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Understanding Society

Cost-sharing and drug pricing strategies: Introducing tiered co-payments in reference price markets*

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Abstract

Health insurances curb price insensitive behavior and moral hazard of insureds through different types of cost-sharing, such as tiered co-payments or reference pricing. This paper evaluates the effect of newly introduced price limits –below which drugs are exempt from co-payments– on the pricing strategies of drug manufacturers in reference price markets. We exploit quarterly data on all prescription drugs under reference pricing available in Germany from 2007 to 2010. To identify causal effects, we use instruments that proxy regulation intensity. A difference–in–differences approach exploits the fact that the exemption policy was introduced successively during this period. Our main results first show that the new policy led generic firms to decrease prices by 5 percent on average, while brand-name firms increase prices by 7 percent after the introduction. Second, sales increased for exempt products. Third, we find evidence that differentiated health insurance coverage (public versus private) explains the identified market segmentation.

JEL: I18, L51, I11, L11

Keywords: Pharmaceutical prices; Cost-sharing; Co-payments; Reference pricing; Regulation; Firm behavior; Health Insurance

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1 Introduction

In markets with insurance coverage, consumers are not directly exposed to the full price of their consumption. In order to reduce ex-post moral hazard and to steer consumption to preferred products or services public policymakers and health plans implement cost-sharing, exploiting consumers' price sensitivity (Berndt, McGuire, and Newhouse, 2011). For example, as a response to rising pharmaceutical expenditures health insurances have implemented reference pricing and tiered co-payments.

Standard micro-theory predicts that in markets with price-insensitive patients firms have fewer incentives to compete in prices. This paper investigates manufacturers' pricing strategies and changes in demand when the co-payment design of a nationwide public health insurance changes over time. In particular, we analyze the introduction of a policy that exempts products from co-payments if firms decrease their prices below a certain threshold: the co-payment exemption level (CEL). Since 2006, the German public health insurance may exempt drugs from all co-payments if firms set prices 30 percent or more below the reference price. The policy can be interpreted as the introduction of tiered co-payments in reference price drug markets where the placement on the lowest tier depends on the drug's price and not on its type. Typically, health plans tier co-payments depending on the drug characteristics: generic, brand-name or not-preferred (Huskamp, Frank, McGuigan, and Zhang, 2005).[1] In recent years managed care plans with tiered coinsurance rates have been on the rise (Baicker and Goldman, 2011) and also most Medicare Part D Prescription Drug Plans differentiate co-payments by drug type (Hoadley, Summer, Hargrave, Cubanski, and Neuman, 2012). From a firm's perspective, the policy aims at reducing (perceived) product differentiation. However, Huskamp, Frank, McGuigan, and Zhang (2005) show that firms' incentives to compete in prices are low once they are assigned to a specific tier. How price dependent co-payment exemptions affect firms' pricing strategies and patients' utilization is an empirical question. In contrast to previous studies, we provide a comprehensive empirical analysis of the effects of reduced cost-sharing on supply and on demand.

Our research is guided by three questions: First, we identify the causal effect of the co-payment exemption levels of low-priced drugs on firms' pricing strategies. Second, we explore changes in the utilization of exempt vs non-exempt drugs. The analysis

[1] Berndt and Newhouse (2012) give a comprehensive overview on pricing and reimbursement in pharmaceutical markets.

for one indication gives insights into the insureds' price sensitivity and the policy's effectiveness in steering demand to cost-efficient drugs. Third, we show that heterogeneous insurance coverage is a driver of observed pricing strategies. In particular, we investigate the spillover effects of the policy on privately insured patients whose out-of-pocket costs are not directly affected by the cost-sharing regulations of the public health insurance.

Throughout, we differentiate between generic and brand-name drugs and take into account the general cost-sharing regulation of the public health insurance, the reference price system.

First, to identify the causal effects of co-payment exemption levels (CEL) on drug prices we implement a difference-in-differences approach and exploit the sequential and partial introduction of the CEL over time. Between April 2007 and October 2010, the policy was exogenously introduced in over 200 of the more than 350 therapeutic markets. To account for the existing cost-sharing regulation and its potential endogeneity, we use instruments for reference prices, which capture regulation intensity. We observe product-level data on all reference price drugs marketed in Germany between 2007 and 2010 (around 70 percent of all drugs). We find an average price decrease of 5 percent for generics while prices of brand-name drugs increase by 7 percent due to the policy. Prices of imports do not significantly change. The results are robust to alternative estimation strategies and several refinements. Thus, we find heterogeneous treatment effects and market segmentation.

Second, it is crucial to understand how demand-side instruments steer drug demand toward cost-efficient products. For example, the increasing utilization due to cost-sharing is expected to generate greater price discounts by manufacturers (Pavcnik, 2002). Using additional data from *IMS Health*, we analyze the policy's effect on sales in the anti-epileptic drug market. The results show that firms gain around 12 percent in sales when decreasing prices below the CEL. In contrast, substantial losses in market shares and quantities occur when the co-payment exemption policy applies but prices are not decreased below the exemption threshold. With fixed-fee co-payments insureds have a very limited incentive to search for or switch to lower-priced substitutes in the same tier (with the same co-payment). Patients face no incremental costs from higher prices, while manufacturers gain market shares through patients' insurance coverage and through patent protection (Frank and Newhouse, 2008). Huskamp, Frank, McGuigan, and Zhang (2005) find that tiered co-payments affect utilization and patients consume more drugs from lower tiers. However, some

authors find relatively low price elasticities for prescription drugs for patients whose benefit plans changed from a two-tier to a three-tier co-payment design in the US (Landsman, Yu, X.Liu, Teutsch, and Berger, 2005; Dalton, 2014). From the patient's perspective, we analyze a drop in co-payments to zero. We therefore also complement previous literature on utilization which analyzes the effect of co-payment drops for high-spending individuals reaching their co-payment limits (Einav, Finkelstein, and Schrimpf, 2015; Gerfin, Kaiser, and Schmid, 2015) or for managed-care plans increasing co-payments from zero to some cost-sharing (Boes and Gerfin, 2015).

Third, we investigate the hypothesis that heterogeneous insurance coverage drives the firms' pricing strategies (Ferrara and Kong, 2008; Ferrara and Missios, 2012). In theory, the role of insurances on pricing strategies was first emphasized by Hellerstein (1998). Ferrara and Missios (2012) show that endogenous market segmentation based on heterogeneous insurance coverage can lead to a price increase of brand-name drugs. The analyzed cost-sharing policy was introduced for members of the statutory health insurance (90 percent of the population). However, the list prices also apply to members of private health plans. That is why we use another data set from *IMS Health* on anti-epileptics and compare the evolution of the payers' market shares of brand-name drugs in markets with and without exemption levels. Since the private payers share has increased in those markets in which the new policy was introduced for publicly insureds, we provide initial empirical evidence of market segmentation due to heterogeneous health insurance coverage.

