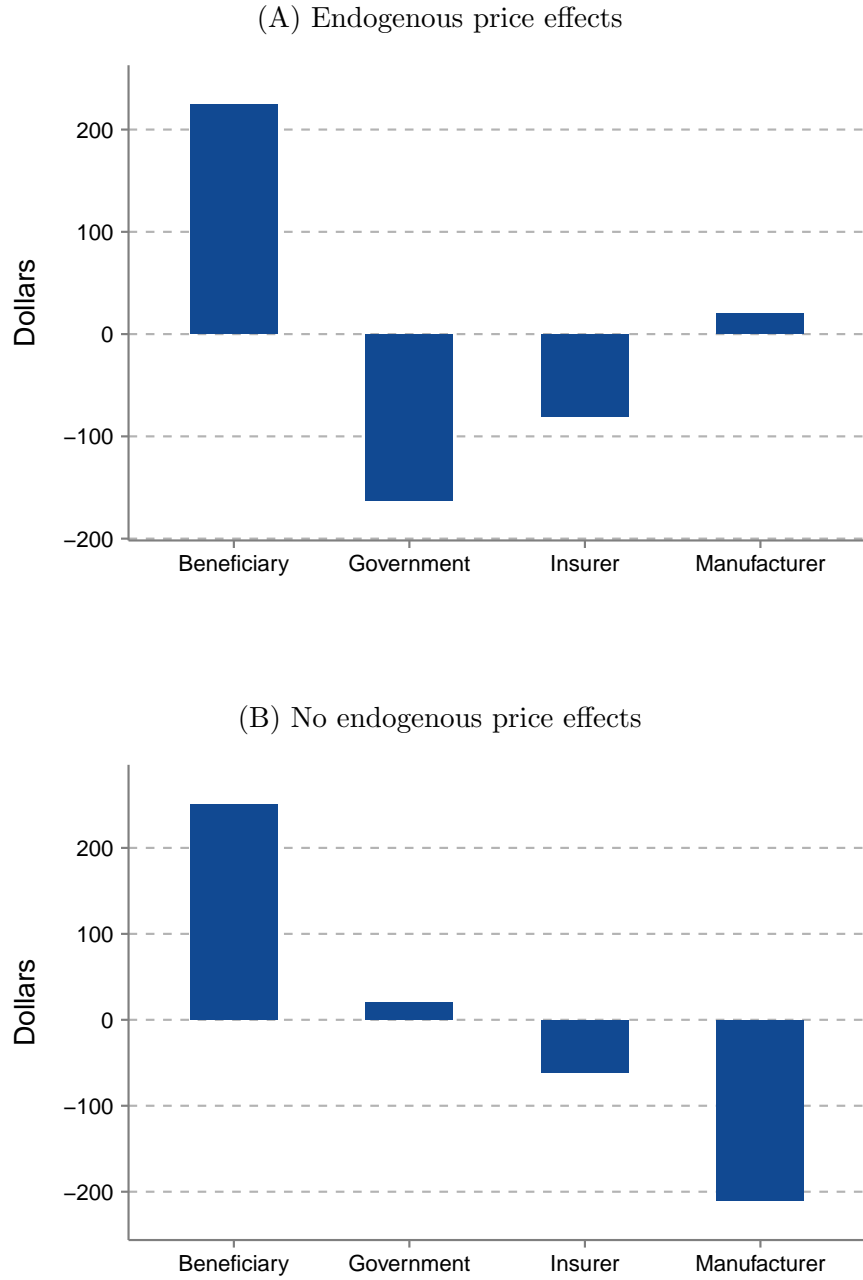
Note: This figure illustrates estimation results for our baseline event study specification (2). Our analysis sample are brand-name drugs sold in Part D in 2010. Our drug-market specific exposure measure is defined in Equation (1). In this specification, we compare drug-markets above versus below the first quartile of the spending-weighted *gap share* distribution. Figure 9 shows a histogram of the exposure measure and Table 7 summarizes key moments of the distribution. The event study includes drug-market, market-year, and patent expiration year-year specific fixed effects. We weight each observation by its drug-market revenue in 2010. Results show the point estimates β^t and 95% confidence intervals. Standard errors are clustered at the drug-market level.

