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Drug Pricing Decisions and Insurance Coverage: Evidence from Medicare Part D

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Abstract

What is the message? This paper explores whether the pricing of drugs relative to their clinical value affects insurance coverage and usage for drugs under Medicare Part D. The authors find that lower generic prices stimulate both greater use and more generous insurance coverage. However, for branded drugs they find no relationship for either coverage or use based on variation across drugs in their cost effectiveness, as estimated by the Institute for Clinical and Economic Review (ICER)

What is the evidence? An analysis of pharmacy-dispensed brand drugs without generic competition in the Medicare Part D market in 2022, with a particular emphasis on drugs which also have external value-based pricing estimates from the Institute for Clinical and Economic Review (ICER).

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Introduction

Brand drugmakers have discretion over the prices of their products. These decisions have attracted significant attention, with many U.S. policymakers arguing that prices are too high relative to external benchmarks or estimated measures of clinical value. However, while drugmakers effectively set prices unilaterally, these decisions can trigger responses from purchasers that affect the quantity sold. In this paper, we explore this dynamic by investigating whether the pricing of drugs, relative to estimates of clinical value, affect the coverage and utilization of branded drugs in Medicare Part D.

In a simplified framework, an insurer that is willing to cover drugs priced well above their value to patients will generate premiums that are unattractively high relative to an insurer that is more judicious in coverage. Of course, an insurer need not passively cover drugs independent of their price. Instead, they have a number of tools that can impede beneficiaries' access to such products. Perhaps most directly, a drug's price can influence an insurer's decision to cover a drug or not. Even conditional on coverage, insurers can impose differential levels of utilization management tools which have first-order effects on utilization. For example, applying prior authorization to a covered product reduces utilization of a drug by nearly 27 percent in Part D (Brot-Goldberg et al., 2023). Further, they can increase cost sharing for a given product or use coinsurance to make the out-of-pocket spending for beneficiaries a direct function of the (list) price of the drug.

We investigate how insurers within Medicare Part D choose to cover drugs with differential pricing strategies. Specifically, we ask whether drugs with particularly high prices, relative to an estimate of their clinical value, are covered at lower rates or subject to greater use of utilization management tools than drugs with lower relative prices. Doing so would reflect a price-volume trade-off for drug makers (while also likely concentrating the use of high-cost products among those with the highest willingness to pay).

Our analysis focuses on pharmacy-dispensed brand drugs without generic competition in the Medicare Part D market in 2022. We place particular emphasis on a subset of drugs which also have external value-based pricing estimates from the Institute for Clinical and Economic Review (ICER). The latter group includes many relatively new, costly products. Combining data on drug pricing, revenues, and plan characteristics, we illustrate a number of results.

First, coverage and utilization management decisions are, unsurprisingly, responsive to first-order differences in the costs of pharmaceuticals. Branded drugs without generics are often excluded from formularies and are frequently subject to restrictions on their use if covered. The average branded drug in our sample is covered by roughly 50 percent of plans, but only covered without prior authorization or step therapy on 27 percent of plans. Among drugs in our ICER subsample, the average product appears on only 4 percent of plans without such utilization restrictions. Moreover, ICER products are almost always on the highest coverage tier, meaning enrollees' cost sharing is in the form of coinsurance. The typical generic is covered more often without utilization management and on lower cost sharing tiers.

Second, among drugs evaluated by ICER, net prices at which they are purchased are typically higher than estimated value-based prices (under a willingness to pay of $150,000 per quality-adjusted life year), but we observe significant variation in the magnitude of this difference. On average, the value-based price (VBP) of these products is 20 percent lower than the observed net price.[1] Twenty-five percent of these products have value-based prices that are at least 60 percent lower than their net price (indicating a particularly "low value") while roughly 25 percent of products have net prices that are actually lower than their VBP (indicating a good value). But while insurers are clearly responsive to first-order cost differences between products, we observe little evidence that coverage rates vary systematically with differences in how prices are set relative to VBPs among products in our ICER subsample. This finding is robust to models that control for time since entry and number of in-class competitors.

Third, we show that plans which cover a larger number of relatively "low-value" branded products are generally more permissive in their coverage decisions of all branded products. In other words, they do not appear to make different decisions about which drugs are worth coving, but instead, are more expansive in their coverage decisions generally. These more permissive plans tend to have higher premiums.

Finally, we examine the early lifecycle revenue patterns for drugs that are priced high or low relative to their estimated clinical value. We do not observe evidence that drugs which are offered at relatively good value prices have differentially fast increases in their revenues. However, this analysis has significant limitations owing to sample size and data availability.

These results are perhaps surprising. On one hand, coverage decisions appear responsive to

first-order differences in costs. Coverage of generic products is generally more permissive than of brand drugs, for example. Within branded products, coverage of those with ICER estimates, which are often costly, is less permissive than the typical brand drug. On the other hand, coverage decisions do not appear to systematically vary with price within the sample of drugs with ICER estimates. These results are consistent with a few potential explanations.

Most directly, the value-based price estimates may simply not capture demand well. Even if these estimates accurately reflect clinical value to the typical patient with the condition, drug makers may set pricing decisions based on beliefs about how that value varies across patients. That is, drug makers may hypothesize that a significant mass of the willingness-to-pay distribution is clustered meaningfully above the average. Indeed, the use of utilization management tools by insurers for effectively all drugs in our ICER sample may serve to concentrate utilization among higher-willingness to pay patients for some products. Thus, the VBP estimate for a typical consumer may be a poor proxy for the willingness to pay of consumers who can access the product.

These results also may reflect institutional features of the Medicare Part D market. Notably, once spending is high enough, plan liability is relatively low. Plans owe just 5 percent of costs in the "coverage gap" and just 15 percent when spending rises higher into the "catastrophic phase" of the benefit (whereupon the federal government covers 80 percent of drug costs). This is in contrast to the initial coverage phase, where plans owe the majority of costs. Thus, plans may have more muted incentives to refine coverage decisions among a sample of highly priced medications that are likely to trigger the catastrophic phase. In the conclusion, we consider potential empirical tests of these theories.

