Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare

By Zarek Brot-Goldberg, Samantha Burn, Timothy Layton, and Boris Vabson*

High administrative costs in U.S. health care have provoked worry among policymakers, but much of these costs are generated by managed care policies that trade off red tape against reductions in moral hazard. We study this trade-off for the case of prior authorization restrictions, a major source of administrative costs, among Low-Income Subsidy beneficiaries of Medicare Part D. Prior authorization restrictions require physicians to fill out paperwork in order for treatment to be covered. They reduce insurer drug spending costs but impose paperwork burdens on physicians. Using auto-assignment to randomly-chosen plans as a source of variation, we find that prior authorization reduces use of focal drugs by 23%. The average prior authorization restriction regime imposes a paperwork burden of $4.8 to $5.7 per patient-year, but results in $23.7 of savings on drug spending, with no apparent effect on patient health. Rather than being pure waste, paperwork burdens may reflect choices along a frontier trading off paperwork costs against program utilization costs.

* We thank Frank Gaunt for excellent research assistance, and Jason Abaluck, Giovanni Compiani, Stuart Craig, Josh Gottlieb, Bruce Landon, Anna Zink, and seminar participants at Chicago, the Chicago Fed, and the 12th Annual Empirical Health Law Conference for helpful comments, and Michael Frakes . We thank Arnold Ventures and the Becker-Friedman Institute for their financial support of this work. All errors are our own.

The cost of bureaucratic administration makes up a substantial portion of the costs of providing health care in the U.S. Accounting estimates of the share of health care expenditures used for administration include 20% for ambulatory settings and 30% for hospitals in 2017 (Dunn et al., 2020), 31% for the entire U.S. system in 2002 (Woolhandler et al., 2003) and 34% in 2017 (Himmelstein et al., 2020). Since health care is roughly one-fifth of U.S. GDP, this represents a nontrivial fraction of economic output, and, in turn, academics, policymakers, and pundits have spilled a great deal of ink opining that rising health care costs can be offset by cutting the administrative burden.

The typical discussion of administrative costs in medicine takes as given, either implicitly or explicitly, that these costs are waste, a key source of productive inefficiency that causes the U.S. health care system to be "on a production possibility frontier that is interior to that of other countries" (Cutler and Ly, 2011). Ultimately, papers in this literature typically conclude that the U.S. health care system could easily become much more efficient by just eliminating all of this administrative waste, suggesting the potential for billions of dollars in savings (Cutler et al., 2012; Cutler, 2020). The promise of reducing these costs is a lynchpin to recent political arguments for single-payer health insurance reform, under the premise that traditional Medicare spends less per beneficiary in administration than private insurers (Archer, 2011; Frakt, 2018).

While such a 'fix' for the US healthcare system is tempting, it relies on a critical assumption: That in the counterfactual U.S. health care system where all administrative costs are removed, nothing else that is welfare-relevant changes—that all of the administrative work in medicine must truly be waste, with no benefits to offset the costs of administration. Given that many of the administrative burdens that are most lamented by healthcare providers—prior authorization and step therapy requirements for drugs and imaging, insurance claims denials for unnecessary or experimental treatments, etc.,—have the explicit goal of correcting provider behavior, such an assumption should not be accepted at face value without considering the value of such corrections, especially given that fulfilling these requirements makes up roughly half of administrative costs (Cutler, 2020).

In this paper, we take seriously the possibility that administrative burden in medicine has both costs *and benefits*. We characterize these benefits for a specific case: Prior authorization restrictions for prescription drugs. Under such policies, patients can only receive coverage for certain drugs (typically high-cost, on-patent drugs) if their prescribing physician fills out pre-specified paperwork making a case for why their patient should receive the drug, often instead of a cheaper generic alternative or a previous-generation drug with a longer track record of proven benefits. If the insurer approves, the patient is granted coverage; if not, the physician must successfully try again or the patient will not receive coverage for the drug and will have to pay the full cost of the drug out of pocket if they choose to take it. The goal of insurers in doing so is to correct the moral hazard (Pauly, 1968) that might occur whereby generous insurance coverage results in excessive

use of drugs whose value to beneficiaries is below the social cost of provision.