Figure 11: Event study, heterogeneity by exposure quartiles



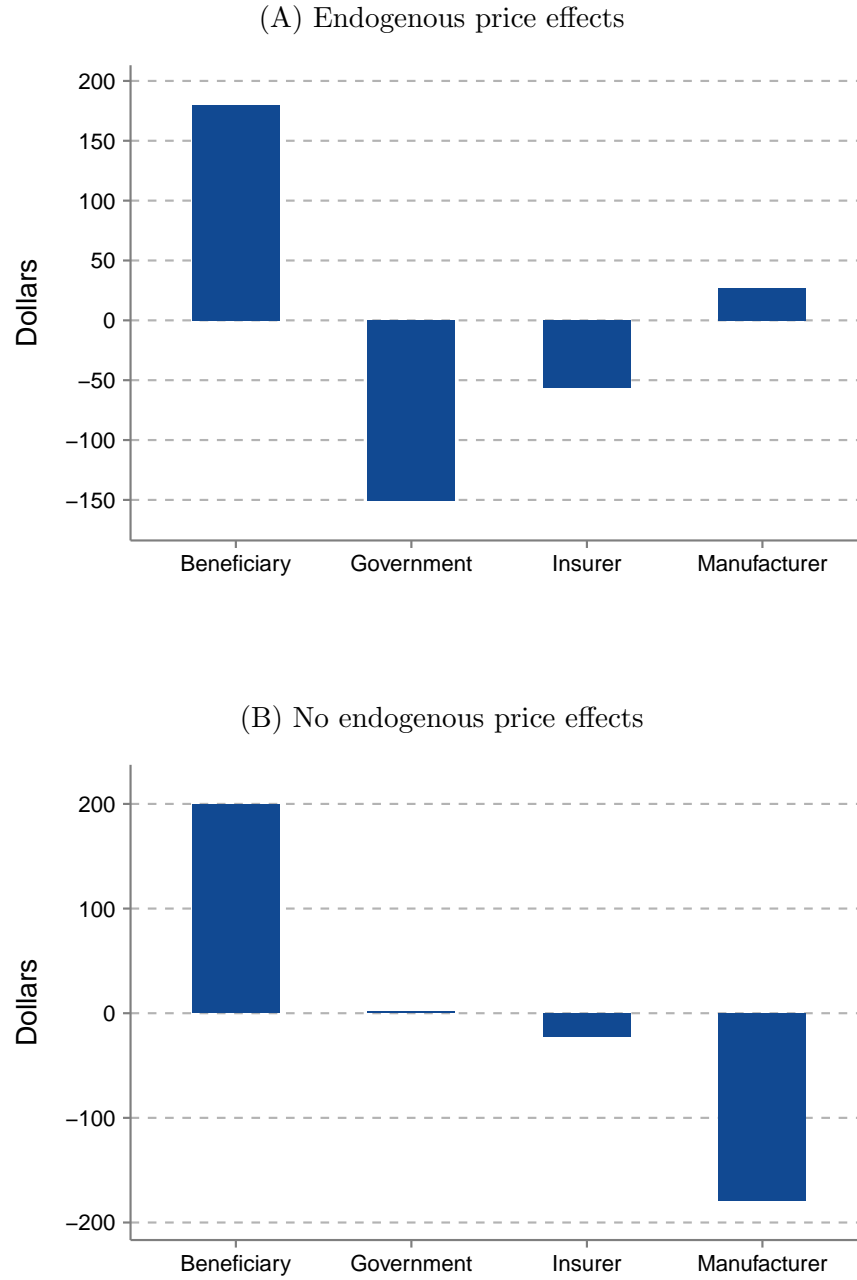
Note: Figure illustrates estimation results for our event study specification with separate indicator variables for the second, third, and fourth quartile of the *gap share* distribution. Our analysis sample are brand-name drugs sold in Part D in 2010. Our drug-market specific exposure measure is defined in Equation (1). In this specification, we compare drug-markets below the first quartile of the spending-weighted *gap share* distribution to drug-markets in the second, third, or fourth quartile. Figure 9 shows a histogram of the exposure measure and Table 7 summarizes key moments of the distribution. The event study includes drug-market, market-year, and patent expiration year-year specific fixed effects. We implement the event study separately for drugs with and without a generic alternative. We weight each observation by its drug-market revenue in 2010. Results show the point estimates and 95% confidence intervals. Standard errors are clustered at the drug-market level.

Figure 12: Distributional incidence of policy change, Laspeyres index



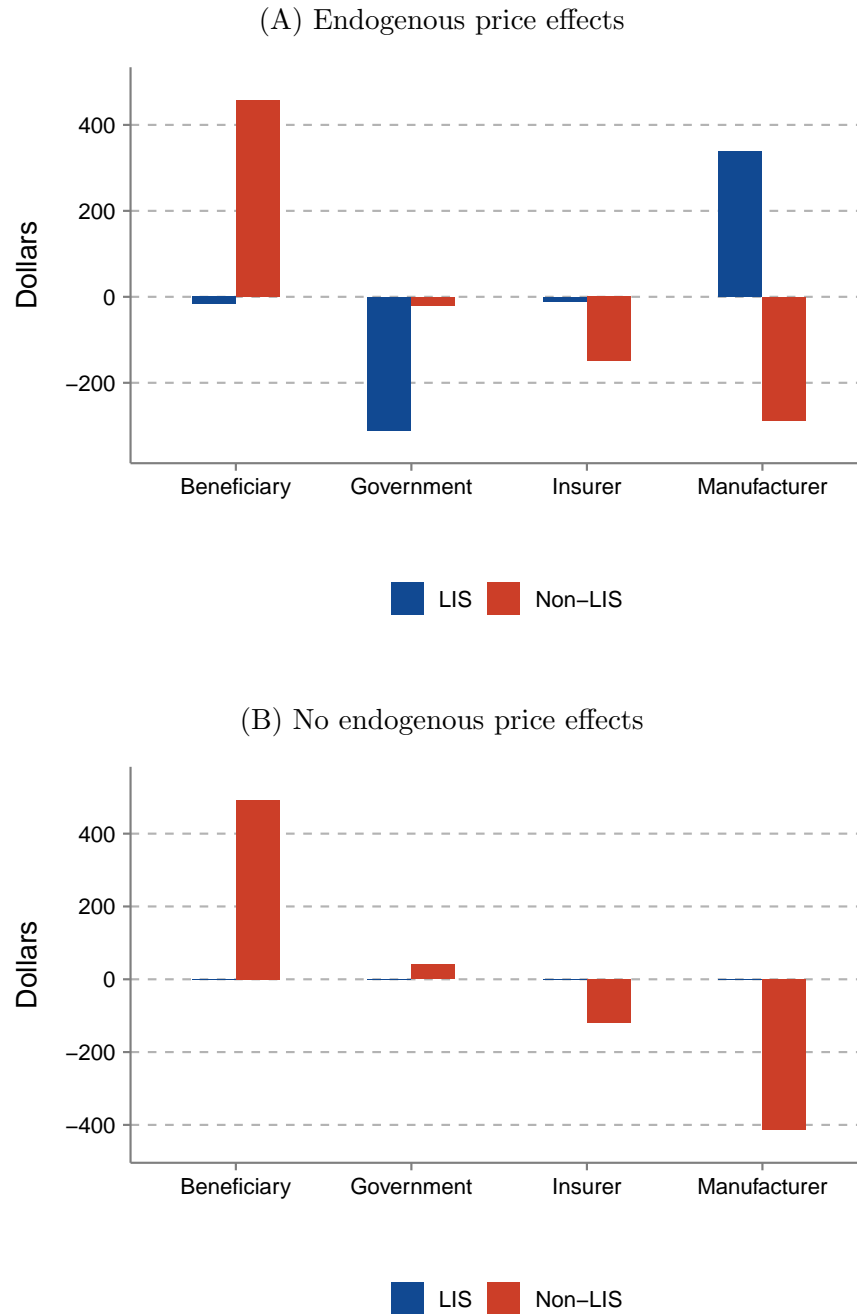
Note: This figure presents the distributional incidence of the closure of the coverage gap by payer (i.e., beneficiary, government, insurer, and manufacturer). The Laspeyres index calculates a first-order approximation of distributional incidence using beneficiary behavior prior to the policy change (i.e., consumption in 2010). The Paasche index calculates a first-order approximation of distributional incidence using beneficiary behavior after the policy change (i.e., consumption in 2018). Panel A presents distributional incidence incorporating general equilibrium price response by manufacturers as estimated in Equation (2) in Section 5. Panel B presents distributional incidence assuming fixed prices.