Our work builds on recent research that shows insurers and Pharmacy Benefit Managers can and do influence the utilization of branded pharmaceuticals via formulary design. Naci et al (2022) show that only 20 percent of drugs launched between 2014 and 2018 that were not in protected classes were covered by more than half of plans a year after launch. Conditional on being covered, utilization management was common. Brot-Goldberg et al. (2023) help quantify the effects of prior authorization—a particularly common form of utilization management that requires the insurer's explicit approval before a drug is covered—on use of drugs within the Medicare Part D market. They show that, even though prior authorization applications are typically approved, imposing that restriction reduces the use of targeted drugs by 27 percent

relative to plans with no such restrictions. Our empirical work builds on this in a few ways. First, we update some prior findings about coverage in Part D using more recent data and highlight how these decisions vary among a sample of relatively notable, high-cost drugs for which we can observe estimates of value-based prices aimed at purchasers in the US health care market. Second, we connect decisions regarding coverage and formulary design with the pricing decisions of specific drugs and investigate how these decisions affect premiums, plan enrollment, and drug revenues.

Institutional Setting

Our empirical setting focuses on Medicare Part D, the prescription drug benefit within the Medicare program. The introduction of Part D was a consequential development for drug markets, increasing utilization of drugs (Duggan and Scott Morton, 2010) and spurning more investment in classes of drugs commonly taken by Medicare enrollees (Blume-Kohout and Sood, 2013).

Coverage in Part D is provided by private insurers on behalf of the government. The federal government defines some features of the benefit design, but insurers are able to differentiate themselves with respect to elements of the plan design like coverage and cost sharing features. Most importantly for our purposes, plans may differ in their formulary design, including whether to cover specific drugs, where on a formulary to place a drug, and whether to impose utilization restrictions on them. As a result of these decisions, premiums and deductibles vary across plans.

If a plan excludes a drug from its formulary, beneficiaries must request an exception to have the drug covered. Otherwise, they must pay the entire costs themselves. Thus, while formulary omission does not formally preclude a beneficiary from taking a drug, it functions as a particularly aggressive constraint on utilization.

Conditional on covering a drug, plans may choose to impose different forms of utilization restrictions. Prior authorization requires that physicians must obtain explicit permission from the insurer before a drug is covered for a beneficiary. Step therapy instead requires that patients try a lower-cost drug first, before being “stepped up” to a more expensive option. Finally, they may impose volume limits on the amount of a given drug that may be dispensed to a beneficiary. While volume limits are relatively common, they can be imposed for multiple reasons (e.g., they

may reflect safety reasons or prevention of off label use). Because of this, our analysis will focus on prior authorization and step therapy.

Federal rules impose some constraints on formulary design. Plans must cover effectively all drugs from six protected classes—antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, antineoplastics.[2] In addition, plans must cover at least two products in each drug class. However, plans may still generally use utilization management tools, like prior authorization for covered drugs.[3]

In addition to premiums from enrollees, plans receive a fixed payment from the federal government, which gives them an incentive to constrain costs. However, once spending is high enough, beneficiaries enter the "coverage gap" and eventually the "catastrophic phase" of coverage. In 2022, plan liability was just 5 and 15 percent in these phases of the benefit, respectively. Moreover, manufacturers were required to provide large discounts during the coverage gap beginning in 2011 which counted towards the enrollees out-of-pocket spending for moving through the benefit. The cost of high-expense enrollees is predominantly borne by the federal government, which pays 80 percent of costs of enrollees once the catastrophic phase is reached.[4] These features reduce incentives of plans to control spending once outlays are high enough. While some of these features will change due to the Inflation Reduction Act of 2022, including an increase in plan liability for high-cost enrollees, these provisions do not take effect during our sample window.[5]

Data and Empirical Methods

Data

Plan Characteristics

Information on Part D plan characteristics comes from Prescription Drug Plan Formulary files from the Centers for Medicare and Medicaid Services (CMS). The most recent data at the time of this analysis covered the third quarter of 2022. Formulary data include information about whether specific drugs are covered, whether they are subject to utilization management, and tier of coverage. A typical Part D plan includes five tiers, with higher tiers corresponding to higher cost sharing. Drugs covered on tiers four or five are effectively always subject to

coinsurance, which links cost sharing to the list price of the product (Cubanski and Damico, 2022). These data also include premium levels, deductibles, enrollment, and region for each plan.

These files indicate drug coverage at the National Drug Code (NDC) level, which is specific to a strength, dose, formulation, labeler, and package size of a product. We map data to the product level using formulary reference files from CMS which allow us to identify branded status of observations. We collapse the data to the product level (i.e., we have one observation for "Humira" per time period). If a drug has a generic competitor, we collapse all NDCs for the generic into a single observation. If an insurer covers any NDC of a product, then we consider it covered on a formulary. We drop plans with fewer than ten enrollees because data on enrollment is suppressed for those.

Value-Based Price Estimates

We use data from the Institute for Clinical and Economic Review (ICER) to provide estimates of the value-based prices (VBPs) for a subset of drugs. These prices are based on cost-effectiveness analysis that utilizes a variety of inputs such as clinical trials, health-related quality of life, and immediate and downstream economic costs of treatment options. In these models, incremental cost-effectiveness ratios are used to summarize the additional costs the healthcare sector or society needs to expend to gain an additional unit of health compared to an existing treatment (usually standard of care). A product's VBP reflects the maximum price for those gains that satisfy a formal willingness to pay constraint. Thus, the VBP reflects the clinical value of a novel treatment relative to the existing standard of care or next-best treatment. It is important to note that the set of drugs with value-based prices is not a random subset of all products. ICER tends to focus on newer treatments with meaningful financial impact, among other considerations (Institute for Clinical and Economic Review, 2023b).

For our analysis, we use VBPs which reflect a willingness to pay, from the healthcare sector, of $150,000 per QALY. In cases where products have multiple VBPs (i.e., because it treats multiple conditions), we conservatively use the highest value. We consider this VBP as an estimate of the willingness to pay for the treatment if purchasing on behalf of the average patient with that condition. Cost-effectiveness modeling like this, while extremely common in ex-US markets, has played an increasingly important role in negotiations between drug makers and payers in the

US. ICER's estimates have been used by state Medicaid agencies, the Department of Veteran's Affairs, commercial market insurers, PBMs, and employer groups.[6]

We use all ICER reports covering 2017 through May of 2022. VPBs were not routinely reported in ICER reports prior to this time period. These reports include the list and an estimate of the net price of a course of treatment for each product, which can be benchmarked to the VBP as they are in the same units (generally either annual or some standardized dose amount).