Basic oligopolistic market models suggest that prices decrease due to more competition. Empirically, an unambiguous effect is found for generics (Wiggins and Maness, 2004; Reiffen and Ward, 2005) while the effect on brand-name prices is less clear. Looking at generic entry, several empirical studies find evidence of the *generic competition paradox*, which subsumes price increases of brand-name products after generic entry (Scherer, 1993; Regan, 2008; Frank and Salkever, 1997; Grabowski and Kyle, 2007; Bhattacharya and Vogt, 2003). Since we identify similar heterogeneous treatment effects we refer to our results on pricing as the *co-payment exemption paradox*.

Finally, the new co-payment exemption policy supplements the long-time existing German reference pricing scheme. In reference price markets, a maximum reimbursement is set based on the distribution of the past prices of all competing drugs. Patients pay all costs above the reference price and are therefore incentivized to

choose products below the average price of competitors.[2] In our model we control for changes in the reference price, applying a linear instrumental variables approach. We find that reference prices have a positive impact on prices, which indicates that they are an effective cost-control in pharmaceutical markets. Reference prices induce price competition since drugs are defined to be substitutable within the same therapeutic market, which has a similar effect as tiered co-payments, decreasing product differentiation. The empirical literature on the effectiveness of (internal) reference pricing regularly shows that prices decrease after it has been established (Brekke, Grasdal, and Holmas, 2009; Brekke, Holmas, and Straume, 2011; Kaiser, Mendez, Rønde, and Ullrich, 2014; Pavcnik, 2002) or reference prices have been adjusted downwards (Augurzky, Goehlmann, Gress, and Wasem, 2009; Herr, Stuehmeier, and Wenzel, 2015). Our research is close to Pavcnik (2002) who analyzes the introduction of reference pricing in selected therapeutic markets in Germany. We improve on her findings due to our identification strategy and extend her work by evaluating the new exemption policy.

The remainder of this paper is structured as follows. We briefly explain the German market for pharmaceuticals and its regulatory framework in section 2. In section 3 we discuss our data. The estimation strategy, and the identification of our key parameters are presented in section 4. Section 5 presents our results. Section 5.1 presents the effects of the co-payment exemption levels on firms' pricing strategies and robustness checks for our identification strategy. Section 5.2 and section 5.3 present changes in utilization and the spillover effects on the private health insurance. Section 6 discusses our findings and concludes.

2 The German market for pharmaceuticals

Health insurance is mandatory in Germany, about 70m inhabitants (or 87 percent of the population) were insured by the public health insurance in 2010.[3] A share of 11 percent of the population are covered by private health insurances where entry hinges on job type (self-employed or civil servant) or on high income. Public insurance cost-

[2] In the following, we use the notion reference pricing for internal reference pricing as opposed to external reference pricing, where reimbursement limits are set comparative to prices in other countries.

[3] The statutory insurance provides universal coverage for most outpatient and inpatient services and pharmaceuticals. Several plans are offered, but differences in plan characteristics are minor and are not relevant for prescription drug markets.

sharing schemes do not apply to private health plans. However, drugs' list prices are the same for private and publicly insured.

The German pharmaceutical market is characterized by homogeneous market conditions (Pavcnik, 2002; Ziebarth, 2010). Drug prices are uniform across all pharmacies and the same co-payment scheme applies to all publicly insured. Incentives to hand out more expensive drugs are low due to regulated wholesale and pharmacy margins. Pharmacists receive payments reimbursed directly from the health insurance, namely a fixed fee per package plus a fraction of the drug's price (3 percent). The pharmacy hands out the drug specified on the prescription or is required by regulation to offer one of the three cheapest products with the same active ingredient, package size, and dosage form. If firms offer rebates to health insurances, for example through a rebate contract with a preferred supplier, pharmacists have to hand out the discounted product, if available. Patients are free to choose one of the drugs offered or another drug (probably with higher out-of-pocket costs) with the same molecule and package size as indicated on the prescription.

Physicians may subscribe all approved drugs and have incentives to prescribe cost-efficient medication due to budget controls of the public insurance. We rely on the standard model of physician decision-making where patients' out-of-pocket costs enter through the physician's concern for the patient's health assuming perfect agency (McGuire, 2000; Iizuka and Jin, 2007). In the German health care market, the vast majority of patients face the same cost-sharing structure, which makes it easy for physicians to acquire information about patients out-of-pocket costs, e.g., formularies (Wang and Pauly, 2005; Epstein and Ketcham, 2014).

Co-payments in Germany are defined as 10 percent of the pharmacy's selling price with a minimum of €5 and a maximum of €10.[4] Patients aged under 18 and low-income insureds with catastrophic health care costs do not need to co-pay.

In 1989, Germany was the first country to introduce internal reference pricing with the aim to lower pharmaceutical expenses. While in Germany the reference price reflects some average price within the therapeutic market, in other countries, for example in Denmark, the reference price is set at the lowest price. In particular, the reference price is set by the Federal Association of Statutory Health Insurances (FASHI or the health insurances) such that it does not exceed the 30th percentile

[4] Although the notion *co-payments* usually describes a fixed amount paid by the insured and *co-insurance* would describe the relative cost-sharing (with fixed upper and lower bounds) in the German drug market correctly, we stick to the former notion.

of the previous year's prices within the defined therapeutic market. The therapeutic market is defined by the self-administered Federal Joint Committee (GBA) representing health insurances, hospitals, and doctors. A therapeutic market comprises drugs that treat the same disease, which might include not only generics but also several molecules, if considered substitutable, with the same form of administration (pills or capsules versus injections, for example) while in Norway each molecule defines one market. In the US, several insurances and governmental agencies also define a maximum reimbursement based on a list of generic equivalents. For example, the maximum allowable costs (MAC) are similar to reference pricing in that patients bear the full costs of drug prices above the MAC (Scott Morton and Kyle, 2012). The average sales price calculated by Medicare follows a similar approach. Furthermore, at least 20 percent of all packages and of all prescriptions must be available for prices equal to or below the reference price at the time of implementation. Products with a market share of less than 1 percent are not considered in the calculation. The health insurances are supposed to review and adjust reference prices every year. However, in our data, reference prices are adjusted every 20 months on average. The number of adjustments per therapeutic market over the observed 16 quarters varies between zero (2,483) and two (478) with most of the packages treated once (14,764). These numbers indicate a heterogeneous timing in regulation.