Figure 13: Distributional incidence of policy change, Paasche index



Note: This figure presents the distributional incidence of the closure of the coverage gap by payer (i.e., beneficiary, government, insurer, and manufacturer). The Laspeyres index calculates a first-order approximation of distributional incidence using beneficiary behavior prior to the policy change (i.e., consumption in 2010). The Paasche index calculates a first-order approximation of distributional incidence using beneficiary behavior after the policy change (i.e., consumption in 2018). Panel A presents distributional incidence incorporating general equilibrium price response by manufacturers as estimated in Equation (2) in Section 5. Panel B presents distributional incidence assuming fixed prices.

Figure 14: Distributional incidence of policy change by LIS status, Laspeyres index



Note: This figure presents the distributional incidence of the closure of the coverage gap by payer (i.e., beneficiary, government, insurer, and manufacturer). The Laspeyres index calculates a first-order approximation of distributional incidence using beneficiary behavior prior to the policy change (i.e., consumption in 2010). The Paasche index calculates a first-order approximation of distributional incidence using beneficiary behavior after the policy change (i.e., consumption in 2018). Panel A presents distributional incidence incorporating general equilibrium price response by manufacturers as estimated in Equation (2) in Section 5. Panel B presents distributional incidence assuming fixed prices.

Table 1: Cost-sharing in the coverage gap of the standard benefit design

Year	Brand-name drugs (%)			Generic drugs (%)	
	Beneficiary	Plan	Manufacturer	Beneficiary	Plan
2010	100	0	0	100	0
2011	50	0	50	93	7
2012	50	0	50	86	14
2013	47.5	2.5	50	79	21
2014	47.5	2.5	50	72	28
2015	45	5	50	65	35
2016	45	5	50	58	42
2017	40	10	50	51	49
2018	35	15	50	44	56
2019	25	5	70	37	63
2020+	25	5	70	25	75

Note: Table presents, for years 2010-2018, the cost-sharing rates in the coverage gap for the government-defined standard plan. Specifically, table illustrates how the cost of a prescription drug claim in the coverage gap is split between the patient, insurance plan, and drug manufacturer (in the case of a claim for a brand-name drug filled by a non-LIS beneficiary).

Table 2: Beneficiary characteristics, by year

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Age	69.6	69.6	69.2	69.2	69.1	68.9	68.9	69.0	69.2	69.4	69.6	69.8	70.1
Female (%)	61.8	61.3	61.2	60.8	60.5	60.1	59.6	59.2	59.1	58.7	58.2	58.0	57.8
OASI (%)	76.4	76.0	74.6	74.0	73.4	73.0	73.0	73.4	76.5	77.7	78.9	80.2	81.5
Non-LIS, pre gap (%)	38.9	36.9	36.8	38.0	38.5	39.3	41.8	43.6	44.4	46.8	49.7	52.3	53.6
Non-LIS, gap (%)	10.9	14.6	13.6	12.4	11.5	11.5	10.4	10.6	11.8	11.6	10.6	9.7	10.3
LIS recipients (%)	50.2	48.4	49.6	49.6	50.0	49.2	47.8	45.9	43.8	41.6	39.7	37.9	36.1
Dual-eligible (%)	39.0	38.5	39.9	40.3	40.8	40.2	39.5	37.9	36.5	34.5	33.1	31.5	30.0
N (beneficiaries)	3,342,938	3,447,934	3,345,512	3,359,779	3,382,016	3,493,419	3,593,369	3,688,403	3,806,862	3,971,679	4,108,377	4,219,480	4,274,781

Note: Table summarizes demographics of beneficiaries in our sample by year: total number of beneficiaries, average age at the end of the year, percentage female beneficiaries, percentage of beneficiaries qualifying for Medicare via the “Old age and survivor’s insurance” (OASI), percentage of beneficiaries who are non-LIS and do not enter the coverage gap, percentage of beneficiaries who are non-LIS and enter the coverage gap or catastrophic phase, percentage of beneficiaries who are LIS recipients, percentage of beneficiaries who are dual-eligible for Medicare and Medicaid.