SSR Health Data

Net price was not included for three ICER reports. In these instances, we used net pricing information in the nearest available quarter from SSR Health. These data rely on publicly-released financial reports from drug makers to estimate payments to drug makers, net of all price concessions.[7] These data cover all brand drugs sold by publicly traded companies, which includes effectively all major drug makers (and includes every drug with a VBP in our sample). These data also include aggregate net revenues at the product level by quarter and class of product. We merge this data with branded products on Part D formularies.

Sample Selection and Empirical Methods

For our primary analysis, we use coverage data from the third quarter of 2022—the latest available Part D data at the time of analysis. We restrict our analysis to stand-alone Prescription Drug Plans (PDPs). This excludes the roughly half of plans which are provided as part of a Medicare Advantage Plan (MA-PD plans). We omit MA-PD plans partly because premium levels are not directly comparable to PDP plans. This is because MA plans may use savings from other areas to "buy down" the Part D premium (in some cases, to zero dollars). Thus, premiums reflect variation in available plan savings and how plans chose to use them, rather than formulary choices. In addition, the strategic decision facing MA plans that provide integrated coverage of drug and medical services may differ from stand-alone drug plans (Lavetti and Simon, 2018). We also drop employer-only group health plans that were not open for general enrollment.

We drop branded drugs that are from any of the six protected classes in Part D because plans have effectively no discretion over these coverage decisions, which is central to our analysis. We define protected classes based on their classification within the US Pharmacopeia (USP)

Medicare Model Guidelines v8.0 using both USP Class and USP Category as appropriate. This restriction excludes 121 products, which is similar to past work identifying protected classes with this data (Hwang et al., 2019).

Our final dataset includes 2,155 products that ever appear on the formulary of a PDP in third quarter of 2022. We observe a total of 569 brand drugs without generic competitors. Of these products, ICER data provide VBP estimates for 45 products. We refer to this set of drugs as the ICER subsample throughout our analysis. We observe 776 plans, which use one of the 63 formularies observed. Notably, plans may use the same formulary as other plans, but premiums and deductibles can still vary across plans owing to other design choices.

For each product we calculate the ratio of its estimated VBP under a willingness to pay of $150,000 per QALY to its net price. A lower VBP-to-net price ratio indicates drugs which have high net prices relative to the VBP (one can think of these as plausibly “low value” drugs), and vice versa. Appendix table A1 lists the ratio for each drug in our sample. We then merge pricing data with Part D coverage data.

We also use net revenue data from SSR Health to provide some insight into how revenue growth varies across products over the first few years of their lifecycles. For this analysis, we measure products’ net revenue in each quarter relative to baseline, which we define as the first full year of sales.

Our analysis proceeds in a few stages. First, we document facts about the rate at which drugs in our sample are covered in Part D and how plans choose to employ utilization management, conditional on coverage. Next, we document pricing strategies of drugs with ICER reports and illustrate how coverage of specific drugs vary with pricing decisions. We then explore plan-level differences in coverage decisions and how that affects premium and enrollment levels for plans. Finally, we consider whether the growth of product net sales vary with pricing decisions.

Results

Coverage of Brand Drugs in Part D

Table 1 summarizes the average coverage rates for drugs in Part D, by branded status. We

calculate the percent of plans which cover each drug and report average coverage rates for each product category. The average generic is covered on 77 percent of plans and is often covered without prior authorization or step therapy. Branded drugs with available generics are covered on 31 percent of plans and are typically on a higher average tier than generics. The typical brand drug without a generic in our full sample is covered on 50 percent of plans, but only on 27 percent of plans without prior authorization or step therapy.

Notably, drugs in the ICER subsample are covered at broadly similar rates to all brands without generics. However, they are almost always subject to restrictions. These products are covered without prior authorization or step therapy on just 4.1 percent of plans. As we show later, this is driven by a couple of products that are commonly-covered without restrictions, while most are never covered without utilization management.[8] Conditional on being covered, drugs in the ICER subsample are placed on very high average tier. They are almost always covered on tier 4 or above, meaning enrollees face the highest cost sharing in the form of coinsurance.

Taken together, these results indicate that plans in this market are, unsurprisingly, responsive to first-order cost differences of products. Branded drugs—particularly those within our ICER subsample—are less frequently covered, face higher cost sharing, and are subject to greater use of utilization management tools.