Pharmaceutical companies cannot negotiate either the assignment to a specific therapeutic market or the reference price itself. The whole procedure is exogenous to the producers, as is the timing of reference price adjustments. The driving rationale for adjustments is the entry of new packages in the respective markets. Firms are always free to change their list prices, which are not negotiated.

Co-payment exemption levels (CEL) define a price threshold below which patients do not co-pay for drugs. Co-payment exemption levels have been introduced successively to several but not all therapeutic markets of reference priced drugs since July 2006. After the introduction of the CEL, firms may decide to decrease prices below that level, which lies at 30 percent below the respective reference price, to exempt patients from co-payments. The new policy is similar to the introduction of a tiered co-payment system.

By law, the selection of markets that have a CEL should be based on expectations to generate savings by the new policy. According to personal discussions with managers of the FASHI the decision vaguely depends on assumptions about patients' substitution behavior and unspecified characteristics of the therapeutic market. We test

for selection bias and show that there is no evidence of any selection criteria in the next section, i.e., the empirical investigation fails to identify drivers of the decision to introduce CEL into specific markets.

3 Data

The sample includes all drugs for which reimbursement is defined by a reference price. These are potential candidates for a co-payment exemption. For 2010, our data covers 71.7 percent of all drug packages sold and 36.6 percent of all pharmaceutical expenses in Germany (Schwabe, Ulrich and Paffrath, 2011). We keep prescription drugs only (dropping 13.4 percent of the observations). Reference prices and co-payment exemption levels are set by the public health insurances using detailed drug information from *Lauer-Taxe*, a private marketing firm listing all pharmacy selling prices and their components.[5] Table 1 presents the timing of the treatment since 2007. Co-payment exemption levels are introduced in 241 therapeutic markets between June 2007 and October 2010. The number of treated products varies between 46 and 728 per quarter.

Table 1: Introduction of co-payment exemption levels (CEL)

	Q3	Q5	Q7	Q9	Q14	Q16
# Therapeutic Markets with new CEL	34	8	11	2	41	145
# Drugs with new CEL	728	278	142	46	255	634

Notes: Data from Q3 (June–Sept. 2007) to Q16 (Oct.–Dec. 2010). Quarters with few treated markets and products are not reported. Data source: FASHI. Own calculations.

Prices (p), reference prices (rp), and exemption levels (CEL) are given at the level of pharmacy selling prices, including VAT and pharmacists' reimbursements (both remain unchanged over the study period). Products are characterized by a unique identification number (PZN), which differentiates packages by active ingredient, package size, strength, form of administration, and therapeutic market.

Prices differ for products before and after the treatment. Table 2 presents descriptive statistics of the treatment group (excluding the control group treated in quarter

[5]The data on prices and reference prices are published quarterly on the website of the German Institute for Medical Documentation and Information (DIMDI, 2011). Product-specific co-payment exemption levels are published on the website of the Federal Association of Statutory Health Insurance Funds (FASHI) (FASHI, 2011) and merged by product id to the above data.

16) by product types before and after the treatment. From here on, we distinguish between generic drugs, branded drugs, and imports. Importers are mainly marketing on-patent drugs and their prices depend on domestic and foreign brand-name drug prices (Ganslandt and Maskus, 2004; Duso, Herr, and Suppliet, 2014). The 364 companies are classified according to their websites.[6]

The summary statistics show that the majority of drugs are generics and that brand-name drugs have higher prices, compared to generics. Drug prices are lower, on average, with a CEL. The average number of firms per market also decreases. Fiercer competition might drive firms out of the market.

Table 2: Summary statistics of the treatment group

	N		Price		Ref. price		# firms	
CEL	Before	After	Before	After	Before	After	Before	After
Generics	3,433	9,849	39.67	22.56	52.78	25.83	5.58	5.00
			(57.92)	(28.23)	(74.74)	(31.22)	(1.28)	(2.26)
Brand	797	2,164	75.21	44.06	79.48	36.28	5.76	4.73
			(106.8)	(63.08)	(117.1)	(59.23)	(2.00)	(1.31)
Importer	775	1,811	39.38	35.32	41.79	31.85	2.39	1.20
			(31.13)	(28.97)	(36.02)	(32.22)	(1.15)	(.42)

Notes: Data of the treatment group from Q1 (Jan.–March 2007) to Q15 (June–Sept. 2010). Means and standard deviations (in parentheses), by firm class before/after the introduction of co-payment exemption levels (CEL). Average # of firms per therapeutic market. Prices and reference prices are inflation adjusted to the base year 2007. Data source: FASHI. Own calculations.

The descriptive results indicate various pricing strategies of brand-name and generic firms. Since reference prices are an important benchmark for a firm's price setting (and for the co-payments), we investigate the pricing patterns relative to reference prices in Table 3. 97 percent of generic firms and around 90 percent of brand-name firms and importers set prices below the reference price before a CEL is introduced. While the share is stable for generic drugs with a CEL, about 25 percent of the brand-name drugs' prices and 15 percent of the imported drugs' prices increase to above the reference price. Before the treatment, on average, all firms set prices between 20 percent below and 2 percent above the reference price. However, all firms increase prices with respect to the reference price. While generic drugs are still available for 11 percent below the reference price, the average price of the brand-name drugs lies 32 percent above the reference price with a CEL. The last column of Table 3 ($P<CEL$) shows that half of the generic drugs are exempt from co-payments while only six

[6] A table with the classification is available from the authors upon request.

percent of brand-name drugs and no imports are exempt. To assess the magnitude of CEL, we compare these figures to the respective shares of hypothetically exempt drugs before the policy where we calculate hypothetical exemption levels from the reference price data. While almost half of the generics would already have been exempt even before the introduction of CEL, the share of exempt brand-name drugs decreases from 14 percent to 6 percent after the introduction. Imported drugs are not available below the CEL once they are applicable.

Table 3: Co-payment exemptions and prices (treated)

	(P<RP)		(p-rp)/rp		P<CEL	
CEL	Before	After	Before	After	Before*	After
Generics	.97	.98	-.20	-.11	.49	.55
	(.15)	(.10)	(.23)	(.23)	(.50)	(.49)
Brand	.91	.69	.02	.32	.14	.06
	(.28)	(.46)	(.41)	(.68)	(.35)	(.24)
Importer	.90	.76	-.02	.20	.13	.008
	(.29)	(.42)	(.29)	(.48)	(.34)	(.09)

Notes: Data of the treatment group from Q1 (January 2007) to Q15 (June 2010). Means and standard deviations (in parentheses) of pricing patterns by firm class before/after the introduction of co-payment exemption levels (CEL). * Hypothetical exemption levels calculated based on reference prices before the actual introduction of the CEL. Data source: FASHI. Own calculations.