Table 3: Average plan enrollment statistics, by year

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
a) <i>Non-LIS, pre gap</i>													
Premium (\$)	29.1	30.2	32.1	38.6	40.9	39.6	38.4	37.8	36.6	36.2	37.4	37.1	36.8
Deductible (\$)	84.3	87.3	65.5	67.4	74.5	86.0	88.0	96.2	108.3	128.5	149.5	176.5	188.9
ICL (\$)	2417.0	2508.6	2501.2	2729.2	2823.9	2734.2	2765.8	2770.6	2615.4	2717.3	2994.8	3274.6	3244.9
Gap coverage, brand (%)	6.8	1.7	0.0	0.0	0.1	2.5	1.9	4.5	13.1	11.1	9.0	10.7	22.3
Gap coverage, generic (%)	10.5	10.8	9.1	8.5	7.6	22.8	8.3	9.5	6.0	13.2	16.6	18.2	29.7
N (beneficiaries)	1,298,753	1,272,600	1,231,178	1,275,640	1,303,171	1,372,395	1,500,816	1,606,421	1,691,116	1,859,031	2,041,124	2,208,818	2,291,629
b) <i>Non-LIS, gap</i>													
Premium (\$)	32.9	35.3	39.1	44.7	46.7	46.8	46.7	46.4	46.6	45.3	47.8	49.4	49.9
Deductible (\$)	93.7	77.3	58.9	62.6	74.1	66.1	67.8	71.2	70.1	76.3	96.8	107.3	112.6
ICL (\$)	2415.5	2505.6	2498.7	2729.2	2824.5	2734.2	2765.8	2770.6	2615.4	2717.3	2994.8	3274.6	3244.9
Gap coverage, brand (%)	0.5	0.1	0.0	0.1	0.3	5.9	4.7	12.5	21.3	18.2	14.9	19.5	39.8
Gap coverage, generic (%)	10.3	23.1	23.6	21.2	18.9	29.5	17.9	19.5	14.7	21.7	22.8	28.4	49.2
N (beneficiaries)	365,230	504,922	453,615	417,088	387,397	402,261	374,347	389,687	450,049	459,347	434,236	410,313	441,511
c) <i>LIS</i>													
Premium, charged (\$)	26.5	25.2	25.4	29.5	31.4	31.4	30.2	30.6	28.0	27.0	27.6	28.4	27.4
Premium, paid (\$)	0.9	1.4	1.7	2.7	2.4	2.1	2.5	2.6	2.8	2.7	3.0	2.8	3.0
Deductible (\$)	155.2	187.0	205.7	239.3	264.1	223.2	252.2	248.5	230.6	186.5	204.4	218.0	209.9
ICL (\$)	2417.4	2512.9	2505.0	2730.6	2829.5	2734.2	2765.8	2770.7	2615.4	2717.3	2994.8	3274.6	3244.9
Gap coverage, brand (%)	0.4	0.1	0.0	0.0	0.0	0.4	0.3	0.8	2.4	2.2	1.8	2.1	4.9
Gap coverage, generic (%)	0.9	1.5	1.1	1.1	0.9	3.5	0.9	1.2	0.8	2.3	3.1	3.4	6.0
N (beneficiaries)	1,678,955	1,670,412	1,660,719	1,667,051	1,691,448	1,718,763	1,718,206	1,692,295	1,665,697	1,653,301	1,633,017	1,600,349	1,541,641

Note: Table summarizes key characteristics of Part D plans (PDPs) chosen by beneficiaries in our sample, by year. We split the sample into a) non-LIS beneficiaries who do not enter the coverage gap in a given year, b) non-LIS beneficiaries who enter the coverage gap at some point in a year, and c) LIS beneficiaries. Across beneficiaries in a group and year, the table shows the average monthly premium amount, the average deductible amount and initial coverage limit (ICL) amount, the percentage enrolled in a plan with some additional coverage in the gap for brand-name or generic drugs, and the number of beneficiaries. We report the average monthly premium charged by the plan and, for LIS beneficiaries, the average monthly premium paid. All nominal amounts are inflation-adjusted to September 2010. We follow CMS' approach to adjust the threshold amounts in the standard plan design and use the September CPI for All Urban Consumers (CPI-U; all items; not seasonally adjusted).

For comparison, the (not) inflation-adjusted deductible amounts in the standard benefit design for 2006-2018 are: 269.1 (250), 277.6 (265), 274.6 (275), 298.4 (295), 310.0 (310), 298.5 (310), 302.1 (320), 303.2 (325), 284.5 (310), 293.8 (320), 325.7 (360), 354.0 (400), 350.5 (405). The initial coverage limits are: 2,422.3 (2,250), 2,514.5 (2,400), 2,506.1 (2,510), 2,730.9 (2,700), 2,830.0 (2,830), 2,734.2 (2,840), 2,765.8 (2,930), 2,770.7 (2,970), 2,615.4 (2,850), 2,717.3 (2,960), 2,994.8 (3,310), 3,274.6 (3,700), 3,244.9 (3,750).

Table 4: Average annual drug spending and consumption statistics, by year

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
a) <i>Non-LIS, pre gap</i>													
Annual spending (\$)	1,072	1,051	983	1,046	1,032	937	879	827	743	704	696	684	640
from branded drugs (%)	74.9	69.6	62.6	61.8	59.4	56.5	51.4	46.4	42.5	40.7	41.1	38.7	37.3
Annual OOP spending (\$)	386	373	329	371	381	345	325	302	289	279	286	293	283
from branded drugs (%)	79.2	72.9	67.9	66.1	60.6	54.6	46.5	42.1	34.6	31.0	28.5	25.0	24.0
Annual days' supply	692	805	877	933	978	990	1,034	1,092	1,084	1,099	1,135	1,156	1,162
from branded drugs (%)	40.6	31.8	23.9	21.2	18.0	14.6	10.8	8.0	6.3	5.1	4.5	3.9	3.4
b) <i>Non-LIS, gap</i>													
Annual spending (\$)	4,263	4,598	4,629	5,078	5,316	5,525	5,967	6,441	7,033	8,234	9,220	10,089	10,353
from branded drugs (%)	81.8	81.1	79.6	80.5	80.6	80.8	80.3	81.2	82.3	85.2	86.7	86.9	87.8
Annual OOP spending (\$)	1,835	1,937	1,939	2,122	2,177	1,661	1,692	1,669	1,660	1,760	1,851	1,870	1,800
from branded drugs (%)	82.5	83.6	82.7	81.8	80.0	74.8	71.9	72.5	70.1	72.2	74.4	73.4	74.1
Annual days' supply	1,821	1,990	2,044	2,064	2,096	2,155	2,218	2,281	2,251	2,255	2,313	2,373	2,381
from branded drugs (%)	51.7	46.0	39.7	38.0	34.9	32.2	27.7	24.3	21.7	20.6	20.1	19.0	18.5
Days until gap	248	232	233	235	235	231	226	227	217	212	212	213	206
Enters catastrophic phase (%)	11.4	12.7	14.1	14.2	14.2	16.2	16.7	17.5	20.4	22.6	24.0	24.8	24.8
c) <i>LIS</i>													
Annual spending (\$)	3,360	3,707	3,832	4,067	4,150	4,193	4,106	4,236	4,742	5,204	5,276	5,369	5,467
from branded drugs (%)	80.3	80.2	78.6	77.8	78.6	78.6	75.2	74.2	76.4	78.3	78.8	79.2	79.9
Annual OOP spending (\$)	79	92	87	93	95	86	73	73	66	65	64	62	60
from branded drugs (%)	71.0	70.1	64.7	60.9	55.9	51.0	45.7	40.3	38.6	36.9	35.8	34.6	33.5
Annual days' supply	1,256	1,412	1,489	1,543	1,572	1,589	1,605	1,675	1,686	1,683	1,696	1,707	1,716
from branded drugs (%)	44.2	39.8	34.9	32.0	29.0	26.4	21.8	18.3	16.8	15.4	14.4	13.3	12.8
Enters gap (%)	44.0	46.2	46.5	45.4	43.9	43.6	41.1	40.3	41.8	40.4	37.7	35.3	35.3
Days until gap	193	186	184	185	185	180	175	180	171	168	170	171	166
Enters catastrophic phase (%)	18.2	19.9	20.9	20.2	19.7	20.7	19.2	19.5	22.0	22.0	21.2	20.8	21.2