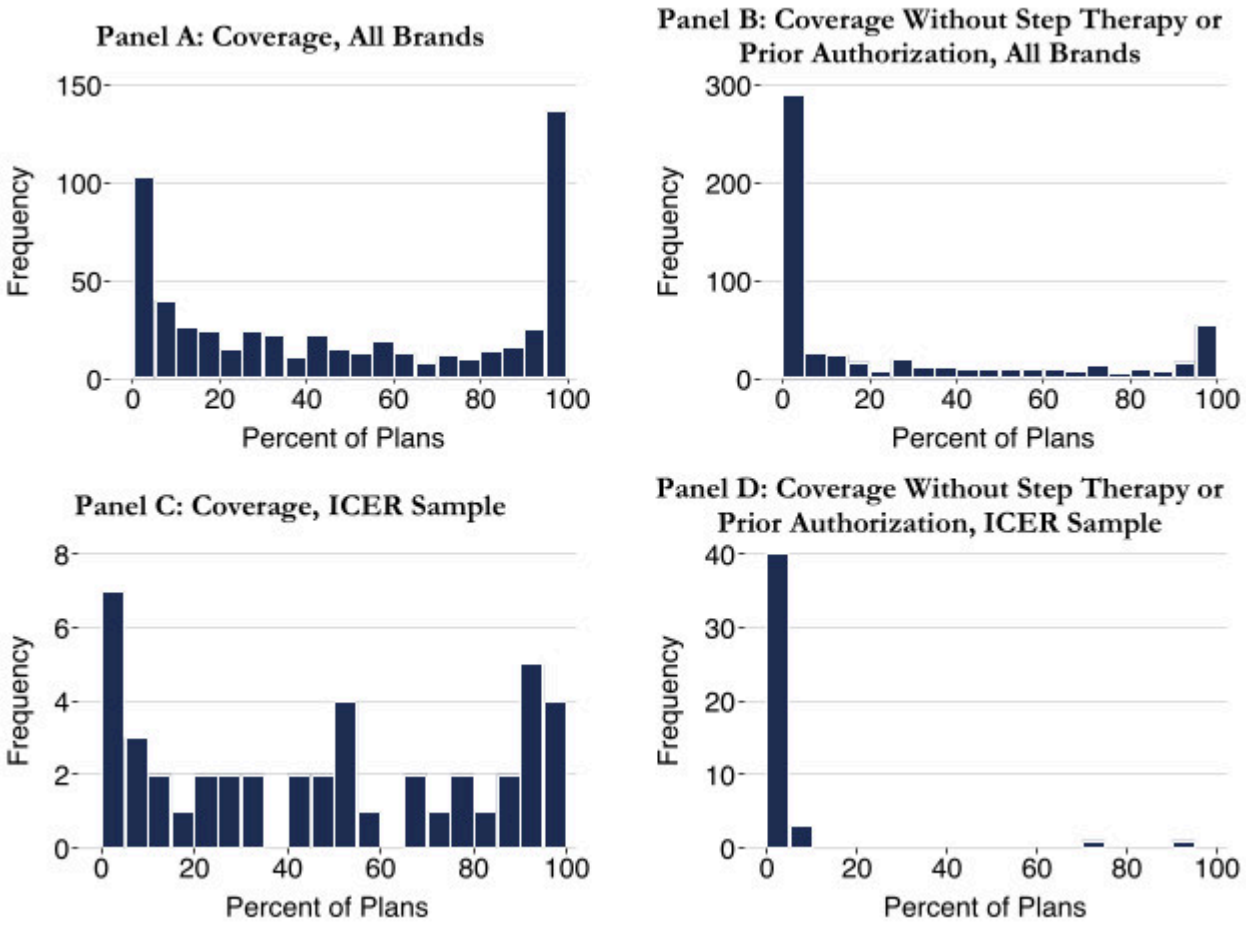
Table 1: Average Coverage by Product Type in Medicare Part D, 2022Q3

	Products	Percent of Plans Covering	Percent of Plans Covering with No Step or Prior Auth	Average Tier, Conditional on Coverage	On Tier 4+, Conditional on Coverage (Requires Coinsurance)
Brand, without generic					
All	569	49.5%	26.7%	4.1	74.7%
ICER sample	45	48.0%	4.1%	4.6	85.0%
Brand, with generic	605	31.2%	26.2%	3.9	79.4%
Generic	981	77.1%	64.4%	3.2	53.9%

Note: This table shows the average coverage rates for drugs in each product category. Data sources are CMS and ICER. Coverage statistics are from the third quarter of 2022. Sample includes all 2,155 drugs that are covered by at least one Part D plan. We exclude branded products from protected classes. ICER Sample includes only those products which also have a VBP estimate from the Institute for Clinical and Economic Review.

Figure 1 illustrates the distribution of coverage rates across individual products within the sample of all brand drugs without generics (panels A and B) and the ICER subsample (panels C and D). Nearly a quarter of products in the full sample are covered by greater than 95 percent of plans, while 18 percent are covered by less than 5 percent of plans. As panel B shows, widespread coverage without step therapy or prior authorization is the exception rather than the norm. These patterns are broadly similar among branded drugs without generics included in our ICER subsample, though coverage without utilization management is rarer among this group. Because prior authorization and step therapy are so common among the ICER subsample, we focus much of our analysis on extensive margin coverage decisions of insurers where we observe more variation in strategies.

Figure 1: Distribution of coverage among branded drugs without generics, 2022Q3



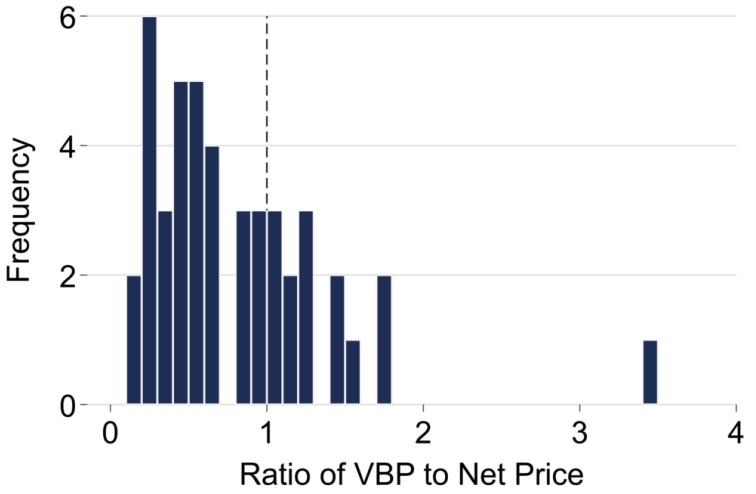
Note: This figure shows the percent of plans that cover individual products. Data sources are CMS and ICER. Coverage statistics are from the third quarter of 2022. Panels A and B include all brand drugs in our data that do not have generics. Panels C and D include only those branded drugs without generics that are included in our ICER subsample.

Pricing and Coverage Decisions

The VBPs of branded drugs in our ICER sample are generally lower than net prices, but by varying degrees. Figure 2 plots the histogram of this VBP-to-net price ratio. Note that a ratio below one implies a drug's net price exceeds its VBP and vice versa. Among our sample, 71.7 percent of products have a ratio less than one. Eighteen drugs have a VPB that is less than 50

percent of the net price. In other words, the VBP estimated by ICER is far below the observed net price of some drugs. On the other hand, some drugs are quite good values by this metric—selling for net prices that are lower than the VBP (indicated by a ratio over one). Appendix A includes the VBP-to-net price ratio of all the drugs in our ICER subsample. Brand drug makers clearly make significantly different pricing decisions relative to this measure of value. This level of variation provides a useful context to consider how plans choose to treat these different products.