4 Estimation strategy

We use quasi-hedonic regressions to analyze the effects of regulatory changes and cost-sharing on the price-setting of firms (Sorensen, 2000; Berndt, Bir, Busch, Frank, and Normand, 2002; Cabrales and Jimenez-Martin, 2013; Berndt, Pindyck, and Azoulay, 2003). Traditional hedonic price functions empirically assess the relationship between prices (and marginal costs) and the characteristics of differentiated products (Pakes, 2003). Similar to our approach, Duggan and Morton (2011) use a price equation and first-differences to identify the negative effect of Medicaid procurement on drug prices.

Here, the pharmaceutical industry equilibrium can be characterized as a Bertrand-Nash outcome (Kaiser, Mendez, Rønde, and Ullrich, 2014). This means that the hedonic price function captures the expected marginal costs plus mark-up condi-

tional on product characteristics (Pakes, 2003). Furthermore, we explicitly model regulation and competition (Danzon and Chao, 2000).[7]

We apply a difference-in-differences approach where we exploit the sequential introduction of CELs across different therapeutic markets to identify causal effects. The preferred control group discussed in detail below consists of drugs treated in the last observed period (quarter 16). To alleviate potential endogeneity concerns with respect to the unobserved correlations of reference prices with the error term of the price equation, we use regulation intensity across different therapeutic markets as instruments for reference prices (discussed below). To address concerns on differences in trends in prices, we use log specifications (Hackmann, Kolstad, and Kowalski, 2015).

The price equation for drug j in time t in therapeutic market m can be written as:

$$\ln p_{imt} = \alpha \ln \hat{rp}_{imt} + \beta CEL_{imt} + \gamma n_{mt} + \tau_t + \zeta_i + \epsilon_{imt} \quad (1)$$

where the logarithm of the price for each drug, $\ln p$, first depends on the instrumented reference price, $\ln \hat{rp}$, and on the co-payment exemption policy indicator, CEL. The variable CEL is 1 from the quarter in which the co-payment exemption policy was introduced for the respective therapeutic market, and 0 before. We include the number of firms within the therapeutic market, n, to capture market size and as a proxy for competition. Time dummy variables, τ_t, control for quarter-specific shocks such as business cycle, seasonality, or inflation. Product fixed effects (α_i) capture the time-invariant drug package's characteristics (such as [unobserved] quality, package size, side effects or efficacy), and ϵ_{it} are normally distributed error terms (Bajari, Fruehwirth, Kim, and Timmins, 2012). In Equation 2, we differentiate the effects by firm type: *gen* (generic), *brand* (brand name), and *imp* (importing):

$$\begin{aligned} \ln p_{imt} = {} & \alpha \ln \hat{rp}_{imt} + \beta_1 (gen_i \times CEL_{imt}) + \beta_2 (brand_i \times CEL_{imt}) \\ & + \beta_3 (imp_i \times CEL_{imt}) + \gamma n_{imt} + \tau_t + \zeta_i + \epsilon_{imt} \end{aligned} \quad (2)$$

The treatment group comprises all therapeutic markets in which the exemption policy was introduced between April 2007 and October 2010. The control group CEL_{late} consists of all drugs that were treated in the last quarter. Both groups

[7] Estimates can be interpreted as implicit prices and we can derive evidence on the role of regulation. However, the interpretation of the estimates as consumers' marginal utilities or as a firm's marginal costs is difficult (Danzon and Ketcham, 2004; Danzon and Chao, 2000; Pavcnik, 2002).

become treated over time and differ only in the timing of the introduction. A range of descriptive and empirical tests confirm the quality of the control group. We need to assume that the treatment decision is independent of the two groups' unobserved characteristics.

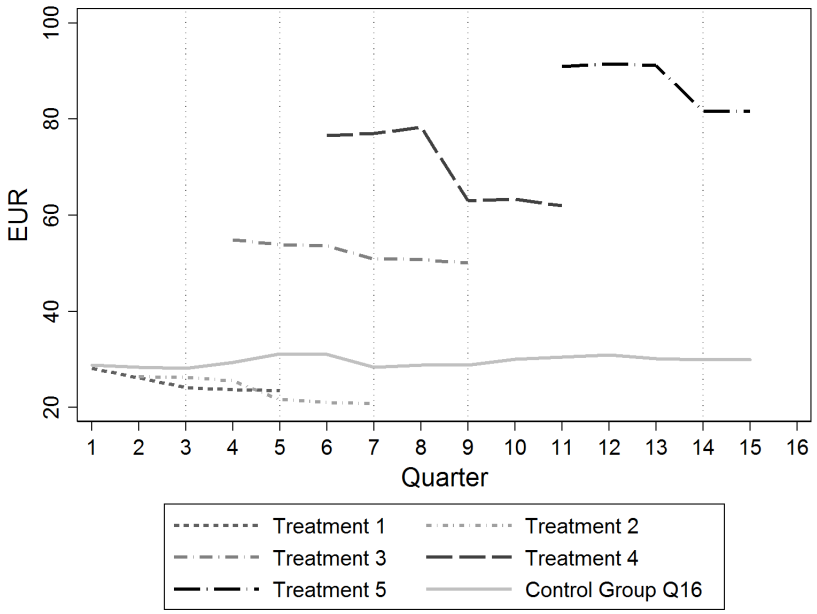

Figure 1: Mean prices of the five treatment quarters presented in Table 1 three quarters before and two quarters after the introduction of a CEL. The solid line shows the mean prices of the control group *CEL late*.

It is essential that pre-treatment prices show similar trends to fulfill the identifying assumption for a difference-in-differences approach: the treatment and the control group must not differ in the unobserved characteristics associated with an inter-temporal variation in prices. Figure 1 presents mean prices over time for the five groups of treated drugs presented in Table 1 and the control group formed by those treated in the last quarter (Q16). The treated therapeutic markets show similar constant pre-policy price-trends as the control group. The figure also provides first descriptive evidence of the policy's effect on prices. Prices decrease after the introduction. Since a CEL is often accompanied by a decrease in the reference price, we need to control for the changes in reference prices to estimate a causal effect of the CEL. Table 9 in the Appendix presents descriptive statistics for the treatment and

the two control groups. The treatment and the late control group (CEL_{late}) show very similar absolute prices and price-to-reference price ratios. As a robustness check, we also present the results for an alternative control group of therapeutic markets that were treated before 2007 (CEL_{early}), where, on average, prices are higher.

We empirically test for independent price trends of the treatment and the control group. Following Pavcnik (2002), we regress prices prior to the treatment on time trends and on the interaction of time trends and treatment ($Quarter\ x\ Treatment$) with time and product fixed effects. The results in Table 4 indicate decreasing prices over time [$Quarter$] and no statistical significant difference between the time trend of the treatment group and the control group.