Note: Table summarizes average annual drug consumption and spending patterns for beneficiaries in our sample, by year. We split the sample into a) non-LIS beneficiaries who do not enter the coverage gap in a given year, b) non-LIS beneficiaries who enter the coverage at some point in a year, and c) LIS beneficiaries. Across beneficiaries in a group and year, the table shows the average annual drug spending, annual out-of-pocket spending, and annual days' supply of prescription drugs. For each component, the table also shows the average percentage from brand-name drugs. For sample *b) Non-LIS, gap*, the table also shows the average number of days in a year after which a beneficiary first entered the gap, as well as the percentage of beneficiaries who enter the catastrophic phase at some point of the year. For sample *c) LIS*, the table also shows the percentage of beneficiaries who enter the coverage gap at some point of the year. All nominal amounts are inflation-adjusted to September 2010. We follow CMS' approach to adjust the threshold amounts in the standard plan design and use the September CPI for All Urban Consumers (CPI-U; all items; not seasonally adjusted).

Table 5: Summary statistics of brand-name drugs in 2010

	Mean	SD	p10	p25	p50	p75	p90
Average price per days' supply (\$)	35.12	211.76	1.76	3.30	6.49	16.68	56.42
Non-LIS gap spending (\$)	5,905	32,806	0	91	487	2,117	8,879
Total spending (\$)	103,548	418,577	1,212	2,802	9,381	46,039	200,439
Government spending, LIS (\$)	27,938	121,052	263	767	2,655	10,757	44,934
Government spending, catastrophic phase (\$)	4,692	24,187	0	7	174	1,165	7,147
Total days' supply	15,614	75,156	350	538	1,049	3,770	23,932
N (drugs)	2,452						

Note: Table shows summary statistics for our sample of brand-name prescription drugs in 2010. For each drug, we compute the revenue-weighted average price days' supply across markets, as well as the unweighted average of non-LIS gap spending, total spending, government spending for LIS, government spending for non-LIS in the catastrophic phase, and total days' supply. Summary statistics are unweighted.

Table 6: Comparison of brand-name drug characteristics by policy exposure

	Below Q1		Above Q1	
	Mean	SD	Mean	SD
Average price per days' supply in 2010 (\$)	68.05	211.97	18.14	77.67
Gap share (%)	2.57	1.20	10.55	3.72
Form, tablet (%)	65.85		57.85	
Form, capsule (%)	13.64		18.09	
Form, solution (%)	7.54		12.01	
Route, oral (%)	79.56		73.93	
Route, subcutaneous (%)	3.55		8.65	
Route, ophthalmic (%)	1.25		2.99	
Protected drug class (%)	62.83		13.77	
Therapy, primarily chronic (%)	43.44		65.79	
Generic alternative available (%)	66.80		71.26	
Approval year observed (%)	97.95		99.81	
Approval year ^{*)}	1999.80	7.76	1999.32	5.98
Patent expiration year observed (%)	91.41		96.17	
Patent expiration year ^{*)}	2020.71	6.10	2020.73	5.76
Loses patent between 2011-2018 ^{*)}	43.04		29.10	
Stays on patent after 2018 ^{*)}	54.10		69.25	
N (drugs)	858		1,594	

Note: Table compares characteristics of brand-name drugs by policy exposure. In particular, we compare drugs with a revenue-weighted average *gap share* below versus above the 25th percentile of 4.92. In addition, we compute the revenue-weighted average price per days' supply in 2010. Drug-level characteristics on form, route of administration, drug class, and availability of generic alternative come from the IBM MarketScan[®] Redbook. Information on drug approval year and patent expiration year come from the DrugsFDA database and the Orange Book. Statistics are weighted by Part D spending in 2010.

^{*)} Only for drugs with observed approval or patent expiration year. Patent expiration is the maximum of patent expiration and marketing exclusivity expiration.

Table 7: Summary statistics of drug-markets in 2010

	Mean	SD	p10	p25	p50	p75	p90
Average price per days' supply (\$)	30.61	145.55	3.49	4.63	6.88	17.80	53.55
Log(average price per days' supply)	2.32	1.16	1.25	1.53	1.93	2.88	3.98
Gap share (%)	8.56	5.71	1.48	4.32	8.26	11.75	15.64
N (drug-markets)	40,652						

Note: Table shows summary statistics for our sample of drug-markets in 2010. Statistics are weighted by Part D spending in 2010.