Figure 2: Ratio of VPB to Net Price, ICER Sample

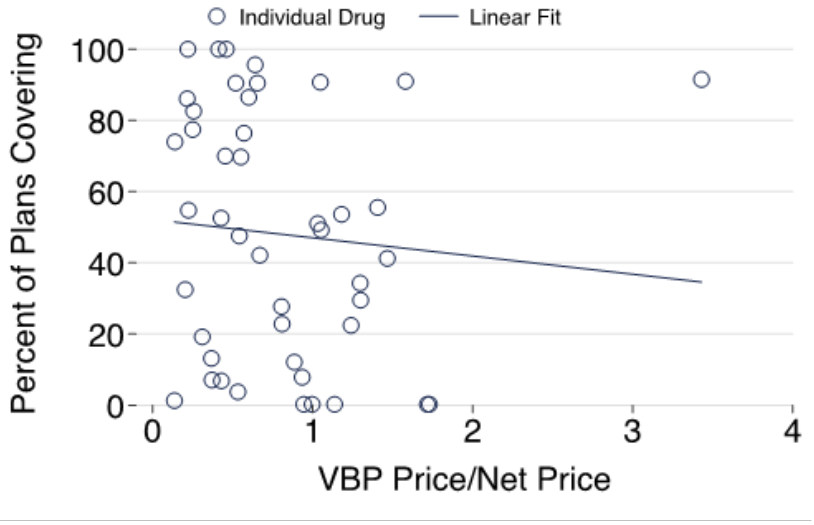


Note: This figure illustrates the ratio of value-based price to net price for each drug in our ICER Sample. The vertical dashed line indicates where a net price would be equal to the VBP. A ratio below one implies a drug's net price is above its VBP, and vice versa. Data come from ICER reports released between 2017-2022. N=45.

Given the substantial variation illustrated in figure 2, we next ask whether insurance coverage varies systematically with pricing decisions within this sample of products. In figure 3, we plot the percent of plans covering each product in this sample against their VBP-to-net price ratio. There is clearly variation in how drugs are treated across plans, but not in a way that varies with price. Drugs with higher VBP-to-net price ratios (indicating a "better value" based on this assessment of clinical value) are not systematically covered with greater frequency than those

which have lower VPB-to-net price ratios.

Figure 3: Coverage Relative VBP-to-Net Price Ratio, 2022Q3



Note: This figure illustrates the relationship between the percent of insurance plans covering each brand drug in our ICER sample and the ratio of the drug's VBP-to-net price. Data on VBPs come from ICER reports released between 2017-2022. Coverage data are from CMS. N=45

The patterns shown in figure 3 may be influenced by variation in drug characteristics. For example, those that have been on the market for longer may face greater market competition over time, potentially influencing coverage decisions and pricing. In column 1 of table 2 we replicate the result from figure 3 with a simple regression. A higher VBP-to-net price ratio has a very small and insignificant negative association with the percent of plans covering a drug. A one unit increase in the ratio, representing more than doubling of the average ratio, is associated with just a 5 percent decrease in the average rate of coverage. Column 2 shows that this result does not change when we control for the time a drug has been on the market. In column 3, we show that the same is true if we control for the number of branded products within class reported in our SSR data (this result is similar if we instead merge data from Redbook that provides a measure of brand and generic competition within class). In other words, these additional controls do not change the relationship that is evident in figure 3—we observe no systematic relationship between coverage of these products and VBP-to-net price ratios.

Table 2: VBP-to-Net Price Ratio and Coverage, 2022Q3

	(1)	(2)	(3)
	Percent of Plans Covering Drug	**Percent of Plans Covering Drug**	**Percent of Plans Covering Drug**
VBP-to-Net Price Ratio	-0.051 (0.118)	-0.038 (0.111)	-0.053 (0.102)
Years Since Launch of Drug		0.009 (0.012)	0.015 (0.011)
Number of Branded Drugs in Class			-0.023 (0.017)
N	45	45	45

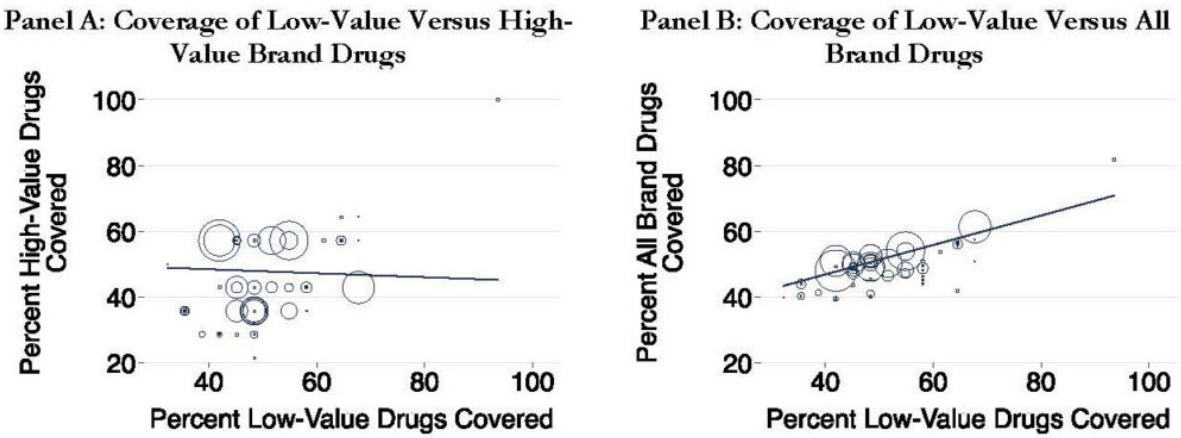
*Note: In this table we show the results of a regression of coverage rate against the VBP-to-net price ratio of products, while controlling for the time since launch for each product and number of drugs in class, defined using class provided by SSR. Data sources are CMS, ICER, and SSR Health. Coverage statistics are from the third quarter of 2022. This regression uses products from our ICER Sample, which includes only those products which also have a VBP estimate from the Institute for Clinical and Economic Review. Class is defined using SSR Health Class definition. * p < 0.1, ** p < 0.05, *** < 0.01*

As figure 3 illustrates, plans clearly make different decisions about whether to cover many branded drugs in our ICER sample, even among “low-value” drugs with prices above their VBP. This could reflect alternative explanations. Plans may simply come to different decisions about the value or market demand for different products. In such a scenario, we might observe different plans covering a comparable number of products, but where they make different choices about which specific drugs to include on their formulary. Alternatively, some plans may simply be more permissive in their coverage decisions of all products. For example, plans which aim to be “benchmark” plans—plans that are made available to enrollees who receive low-

income subsides at no premium—may take a low-cost coverage approach relative to plans targeting other parts of the market which may have a higher willingness to pay.