Table 4: Price trends prior to treatment

	$Price[ln]$
Reference Price [ln]	.248***
	(.039)
Quarter	-.344***
	(.048)
Quarter × Treatment	.079
	(.056)
N	11,660
R^2_{adj}	.91

Notes: Clustered standard errors in parentheses; constants are not reported; * $p < .05$, ** $p < .01$, *** $p < .001$; Sample includes only observations for pre-CEL periods. Data source: FASHI.

The main identifying assumption underlying equations 1 and 2 is the exogeneity of the CEL introduction and of the reference price $[CEL|\epsilon = 0; rp|\epsilon = 0]$. In Germany, the FASHI implements CELs based on the legislative goal to generate savings. As discussed above, we could not find any pre-defined rules as to when to introduce a CEL to which therapeutic market, which was confirmed by the decision committee and business professionals. The implementation is an administrative decision which can be characterized as a black box.

Nevertheless, we empirically test for drivers of the decision to introduce the policy and estimate the likelihood to belong to the treatment group (as opposed to the respective control group) on potential drivers of the introduction using a logistic regression. Since the political goal of the policy is to generate savings, potential variables of interest are reference prices, prices, and market size approximated by the number of firms. We collapse our data at the molecule level (mean) where

observations after the introduction are dropped.[8] Table 5 shows that there is no significant difference between the treatment group and the preferred control group (CEL late) with respect to absolute prices, reference prices or competition in column (1) and only a slight difference to the alternative control group (CEL early) in column (2). Compared to the early treated, the number of firms is statistically significant and positive for treated therapeutic markets. Thus, we control for the number of firms in our price regressions.

Table 5: Drivers of the decision to introduce CEL

	Treatment Decision: treated = 1	
	CEL late	CEL early
Reference Price (ln)	-0.068	-0.23
	(1.57)	(1.12)
Price [ln]	0.06	0.39
	(1.59)	(1.13)
# Firms	0.13	0.09*
	(0.08)	(0.05)
N	103[a]	251[b]

Notes: Logistic regression with outcome variable treatment (1) or no treatment (0). Observations are dropped after first treatment and then collapsed at the molecule level. Treatment: drugs facing a CEL between Q2 2007 and Q3 2010, CEL_late: the preferred control group treated in the last quarter (Oct.–Dec. 2010). CEL_early: the control group treated in or before Q1 2007. 50 treated molecules. a: 53 treated late. b: 201 treated early * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$; Data source: FASHI.

Since we observe the same drugs over time, we expect their unobservables to be correlated and cluster all standard errors at the product level. Due to the panel data structure, clustered standard errors allow us to control for a potential first-order correlation of the error terms.

We argue that endogeneity issues cannot be severe in the German system although reference prices and their adjustments depend on lagged competitors' prices. First, adjustments happen irregularly (zero to two adjustments over four years) and cannot be foreseen (on average every seven to eight quarters varying between two and 16). Second, they are based on prices that are lagged by eight months on average (own

[8] The number of treated molecules is smaller here than the number of therapeutic markets in Table 1 since the definition of a therapeutic market takes package specifics such as the form of administration within the same molecule into account. In the main regression, package fixed effects account for this.

calculation). However, there seems to be no systematic pattern: official documents show variations in lags from seven to 60 weeks before the adjustment (FASHI, 2011). Third, prices of drugs with small market shares below 1 percent are not considered, and fourth, at least 20 percent of all packages must be priced below the reference price. Thus, the regulation hinders strategic price setting. Since an average of 23 firms are selling one molecule, a stable mechanism to collude in such an environment does not seem very credible.

However, to eliminate any endogeneity concerns, we nevertheless apply a two-stage least squares with fixed effects estimation approach and replace the reference price by its first-stage prediction using two instrumental variables, Z. First, we use the average reference price in all other therapeutic markets, which is correlated with the own reference price but does not directly influence the price. This instrument exploits the fact that adjustments take place irregularly. How often and by how much reference prices change and in which therapeutic markets depends on the regulator's focus and resources. Taking into account that the resources of the health insurances are limited, the regulatory activity in one market can indicate how much the regulator focuses on all other markets. We expect that the regulator first focuses on markets with higher expenses and adjusts reference prices downwards if necessary. Since resources are limited, we hypothesize that the change of the own reference price and the change of the average reference price are negatively correlated.

Second, by the same rationale, we assume that the average number of products in other therapeutic markets can serve as an indicator for the regulator's focus. The larger a market, the more important it is that the health insurance adjusts the reference price downwards. Thus, we expect the correlation with the own reference price to be positive.

Finally, there is no evidence that prices are correlated with the characteristics of other markets or the regulator's resources other than through reference prices. Thus, the exclusion restriction $\text{Cov}(Z, \epsilon) = 0$ holds.

The first-stage results are presented in the Appendix, Table 10, with all coefficients showing the expected signs. The F-statistics of excluded instruments are *123* and *127* for the two estimations, and tests for weak instruments (Stock, Wright, and Yogo, 2002) are above the relevant thresholds (p-value = 0.13 and 0.14). The overidentification test suggested by Hansen (1982) cannot be rejected.

5 Empirical results

Section 5.1 presents the main results of the effects of the co-payment exemption levels on firm's pricing strategies and robustness checks for our identification strategy. Section 5.2 presents and discusses the demand effects of the policy, looking at one specific indication. In that section, we also look at one potential driver of the heterogeneous treatment effect.

5.1 Price effects of co-payment exemptions

Our main results in Table 6, columns (1) and (2), show that firms set lower prices on average if a CEL is in place.

While the OLS results show price reductions of 3 percent, controlling for unobservables in the two-stage least squares framework decreases the effect of the exemption policy to 2 percent. Given that a CEL lies 30 percent below the reference price, average price changes do not seem very large.

Expecting heterogeneous treatment effects, we differentiate the introduction of co-payment exemption levels by firm-type (Eq. 2) and present the results in Table 6, columns (3) and (4). In the 2SLS specification, prices for generics decrease by 6 percent indicating that generic firms respond stronger to the incentives of lower co-payments than the other firm types. In contrast, brand-name firms increase their prices by 5 percent on average. Our findings indicate differentiated pricing strategies of pharmaceutical firms. Generic manufacturers compete in prices and, on average, decrease them due to the new policy. The effect is driven either by inefficient firms leaving the market or by reduced mark-ups. Importers tend not to change their pricing strategies. Their production costs are mainly the sourcing costs of originators' drugs in other European countries which are largely exogenous to them (Ganslandt and Maskus, 2004; Duso, Herr, and Suppliet, 2014).