Table 8: Event study, baseline specification and robustness checks

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
	Baseline	Group-year FE	Balanced panel	Matched NDA	Simple exposure	With generic	Without generic	Loses patent	Stays on patent
$\mathbb{1}\{2006\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.022*** (0.007)	0.012* (0.007)	0.011 (0.008)	0.006 (0.007)	0.023*** (0.008)	0.021*** (0.007)	0.035* (0.018)	0.002 (0.008)	0.006 (0.011)
$\mathbb{1}\{2007\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.003 (0.006)	-0.001 (0.006)	-0.008 (0.007)	-0.006 (0.005)	0.003 (0.006)	0.014*** (0.005)	0.010 (0.016)	0.003 (0.006)	-0.017** (0.008)
$\mathbb{1}\{2008\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	-0.006 (0.005)	-0.003 (0.005)	-0.014** (0.006)	-0.014*** (0.004)	-0.009 (0.005)	0.003 (0.004)	-0.004 (0.013)	-0.001 (0.005)	-0.021*** (0.006)
$\mathbb{1}\{2009\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	-0.000 (0.003)	-0.000 (0.004)	-0.007** (0.003)	-0.003 (0.003)	-0.002 (0.003)	0.003 (0.003)	0.003 (0.007)	0.001 (0.003)	-0.006 (0.005)
$\mathbb{1}\{2010\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)
$\mathbb{1}\{2011\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.017*** (0.003)	0.010*** (0.003)	0.011*** (0.003)	0.021*** (0.002)	0.016*** (0.003)	0.009*** (0.003)	0.019*** (0.006)	0.007** (0.003)	0.032*** (0.003)
$\mathbb{1}\{2012\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.043*** (0.004)	0.031*** (0.004)	0.031*** (0.005)	0.049*** (0.004)	0.042*** (0.004)	0.032*** (0.004)	0.046*** (0.009)	0.035*** (0.006)	0.058*** (0.004)
$\mathbb{1}\{2013\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.078*** (0.006)	0.074*** (0.007)	0.067*** (0.007)	0.084*** (0.006)	0.076*** (0.006)	0.053*** (0.008)	0.089*** (0.009)	0.072*** (0.011)	0.094*** (0.006)
$\mathbb{1}\{2014\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.120*** (0.008)	0.113*** (0.009)	0.107*** (0.009)	0.124*** (0.008)	0.117*** (0.008)	0.096*** (0.011)	0.120*** (0.011)	0.146*** (0.016)	0.112*** (0.009)
$\mathbb{1}\{2015\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.151*** (0.010)	0.131*** (0.010)	0.143*** (0.011)	0.155*** (0.010)	0.149*** (0.010)	0.125*** (0.014)	0.144*** (0.014)	0.189*** (0.020)	0.139*** (0.011)
$\mathbb{1}\{2016\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.169*** (0.012)	0.157*** (0.012)	0.154*** (0.014)	0.172*** (0.012)	0.168*** (0.012)	0.141*** (0.016)	0.156*** (0.017)	0.190*** (0.024)	0.162*** (0.012)
$\mathbb{1}\{2017\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.179*** (0.013)	0.168*** (0.013)	0.169*** (0.015)	0.182*** (0.013)	0.181*** (0.013)	0.146*** (0.019)	0.162*** (0.019)	0.199*** (0.027)	0.174*** (0.014)
$\mathbb{1}\{2018\} \times \mathbb{1}\{\text{gap share} > Q_1\}$	0.188*** (0.015)	0.186*** (0.014)	0.171*** (0.018)	0.191*** (0.015)	0.188*** (0.015)	0.142*** (0.023)	0.178*** (0.021)	0.172*** (0.033)	0.199*** (0.015)
Q_1	4.32	4.32	4.66	4.34	2.70	4.32	4.32	4.57	4.57
R^2	0.982	0.985	0.982	0.981	0.982	0.974	0.989	0.971	0.984
N	356,446	356,446	178,366	316,712	356,446	237,691	118,755	108,793	149,600

Note: Table summarizes estimation results of our event study. Our analysis sample are brand-name drugs sold in Part D in 2010. Our drug-market specific exposure measure is defined in Equation (1). In all specifications, we compare drug-markets above versus below the first quartile of the spending-weighted *gap share* distribution. All specifications include drug-market, market-year, and patent expiration year-year fixed effects. Column (1) reports our baseline specification in Equation (2). Column (2) adds therapeutic group \times year fixed effects to the baseline specification. Column (3) adds drug approval year \times year fixed effects to the baseline specification. We assign drugs with missing approval year to a separate category. Column (4) adds patent expiration year \times year fixed effects to the baseline specification. We take maximum of the patent expiration year and the marketing exclusivity expiration year. We assign drugs with missing patent expiration year to a separate category. Column (5) reports our baseline specification estimated on a balanced panel of drug-market-years. Column (6) reports our baseline specification estimated on the subset of drugs successfully linked to a New Drug Application (NDA) number. Column (7) reports our baseline specification using a simplified exposure measure that does not subtract government-financed spending from total drug-market revenue in 2010. In estimation, we weight each observation by its drug-market revenue in 2010. Standard errors, in parentheses, are clustered at the drug-market level. Q_1 denotes the 25th percentile of the respective revenue-weighted *gap share* distribution used to split the sample into high- and low-exposure. N denotes the unweighted number of observations (drug-market-years). * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

Appendix

Appendix A: Sample construction

This section details the construction of our analysis samples.

1. Administrative Medicare Part D beneficiaries and claims data: Our sample of Part D beneficiaries is derived from a 20% random sample of the Medicare population from 2006-2018. We select all individuals enrolled in a Part D standalone prescription drug plan. Thus, we exclude Medicare-Advantage, employer-sponsored, and PACE plans—the latter two plan types are not required to report benefit package information. We measure an individual’s plan and cost-sharing group (LIS or non-LIS) in December of a given year. We group together LIS beneficiaries receiving partial or full premium and cost-sharing support. We identify all prescriptions filled by an individual in our sample and exclude claims for drugs not covered by the plan. The final sample comprises 8.2 million beneficiaries, 48 million beneficiary-years, and close to 1.9 billion claims for 74,765 unique NDC codes. This dataset is used to analyze the beneficiary response to the closing of the coverage gap in [Section 4](#).