In figure 4, we investigate whether coverage of low-value products, defined as having VBP-to-net ratios less than 1 (N=31) is indicative of broader patterns of coverage by plans. Because plans using the same formulary will mechanically cover the same percentage of drugs, we illustrate these data at the formulary level. Each observation is then weighted by the number of enrollees in plans which use each formulary. Panel A indicates that formularies including a larger percentage of low-value branded drugs in the ICER sample are not systematically doing so at the exclusion of high-value products (N=14). Panel B shows that formularies which do cover larger percentages of these low-value products tend have more permissive coverage of all branded drugs without generics, however.

Figure 4: Formulary Coverage ICER Subsample and All Branded Drugs, 2022Q3

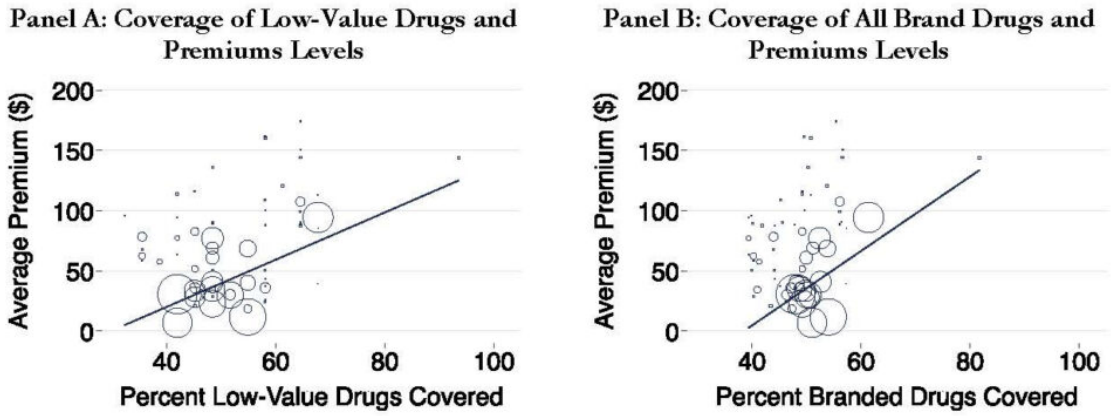


Note: This figure illustrates the percent of drugs covered on each formulary. Low-value drugs are defined as those within the ICER subsample with VBP-to-net price ratios below 1 (N=31). High-value drugs are defined as those with VBP-to-net price ratios above 1 (N=14). All brand drugs include the 569 products without generics in the full sample. The data include 63 formularies, and each observation is weighted by the number of enrollees on plans using each formulary. The solid line represents a linear regression between the two variables.

Plan Coverage Decisions and Premium Levels

Figure 5 investigates how different coverage strategies by plans translate to monthly premium levels. Again, because plans using the same formulary cover the same percent of products, we illustrate this at the formulary level. For each formulary, we average the premiums of plans using it. Each observation is weighted by the number of enrollees in plans using it. Unsurprisingly, plans using formularies which cover a larger percent of low-value drugs (panel A) or all brand drugs (panel B) tend to have higher premium levels. It is also implicitly evident from the size of each observation that enrollment tends to be larger in lower-premium plans.

Figure 5: Coverage Rates and Premium Levels, 2022Q3



Note: This figure compares premium levels with the percent of drugs covered on each formulary. Each observation is a formulary (the percent of drugs covered is constant across plans using the same formulary). Average premium represents the mean premium level across all plans which use each formulary. Low-value drugs are defined as those within the ICER subsample with VBP-to-net price ratios below 1 (N=31). All brand drugs include the 569 products without generics in the full sample. The data include 63 formularies and each observation is weighted by the number of enrollees on plans using each formulary. The solid line represents a linear regression between the two variables.

There is still non-trivial variation in premiums across plans that cover similar numbers of products in either case, which may reflect other differences in plan design. Column 1 of table 3 replicates the results from figure 5a in a regression. Covering one additional percent of low-value drugs covered is associated with an increase of $1.88 in premiums. This coefficient falls to $0.928, when we control for the average deductible of plans using the formulary and include Part D plan region specific fixed effects. We observe the same basic result when using the percent of all brand drugs covered. However, this effect is more sensitive to inclusion of additional controls for deductible and region.

Table 3: Regression Results: Premium Levels and Coverage Rates, 2022Q3

	(1)	(2)	(3)	(4)
	Premium Level	**Premium Level**	**Premium Level**	**Premium Level**
Percent Low-Value Drugs Covered	1.88** (0.719)	0.928* (0.462)		
Percent All Brand Drugs Covered			2.984** (1.427)	1.196 (0.984)
Deductible		-0.082** (0.025)		-0.089** (0.026)
Region FE		Y		Y
N	63	63	63	63

Note: In this table we show the results of a regression of premium levels against coverage rate of drugs. Data are at the formulary level (N=63). Premium levels represent the average premiums of plans using a given formulary. In models (1) and (3), we do not add additional controls (thus, they summarize the results in figure 5). Models (2) and (4) include controls for average deductible of plans using the formulary and region fixed effects. Data sources are CMS,

*ICER, and SSR Health. Regressions are weighted by the number of enrollees on plans using each formulary. Data are from the third quarter of 2022. * $p < 0.1$, ** $p < 0.05$, *** < 0.01.*

Drug Revenues

Throughout our analysis, we have effectively considered coverage decisions as a proxy for utilization of products. Lower coverage rates, or greater rates of utilization management when covered, should lower utilization of products. Thus, the inconsistent relationship between pricing decisions and coverage of products in our ICER subsample suggest that there would be a similarly inconsistent relationship between pricing and revenues.