Brand-name manufacturers do not participate in price competition. We are the first to show that the phenomenon of price increases after changes in the cost-sharing structure. Since our results show similar effects as the "generic competition paradox" (Scherer, 1993) we refer to these findings as the "co-payment exemption paradox." Our results identify market segmentation where branded drugs maintain higher prices, even with additional competition-enhancing instruments (Regan, 2008; Pavcnik, 2002).

Table 6: Price effects of the co-payment exemption policy

Price [ln]	(1) (OLS)	(2) (2SLS)	(3) (OLS)	(4) (2SLS)
Reference Price [ln]	0.21***	0.25***	0.20***	0.26***
	(0.01)	(0.02)	(0.01)	(0.02)
CEL	-0.03***	-0.02***		
	(0.00)	(0.01)		
CEL × generic			-0.06***	-0.05***
			(0.01)	(0.01)
CEL × innovator			0.05***	0.07***
			(0.01)	(0.01)
CEL × importer			0.00	0.01
			(0.01)	(0.01)
# of firms [ln]	-0.02***	-0.02***	-0.02***	-0.02***
	(0.01)	(0.01)	(0.01)	(0.01)
Product FE	yes	yes	yes	yes
Quarter FE	yes	yes	yes	yes
R^2_{adj}	0.44	0.44	0.46	0.46
N	23,757	23,757	23,757	23,757
F	134.99	136.04	136.03	134.71

Notes: 2SLS: reference price instrumented with the average reference price and the average number of products in other therapeutic markets. Standard errors are clustered at the package level and presented in parentheses; constants are not reported; * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$; CEL: co-payment exemption level. Data source: FASHI.

There are four channels identified in the literature which may explain market segmentation after changes, such as generic entry, in the competition structure. First, the literature on brand loyalty assumes exogenous segmentation of the market upon entry where one group consists of price-sensitive patients and the other switches to the cheapest substitute (Regan, 2008; Frank and Salkever, 1997). These models hinge on the assumption of Stackelberg competition and specifics of the demand curve. Second, promotional activity over the drug's life cycle may explain low prices and high advertising levels in early years and high prices and lower advertising in later years (Bhattacharya and Vogt, 2003). Third, substitution between generic and brand-name drugs may be imperfect from a medical point of view (Nabin, Mohan, Nicholas, and Sgro, 2012). Finally, health insurance coverage explains market segmentation, which can lead to price increases of brand-name drugs (Ferrara and Kong, 2008; Ferrara and Missios, 2012). The first three channels do not apply to the German market (distribution rules hinder free choice for publicly insured, which influences brand loyalty, and advertising is not allowed for prescription drugs). However, we show in section 5.2 that health insurance coverage indeed plays a role for the patient's substitution behavior.

In all specifications, prices decrease by 2 to 2.5 percent when reference prices decrease by 10 percent, a number that is in line with previous research (Kaiser, Mendez, Rønde, and Ullrich, 2014; Augurzky, Goehlmann, Gress, and Wasem, 2009; Herr, Stuehmeier, and Wenzel, 2015).

In Table 7, we present alternative estimations. Columns (1) and (2) show that the results hold for another control group: clusters which had been treated between October 2006 and March 2007 (CEL_{early}). Results change marginally in magnitude and standard errors. Prices and reference prices are positively correlated and the co-payment exemption policy has a negative effect on the prices of generic drugs and a positive effect on the prices of brand-name drugs. Results of first-difference regressions, which control for first-order correlation of the error terms, in columns (3) and (4) in Table 7, show a more intense negative price effect of co-payment exemption levels on prices. The effect of the policy is -6 percent for generics and +4 percent for brand-name drugs in the FD-2SLS specification.

Table 7: Robustness checks

	CEL early		FD (CEL late)	
Price [ln]	(1) (OLS)	(2) (2SLS)	(3) (OLS)	(4) (2SLS)
Reference Price [ln]	0.31***	0.43***	0.16***	0.26***
	(0.00)	(0.01)	(0.01)	(0.03)
CEL × generic	-0.07***	-0.04***	-0.09***	-0.06***
	(0.01)	(0.01)	(0.01)	(0.01)
CEL × innovator	0.04***	0.06***	0.02***	0.04***
	(0.01)	(0.01)	(0.01)	(0.01)
CEL × importer	-0.01	0.01	-0.03**	-0.00
	(0.01)	(0.01)	(0.01)	(0.01)
# of firms	-0.04***	-0.03***	-0.01***	-0.01***
	(0.00)	(0.00)	(0.00)	(0.00)
Product FE	yes	yes	yes	yes
Quarter FE	yes	yes	yes	yes
N	269,764	269,764	21,690	21,690
R^2_{adj}	0.39	0.31	0.21	0.19
F	802	797	100	100

Notes: CEL early: alternative control group treated in or before Q1 2007. FD: estimation in first differences with CEL late as control group. 2SLS: reference price instrumented with the average number of products and the average reference price in other therapeutic markets. Standard errors are clustered at the product level and presented in parentheses; constants are not reported; * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$; CEL: co-payment exemption level. Data source: FASHI.

5.2 Demand effects of co-payment exemptions

The success of the co-payment exemption policy also depends on the substitution behavior of patients. To address the question of how the co-payment policy translates into quantity changes, we utilize monthly data by *IMS Health* (Pharmascope National) on all epileptic drugs sold to the public health insurance in Germany from 2004 to 2010 (almost 130,000 observations). This sample comprises several generic and brand-name drugs and 22 molecules. Seven molecules are part of a reference pricing scheme and for five of these molecules co-payment exemption levels were introduced after mid-2006. The sample is restricted to drugs that were treated at some point during the observation period to ensure homogeneous market conditions.[9] The data contains product-level information on prices, sales, and product characteristics over 84 months. Furthermore, it provides indicators of whether the drug was treated by the co-payment exemption policy and on whether the firm decreased the price below the exemption level. The data does not contain information either on reference prices or on the co-payment exemption levels themselves. For drug i in therapeutic market m and time t we estimate the following equation

$$\ln q_{imt} = \theta \ln \hat{p_{imt}} + \lambda \hat{exempt}_{imt} + \kappa policy_{mt} + \tau_t + \zeta_i + \epsilon_{imt} \quad (3)$$

where the quantity for each drug, $\ln q$, depends on the instrumented drug's price, $\ln \hat{p}$, and on whether the drug is exempt from co-payments. The instrumented indicator $\hat{exempt}$ is 1 for exempt products and 0 for non-exempt products. The baseline effect of the introduction of the co-payment policy on sales is captured by *policy* which is 1 from the period onward when the policy was implemented in a specific molecule market. As argued in section 4, the timing of the introduction is exogenous to individual manufacturers. Time dummy variables, τ_t, control for quarter-specific shocks. Product fixed effects (ζ_i) capture constants over time (such as [unobserved] quality, package size, side effects or efficacy), and ϵ_{it} are normally distributed error terms.