2. Drug characteristics from IBM MarketScan® Redbook: We combine the Part D claims data with the IBM MarketScan® Redbook, which contains NDC-level information on brand status, form, route of administration, therapeutic group, and the product name given by the manufacturer. Importantly, the Redbook also contains a variable that identifies all NDCs describing pharmaceutically equivalent products, meaning products that contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration. We successfully merge 94.9% (70,953) of all NDCs from the Part D data, which account for more than 99.9% of Part D revenue.

3. National Drug Code Directory, Drugs@FDA, and Orange Book: We obtained historical versions of NDC Directory, Drugs@FDA, and the Orange Book for the years 2006-2018 from the [Wayback Machine](#). The NDC Directory lists the universe of drug products, at the NDC level, for sale in the U.S. Importantly, it links NDC codes to the FDA-registered drug application number. The Drugs@FDA database includes information in the universe of drugs approved for human use in the U.S., such as application type (e.g., New Drug Application, Biologics License Application, or Abbreviated New Drug Application) and drug approval year. Lastly, the Electronic Orange Book contains patent and marketing exclusivity expiration dates for drugs that were ever granted such a right. We combine these three data source, which allows linkage from NDC codes to patent and marketing expiration dates.

Appendix B: Empirical evidence on price concessions for brand-name drugs

Several studies have analyzed estimates of net-of-rebate prices from SEC filings of publicly traded pharmaceutical companies (Hernandez et al. 2020; Kakani et al. 2020; Sood et al. 2020). However, these data do not apply directly to our setting for two reasons: First, they are economy-wide estimates of rebates, averaging across payers such as Medicaid which mandates significantly higher price concessions (Sood et al. 2020). Second, rebate estimates capture all types of manufacturer discounts, including copay coupons and 340B discounts which are not available to Part D beneficiaries due to the Anti-Kickback Statute. Both reasons let us believe that economy-wide estimates likely overestimate rebates provided in Part D. Only Sood et al. (2020) single out Medicaid rebates and find that discounts across all other US payers increased from 23% to 51% between 2007-2018. Notably, these numbers are weighted by utilization and adjusted for inflation.

Most related to our setting is a report by the Office of the Inspector General Inspection General (2019b), which uses data on direct and indirect remunerations reported by Part D plans to study rebate trends for 1,510 brand-name drugs between 2011-2015. The report finds that rebate payments are highly concentrated with about 10% of drugs accounting for 90% of total rebate amount. In addition, between 2011 and 2015, 58% of reviewed drugs experienced an increase in the per-unit rebate amount, while 42% experienced a decrease. While almost all drugs saw an increase in the retail price, the rebated amount increased for only 56% of drugs. Overall, the rebate rate decreased for over half of reviewed drugs: the median rebate rate was 1.6% in 2011 and 0.3% in 2015. While these numbers suggest that rebate rates in Part D are fairly low, contrary to the findings in Sood et al. (2020), it is unclear how they relate to drug spending and policy exposure.

In addition, the Board of Trustees (2019) presents aggregate rebate numbers of the Part D market.

Appendix C: Further provisions of the ACA related to the pharmaceutical market

This section summarizes further provisions that were implemented under the Affordable Care Act (ACA) of 2010 and involved the pharmaceutical market. The summary is largely based on the Board on Health Care Services, [2014](#), Aitken et al. ([2016](#)) and Conti et al. ([2020](#)). Only the first provision, the *Branded Prescription Drug Fee*, coincided with the start of the closure of the coverage gap.

Introduction of the *Branded Prescription Drug Fee*: Starting January 2011, high-revenue drug companies (exceeding \$5 million of annual sales to government programs) have to collectively finance the Branded Prescription Drug Fee (\$2.5-4.1 billion annually), which funds the Medicare Part B (outpatient benefit) Trust Fund. The fee is divided up proportionately so that companies with a larger share of sales pay more.

Increase in mandatory minimum Medicaid rebates: Starting January 2010, the mandatory minimum rebate that manufacturers have to provide for brand-name drugs sold under Medicaid increased from 15.1% to 23.1%. In addition, manufacturers have to pay an additional rebate if drug prices increase faster than inflation. The latter provision has been the main reason for the rise of Medicaid rebates over time (Office of the Inspector General Inspection General ([2019a](#))).

Health Insurance Marketplaces: Individuals could enroll in insurance plans offered through the ACA Marketplaces for the first time in October, 2013.

Medicaid Expansion: Starting January 2014, expansion states increased the eligibility criteria to qualify for Medicaid coverage.

Appendix D: Additional descriptive statistics

Below, we include further descriptive statistics about the sample of brand-name drugs. This sample is the basis of our analysis of the effect on retail prices.

Appendix Table A1: Annual percent of total Part D spending, days' supply, and claims for brand-name drugs

Year	Spending (%)	Days' supply (%)	Claims (%)
2006	79.7	44.7	42.6
2007	79.0	39.4	37.7
2008	76.8	33.3	32.3
2009	76.3	30.3	29.7
2010	76.5	27.0	26.7
2011	76.4	24.1	24.0
2012	73.3	19.4	19.9
2013	72.5	15.9	17.0
2014	74.5	14.3	15.5
2015	76.6	12.7	14.1
2016	77.3	11.5	13.0
2017	77.1	10.3	12.0
2018	78.1	9.8	11.7

Note: Table shows, by year, the percent of total Part D spending, days' supply, and number of filled prescription drug claims that are accounted for by brand-name prescription drugs.