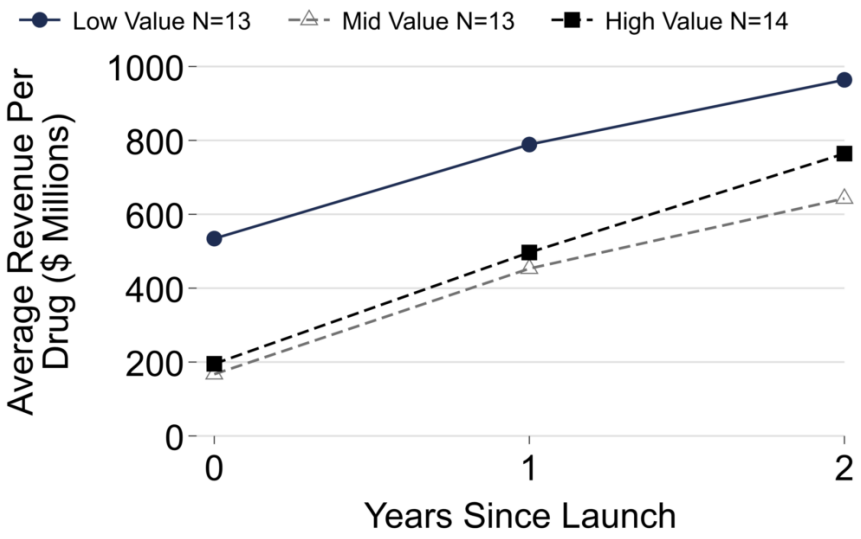
However, this is not necessarily mechanically true. First, we only observe decisions made by insurers in Part D, which may or may not be indicative of coverage decisions in other markets. Moreover, our analysis implicitly assumes that impediments to utilization, like prior authorization, are similar across drugs. This need not be true. Utilization management for well-priced drugs may represent a lower bar (e.g., requiring only that the drug is prescribed for an on-label indication) than for more expensive medications (e.g., requiring failure of other therapy types and a minimum level of severity of a condition).

Considering how pricing decisions affect revenue is relatively challenging, though, because it is unclear how to define the counterfactual—namely, how much a given product would have sold under different pricing strategies. Nonetheless, we can provide some information about how revenues of products with different pricing strategies evolve early in their lifecycle.

Because we cannot observe revenue data prior to 2008, we exclude 5 products in our ICER sample that launched prior to that. We divide the remaining products into low-value (VBP-to-net price ratio between 0 and 0.5), medium value (ratios between 0.5 and 1), and high value (ratios over 1). We then ask how revenues evolved over the first three full years of sales for products in these groups. For context, most drugs see rising revenues over this period as it takes some time to build market share, but it is easy to imagine pricing strategies affecting this diffusion. If drug makers choose to set relatively low prices with the hopes of targeting a large swath of patients with a condition, one might imagine this growth to be relatively rapid. Instead, we observe (1) low-value products tend to have relatively high revenues, and (2) grow at roughly the same rate as those products priced much lower relative to VBP estimates. There are clear limits to this

analysis, however, the results are consistent with the lack of a clear relationship between pricing decisions and coverage of products by the insurers we study.

Figure 6: Revenue Growth Early in Product Lifecycle



Note: This figure illustrates the average annual revenue of drugs after launch, broken out by their external assessment of clinical value. Low-value drugs are defined as those within the ICER subsample with VBP-to-net price ratios below 0.5 (N=13) Medium, below 1 (N=13). High-value drugs are defined as those with VBP-to-net price ratios above 1 (N=14). Five drugs are excluded as they launched prior to 2008 and we are not able to calculate their revenue using SSR data.

Conclusion

In this paper we investigated whether the pricing strategies of brand drugs was related to the way that insurers chose to cover those drugs. Namely, are drugs priced closer to value-based pricing estimates covered in ways that are likely to result in greater access and utilization? In short, we find limited evidence in favor of such a hypothesis.

Our data suggest that insurers in the Medicare Part D market react to first-order differences in the costs of pharmaceuticals. This is evident in the relatively permissive coverage of generic

products relative to brands. It is also illustrated in the very aggressive use of utilization management tools for branded products—particularly those in our ICER subsample, which are covered without prior authorization or step therapy on only 4 percent of plans in 2022.

We show that branded drugs within our ICER subsample make meaningfully different decisions about how to price their products relative to value-based price estimates that are based on cost-effectiveness analysis. However, we observe little systematic relationship between these pricing decisions and coverage by insurers. High value products are not covered at greater frequency than low value products in this market.

Moreover, insurers that tend to cover more low-value products appear to be relatively permissive in their coverage decisions more generally, as opposed to making different decisions about which drugs to cover. We provide some evidence that this tends to result in higher premiums. This is consistent with insurers targeting different parts of the market (i.e., some insurers taking a lower-cost approach to qualify as “benchmark” plans).

While our analysis of drug revenues is limited by data availability, we find that the early revenue trends of high, medium, and low value products are generally similar. Notably, low-value products, appear to have higher revenues initially, but with similar revenue trajectories as utilization increases.

Mechanically, the results suggest that the value-based prices from ICER do not capture willingness to pay for these products in the Part D market. It is important to consider what might underlie this fact. Perhaps most directly, the VBPs may simply not accurately reflect the full value of the product—be it clinical or non-clinical value. Alternatively, our results may implicitly reflect beliefs of drug makers about the distribution of willingness-to-pay levels across patients with a given condition. A drug maker that sets a relatively high price may believe that the willingness-to-pay distribution is not tightly grouped around the central estimate provided by ICER at 150,000 dollars per QALY and, instead, has a large mass at higher levels. Future research may be able to better inform this hypothesis by investigating how utilization changes following generic entry. If a drug maker is targeting a subset of consumers with particularly high demand, then once a generic enters, one may expect relatively large increases in aggregate utilization of the drug (either the brand or generic version). To the extent that such a response is correlated with the original price of the brand drug, it is consistent with this targeting theory.