Causal effects rely on instrumental variables for the two strategic firm variables: price and exempting products from co-payments. First, product-specific cost-shifters are approximated by Danish prices which are independent of demand shocks in Ger-

[9] Results hold for estimations with the full sample. The direction of estimated coefficients are the same and coefficients are, on average, larger (not reported).

many.[10] Second, the firm's decision to decrease prices below co-payment exemption levels should be driven by competition in the respective market. Therefore, we choose the number of firms and the number of products of competitors in the same molecule market as instrumental variables for the firm's decision. Table 8 presents OLS and 2SLS estimation results for sold quantities (daily doses) and market shares within the molecule as dependent variables. Results throughout all specifications show the positive effects of co-payment exemptions on sold quantities. The effects are even larger for the 2SLS specifications and also hold for columns 3 and 4 where market shares are the dependent variable. While the introduction of the policy has, on average, negative effects on sales (baseline effect), the sum of the two coefficients λ and κ is positive but small. Firms can compensate the losses of the price decreases below the co-payment exemption level by increases in sales of 12 percent and in market shares of about 1.5 percentage points. The results are conditional on price levels that negatively affect sold quantities indicating downward sloping demand.

Table 8: Quantity effects in the anti-epileptic drugs market

	Quantity		Market Share	
	OLS	2SLS	OLS	2SLS
Price [ln]	-.399***	-1.799***	-.016***	-.156***
	(.063)	(.349)	(.004)	(.042)
With CEL = 1	-.264***	-.764***	-.009***	-.086***
	(.035)	(.029)	(.256)	(.026)
Exempt = 1	.423***	.857**	.018***	.107**
	(.034)	(.37)	(.004)	(.042)
Product FE	yes	yes	yes	yes
Period FE	yes	yes	yes	yes
N	84,184	84,184	84,184	84,184
F-test exluded ins.		25, 65		65, 82
Hansen j (p-val)		.0035		0.81

Notes: 2SLS: Price and exemption status are instrumented with Danish prices and the number of other products and firms in the same molecule market, respectively. Standard errors are robust and presented in parentheses; constants are not reported; * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$; CEL: co-payment exemption level. Data source: *IMS Health, Pharmascope National.*

Our findings indicate that consumers switch to drugs without co-payments, controlling for differences in qualities and prices. Furthermore, the results indicate that

[10] The prices of all authorized pharmaceutical products marketed in Denmark are publicly available at `http://medicinpriser.dk/`. We replace the drug price with Danish mean prices of therapeutically equivalent products if the same product is not available in Denmark.

firms that do not respond to the policy by decreasing prices, e.g., brand-name firms, face considerable losses in sales.

5.3 Spillover effects on private health insurances

Ferrara and Missios (2012) show that differentiated insurance coverage can lead to the generic competition paradox where the prices of brand-name drugs increase although generic entry induces more price competition. In Germany, approximately 10 percent of the population are covered by private insurances and their plans are generous regarding drug reimbursements compared to the public insurance. Furthermore, privately covered patients have co-payment schemes that are different to the public insureds and, as such, they are not directly affected by the introduction of the CEL. Following Ferrara and Missios (2012), we hypothesize that the market shares of brand-name drugs for privately insureds increase when a CEL is in place. Since market conditions are unchanged for privately insureds, we are investigating a spillover effect of the introduction of CEL in the public health insurance on the privately insureds.

We use information on pharmacy sales to privately insured patients from *IMS Health* (The Pharmaceutical Market in Germany). The data contain information on the overall market shares of anti-epileptics covered by public and private health insurances. We limit the data to brand-name drugs and investigate whether relatively more privately insureds received a brand-name following the introduction of a CEL. Figure 2 shows the percentage of brand-name drugs sold to privately insureds from 2004 to 2010 by treatment status. The brand-name share of privately insured patients in the treated and non-treated groups was roughly the same before the first introduction of CEL. It varies between 5 to 10 percent, which corresponds to the share of privately insured patients in the overall population. However, the descriptive evidence shows that brand-name market shares of privately insured patients increase to around 20 percent after the introduction of the co-payment exemption policy where the solid vertical lines indicate the introduction of the CEL in the anti-epileptics market. Our results suggest that the policy incentivizes the publicly insureds to choose cost-efficient drugs and brand-name firms to focus on privately insureds (niche strategy).

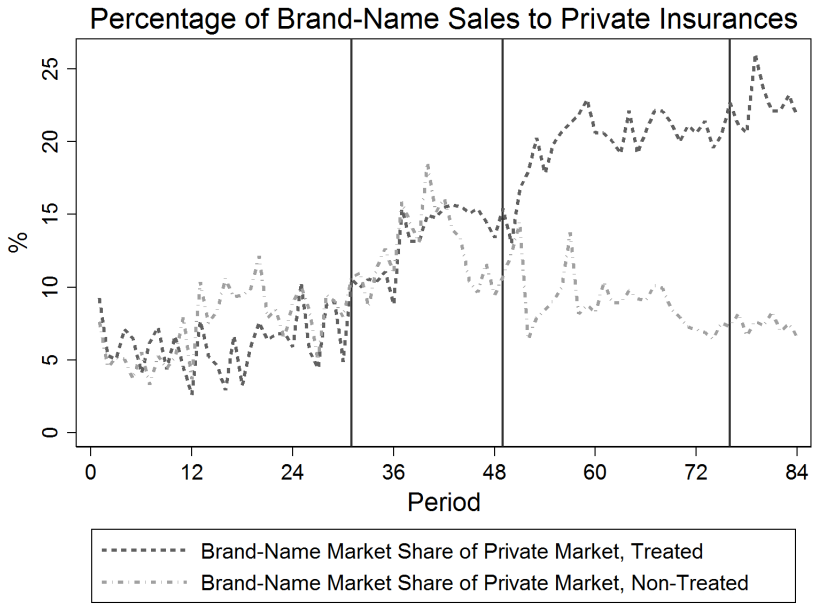

Figure 2: Market share of anti-epileptic brand-name drugs across all privately insured in Germany from 2004 to 2010. The solid vertical lines indicate the introduction of the CEL policy in the anti-epileptic drugs market. Data source: *IMS Health, The Pharmaceutical Market in Germany.*

6 Discussion and conclusion

This paper shows that the combined introduction of the favored US-approach of tiered co-payments and the dominant European regulation of reference pricing can lead not only to decreasing drug prices but also to market segmentation. In particular, we analyze manufacturers' pricing strategies when health plans offer the option of zero co-payments if drug prices lie below a pre-defined level. Our paper exploits the institutional features of a newly introduced exemption policy in Germany, its application to pharmaceuticals with reference pricing, and its successive implementation in different therapeutic markets. We analyze whether the incentive for patients to switch to lower-priced drugs impacts the pricing strategies of firms. We utilize quarterly price data of all prescription drugs sold in Germany between 2007 and 2010 and show that the policy has a significant negative effect of -5 percent on generic prices (-4 to -9 percent, depending on the empirical specification) while brand-name firms increase prices by 2 to 7 percent due to the new regulation. We refer to these findings as the "co-payment exemption paradox" since they are similar to the price increases of brand-name drugs after generic entry, which is called the "generic competition paradox."