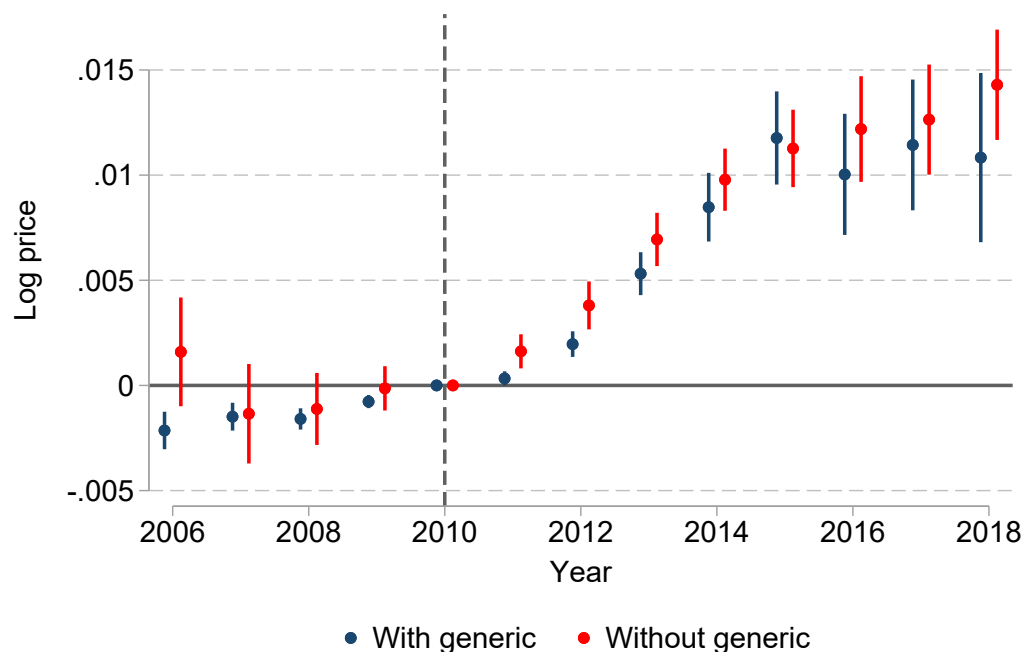
Appendix Table A2: Annual percent of spending, days' supply, and claims captured by brand-name drugs in our analysis sample

Year	Spending		Days' supply		Claims	
	Total	Branded	Total	Branded	Total	Branded
2006	73.7	92.5	41.9	93.7	39.5	92.7
2007	74.7	94.6	37.7	95.7	35.9	95.2
2008	74.4	96.9	32.6	98.1	31.6	97.8
2009	75.1	98.5	30.1	99.3	29.4	99.1
2010	75.7	99.0	26.9	99.7	26.6	99.6
2011	74.6	97.6	24.0	99.3	23.8	99.1
2012	69.0	94.2	19.0	98.0	19.4	97.6
2013	64.5	89.1	15.1	95.0	16.0	94.4
2014	57.6	77.3	12.9	90.3	13.8	89.2
2015	50.9	66.5	10.7	84.1	11.7	82.9
2016	46.6	60.3	8.9	77.2	9.8	75.8
2017	41.5	53.8	7.1	69.1	8.1	68.0
2018	35.7	45.6	6.0	61.1	7.0	59.7

Note: Table shows, by year, the percent of total (brand-name) Part D spending, days' supply, and number of claims accounted for by the brand-name drugs in our analysis sample.

Appendix E: Additional event study results

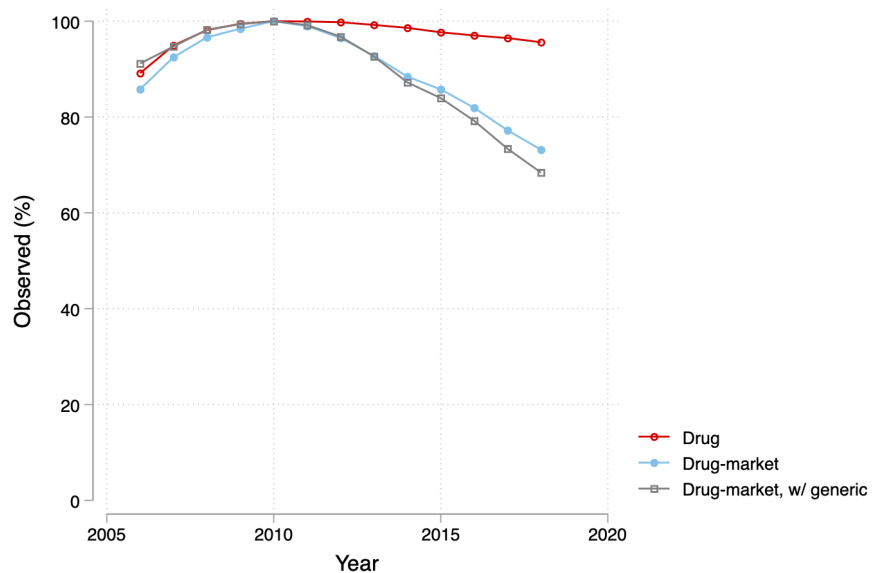
Appendix Figure A1: Event study, linear exposure effect



Note: This figure illustrates the estimation results of our event study specification with a linear effect of policy exposure on retail prices. Our analysis sample are brand-name drugs sold in Part D in 2010. Our drug-market specific exposure measure is defined in Equation (1). In this specification, we replace the exposure indicator in Equation (2) with the continuous *gap share* variable. Figure 9 shows a histogram of the exposure measure and Table 7 summarizes key moments of the distribution. The event study includes drug-market, market-year, and patent expiration year-year fixed effects. We estimate the event study separately for drugs with and without a generic alternative. Results show the point estimates for a one-unit increase in *gap share*, together with 95% confidence intervals. Standard errors are clustered at the drug-market level.

Appendix F: Attrition from brand-name drugs sample

Appendix Figure A2: Attrition from branded-drugs sample



Note: Figure illustrates attrition from our analysis sample of brand-name drugs sold in Part D in 2010. For each year, we show the share observed, weighted by 2010 revenue, at the drug level and the drug-market level. We separately show attrition for drugs with a generic substitute available. Attrition at the drug level is limited and with most variation in policy exposure and prices at the drug level (rather than drug-market level), sample attrition has little effect on our estimation results.