Our results may also reflect institutional features of this market which can mute the competitive benefits for insurers that do make coverage decisions in a more value-based manner. Beneficiary choice across Part D plans is heavily focused on premium levels and whether a plan covers the medications an enrollee takes, independent of how they are priced compared to a measure of value. (Indeed, the Medicare Plan Finder directs enrollees to list their specific medications when guiding them to a plan selection). Enrollees can also change plans over time. This begs the question: how do coverage decisions for drugs not taken by the enrollee affect competition among insurers? An insurer employing a value-based approach may be able to charge lower premiums than one using a generally permissive approach. However, this may still be dominated by a simple, low-coverage approach that pays little attention to VBPs (within coverage constraints imposed by Medicare Part D). Such an approach would tradeoff lower enrollment of beneficiaries taking those expensive medications against the ability to offer more competitive premiums more generally. These incentives may differ in settings where purchasers have to consider the demand for products among a large group of individuals (e.g., the employer market) rather than the drug consumption of a single person. Future research can help inform this hypothesis by comparing behavior of insurers in the employer-sponsored markets to those studied here.

The competitive benefits from employing a value-based coverage rule for high-cost drugs may be further muddied by the design of the Part D benefit during this period. Because insurers have relatively low liability once spending progresses beyond the initial coverage phase, they may have limited incentive to refine coverage decisions based on price within a set of costly medications. This theory is testable in the coming years because of provisions included in the Inflation Reduction Act of 2022 (Inflation Reduction Act, 2022). Specifically, the IRA will alter the Part D benefit design so that insurers have much greater liability for high-cost enrollees. Starting in 2025, federal spending in the catastrophic phase will fall from 80 percent of brand drug spending, under current law, to just 20 percent. Plans will be responsible for 60 percent of brand spending, while drug makers will be responsible for 20 percent. Enrollees will owe nothing in this portion of the benefit and will have total annual out-of-pocket spending capped at $2,000 per year (Centers for Medicare and Medicaid Services 2022). These changes should make plans more sensitive to differences in spending among high priced products. If this feature of the program design is partly responsible for the patterns we observe in this paper, one would predict coverage decisions to vary more systematically with prices of brand products (particularly within high-cost subset) beginning in 2025. This represents a promising topic for

future study.

Footnotes

[1] This result is consistent with findings in Bloudek et al, 2021.

[2] For a discussion, see Centers for Medicare and Medicaid Services (2019).

[3] There are some exceptions to this rule. Prior authorization and step therapy are not allowed for antiretrovirals. These tools can be used for drugs in other protected classes, but only for new patients.

[4] For a discussion of the benefit design and changes from the Inflation Reduction Act, see Kaiser Family Foundation (2022).

[5] The most relevant changes to the benefit design will be implemented in 2025. For more information on the implementation timeline of key features from the Inflation Reduction Act, see CMS (2022).

[6] For a discussion see Institute for Clinical and Economic Review (2023a).

[7] For a full description of these data, see Ippolito and Levy (2022).

[8] These general trends are consistent with a related analysis of older data from Naci et al. (2022).

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Appendix A: Product Level Data for ICER Subsample

In this section we provide more granular data about the drugs which make up our ICER subsample—the set of brand drugs which are included in a report from the Institute for Clinical and Economic Research. In order to be included, a product needed to be reviewed by ICER from 2017-2022, and provided sufficient data in the published ICER report that a VBP-to Net Price ratio could be calculated. This includes a total of 45 products, with the majority of these products were launched recently, with 30 coming to market since 2015.

Table A1 illustrates the VBP-to-net price ratio for each drug, along with the VBP and net price separately. In addition, we include the year in which the drug came to market (market start quarter) and when it was reviewed by ICER.

Table A1: Product-Level Pricing Information for ICER Subsample

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Product	Market Start Quarter	Year of Review	VBP-to-Net Price Ratio	VBP ($150k willingness to pay	Net Price
Actemra	2010q1	2017	0.81	21779	26923
Aimovig	2018q2	2018	1.58	7900	5000
Ajovy	2018q4	2018	1.24	6200	5000
Aubagio	2012q4	2017	0.37	25354	68951
Austedo	2017q2	2017	0.14	9158	65752
Avonex	1996q2	2017	0.31	20362	65654
Benlysta	2011q1	2021	0.60	56137	93465
Betaseron	2004q1	2017	0.64	36083	56328
Cinryze	2008q4	2018	0.54	217577	401512
Cosentyx	2016q1	2018	1.03	39400	38200
Dupixent	2017q2	2017	1.41	43726	31100
Fasenra	2018q1	2018	0.43	11900	27800
Ingrezza	2017q2	2017	0.20	11260	55326
Kalydeco	2012q1	2020	0.22	68600	311704
Kevzara	2017q2	2017	0.94	16816	17810*
Lupkynis	2021q1	2021	0.43	92539	215296
Nexletol	2020q1	2021	0.81	2300	2856
Nucala	2016q1	2018	0.45	13400	29500
Nurtec ODT	2020q1	2020	1.30	4640	3570
Olumiant	2018q2	2017	1.72	33300	19400
Orencia	2006q1	2017	0.67	28345	42306
Orilissa	2019q1	2018	1.73	12800	7400
Orkambi	2015q3	2020	0.22	58900	272623
Otezla	2014q2	2018	1.18	36600	31000
Oxbryta	2019q4	2020	0.14	12625	92584
Plegridy	2014q4	2017	0.53	39329	73760
Praluent	2015q3	2019	1.47	3997	2725*
Rebif	2002q1	2017	0.37	27245	73454
Repatha	2015q3	2017	0.25	2242	8970
Reyvow	2020q1	2020	1.00	3350	3360
Rinvoq	2019q3	2021	0.65	41500	63400
Rybelsus	2019q4	2019	1.05	6396	6103
Siliq	2018q1	2018	1.14	41500	36500
Skyrizi	2019q2	2018	0.52	39800	76597*
Stelara	2009q4	2018	0.41	37800	91609
Symdeko	2018q1	2020	0.22	65500	292200
Takhzyro	2018q3	2018	0.89	374857	423344
Taltz	2016q2	2018	1.05	39700	37700
Tremfya	2017q3	2018	0.93	41500	44400
Trikafta	2019q4	2020	0.26	79900	311741
Tymlos	2017q2	2017	0.55	7963	14443
Ubrelvy	2020q1	2020	1.30	4630	3570
Xarelto	2011q2	2019	3.43	7597	2215
Xeljanz	2012q4	2017	0.57	25010	43800
Xolair	2003q2	2018	0.46	13300	28900

*Note: Data are primarily from ICER. * indicates cases where data from SSR Health was used to impute net price.*