Additional analysis supports theoretical findings that emphasize the correlation between changes in drug prices and differentiated health plan coverage (Ferrara and Missios, 2012). In Germany, 11 percent of the population are covered by private health plans for which the analyzed co-payment rules do not apply. We exploit this fact and find that the share of private to public payers consuming brand-name drugs increases in treated markets while it remains quite stable in untreated markets over the sample period.

Furthermore, it is crucial to understand how demand-side instruments can steer drug demand toward cost-efficient products. While reference pricing means that the consumers of comparatively more expensive drugs have higher co-payments, the new policy rewards lower-priced drug users with zero costs. A more detailed analysis with product-level data from the anti-epileptics market indicates increases in sales of about 12 percent when firms decrease their prices below the exemption level.

In a simplified back-of-the-envelope calculation that quantifies the economic impact of the policy, we multiply the overall effect of CEL (-2 percent) with the total spending of the public health insurance on prescription drugs regulated by reference pricing of €12.14bn in 2010. The reform would have led to savings of about €242m, assum-

ing that the reform was introduced for the first time for all drugs simultaneously in 2010. However, analyzing the social welfare effects of the policy requires more information on sales to quantify substitution after the policy change, data on physician or hospital visits, and follow-up costs.

Compared to other European countries and to the US, the fraction of drug co-payments is small in Germany (Arcidiacono, Ellickson, Landry, and Ridley, 2013; Baicker and Goldman, 2011) and lied at €2.40 per package in 2010 (ABDA, 2016). Hoadley, Summer, Hargrave, Cubanski, and Neuman (2012) state that in most Medicare Part D Prescription Drug Plans (PDP) median cost-sharing across all insureds was only $5 for generics, but $41 for preferred brands, and $92 for non-preferred brands in 2012. Baicker and Goldman (2011) argue that cost-sharing should be (near) zero for drugs that both save money and improve health. The German approach of exempting very low-priced drugs can be seen as an incentive to lower prices for manufacturers and increase consumption of preferred products. The relevance of the policy during our observation period is supported by additional information from the health insurances which indicates that most exempt products (12,887) were sold in March 2010 (numbers have been increasing steadily since 2006) while the overall number of products in the market remained constant (FASHI, 2011).

Empirical evidence shows that tiered co-payments successfully curb the overuse associated with generous health insurance coverage (Gruber, 2006). Some researchers have raised concerns about adverse health outcomes due to higher drug expenditures by patients (Baicker and Goldman, 2011). The approach to exempt very low-priced drugs from co-payments would alleviate problems of high drug expenditures. The problem of overuse is not addressed in this paper. Here, this is unlikely to be a problem since first, we only consider prescription drugs, and second, only very low-priced drugs are exempt from co-payments.

In the context of the optimal design of health insurance plans, cost-sharing and premiums can be interpreted as characteristics of a two-part pricing contract (Lakdawalla, Sood, and Gu, 2013). Consumers face low unit prices (cost-sharing) and transfer their consumer surplus (premiums) to insurers. Under the assumption that the benefits and costs of consumption are equal at the margin, insurances must provide goods and services at marginal costs (Lakdawalla and Sood, 2013). We show the effectiveness of the CEL policy to eliminate margins above marginal costs from treated drugs.

The price effects of the CEL policy indicate some price elasticity of demand in the German drug market. We may underestimate the negative effect of co-payment exemption levels due to private information about preferred-supplier contracts between health insurances and *generic* producers (Blankart and Stargardt, 2016). Sometimes, insurers offer their insureds the option of co-payment exemptions or 50 percent reductions for selected rebated drugs (ABDA, 2016). Not considering these rebates on list prices, our estimates for the effect on generics can be interpreted as lower bounds. Brand-name drugs do not take part in these rebate negotiations. Since the list prices for these drugs correspond to the true prices we do not overestimate the positive branded drug effect.

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Appendix

Table 9: Descriptive statistics of treatment and control groups

Sample	Price	Price<RP	Price<CEL	CEL (1=yes)	N
	mean (std)	mean (std)	mean (std)	mean (std)	
Treatment	32 (47)	.92 (.26)	.41 (.49)	.73 (.45)	18,829
Control: CEL late	29 (23)	.93 (.25)	.	.	6,032
Control: CEL early	55 (133)	.96 (.19)	.53 (.49)	1 (0)	252,039
All	45 (115)	.94 (.22)	.51 (.49)	.76 (.42)	373,056

Notes: Statistics of the treatment group and the two control groups from Q1 (Jan.–March 2007) to Q15 (June–Sept. 2010). Treatment: drugs facing a CEL introduction after January 2007 and before October 2010, CEL_{late}: the preferred control group treated in the last quarter (Oct.–Dec. 2010). CEL_{early}: the control group treated in or before January 2007. Means and standard deviations (in parentheses). Prices and reference prices are inflation adjusted to the base year 2007. Data source: FASHI. Own calculations.

Table 10: 2SLS first-stage results (2nd stage, see Table 6)

	Reference Price [ln]	
CEL	-0.15***	
	(0.01)	
CEL × generic		-0.18***
		(0.01)
CEL × innovative		-0.10***
		(0.02)
CEL × importer		-0.10***
		(0.02)
# of firms (ln)	0.03***	0.02**
	(<0.01)	(<0.01)
RP other markets	-0.49***	-0.49***
	(0.03)	((0.03)
# of products (other)	0.03***	0.03***
	(<0.01)	(<0.01)
Product FE	Yes	Yes
Quarter FE	Yes	Yes
N	23,757	23,757
R^2_{adj}	0.62	0.63
F test excluded inst.	123	127
Hansen j (p-val)	0.13	0.14

Notes: First stages of the 2SLS estimations in Equations (1) and (2). Second stages presented in Table 6, columns 2 and 4. Standard errors are clustered at the product level and in parentheses; * $p < 0.1$, ** $p < 0.05$, *** $p < 0.01$; CEL: co-payment exemption level. Data source: FASHI.