However, imposing prior authorization restrictions comes with costs: Making authorization requests is a major source of administrative effort, requiring an average of 20.4 manpower hours per physician per week, the second greatest administrative burden for physician practices (Casalino et al., 2009). This burden is the source of criticism, especially from physicians, with the common sentiment that "because the great majority of [prior authorization] requests are ultimately approved, the value of [prior authorization] requirements and their impact on patient safety should be reevaluated" (Wallace et al., 2020a). From many physicians' perspective, authorization requirements are simply a hurdle that benefits no party.

We start by developing a conceptual model to understand the key trade-offs of prior authorization. We think about prior authorization as an ordeal, in the terminology of Nichols and Zeckhauser (1982), that acts to ration access to prescription drugs to those whose physician is willing to overcome the administrative costs associated with the authorization requirement. We show that there are two key effects of prior authorization restrictions. First, prior authorization results in some marginal patients-who would fill the prescription in the absence of the requirement-not filling the prescription when the restriction is in place. This marginal change may improve social surplus if drugs consumed only in the absence of authorization restrictions have social value below cost. Second, the administrative cost must be paid for every inframarginal patient who takes the drug with or without the prior authorization restriction. A social planner considering a regime of restrictions therefore faces a trade-off of 'sludge' imposed for inframarginal prescriptions against savings coming from the reduction in marginal prescriptions. We show that prior authorization is most likely to be socially beneficial when (1) the size of the marginal group is large relative to the size of the inframarginal group, and (2) a close clinical substitute is available at a much lower price and most consumers in the marginal group opt for that substitute drug rather than the outside option when facing the prior authorization restriction.

We then study prior authorization empirically in the Medicare Part D Low-Income Subsidy (LIS) program. This setting has a number of important features that make it useful for studying the effects of prior authorization. First, it is large: In 2021, 13 million beneficiaries, or 4% of the US population, are enrolled in the LIS program, and these beneficiaries make up a large and outsized share of government outlays on health care. Second, there is effectively no cost-sharing in the LIS. Instead, the *only* sources of differentiation across drug insurance plans are prior authorization restrictions and outright drug coverage exclusion. Third, and most importantly, a large subset of LIS beneficiaries are randomly assigned to drug plans that differ substantially in their regimes of prior authorization requirements for different drugs, providing exogenous variation in exposure to prior authorization at the person-drug level. Among this population, in 2015, prior authorization restriction policies covered roughly 5% of prescriptions making

up 22% of drug spending.

We start by asking the simple question of whether the administrative burden of prior authorization requirements has any effect at all on prescription drug fills or whether these requirements are pure waste. Our estimates indicate that prior authorization restrictions imposed on a drug reduce the probability that a beneficiary consumes that drug by 22%. Our research design uses two-way fixed effects that allow us to control for secular differences in utilization across drugs as well as across plans. This result is robust to various measures of drug utilization, and holds when controlling for authorization restrictions imposed on other potential substitute drugs in the same therapeutic class. This effect of prior authorization is large: indeed, it is 64% of the size of the consumption effect of excluding the drug from the formulary entirely.

While we estimate large insurer savings from prior authorization, our direct effects may overstate these savings if beneficiaries substitute towards other drugs. We estimate substitution patterns within a discrete-choice model of patient demand for a single drug within a therapeutic class, akin to recent approaches in the literature on the industrial organization of drug markets (Dubois et al., 2019; Ganapati and McKibbin, 2019). We impose a nested logit structure, allowing the nesting parameter to govern the extent to which authorization restrictions induce intensive-margin substitution to other drugs within class or extensive margin substitution away from drug use altogether. For each class, we simulate utilization and spending under the historical prior authorization regimes undertaken by Medicare Part D insurers, as well as in a counterfactual world in which no authorization restrictions were ever imposed. We find that prior authorization restrictions reduced spending by 1.5%, equaling approximately $23.7 per beneficiary-year.[1]

We use our demand model estimates to evaluate the trade-off between spending reductions and administrative costs borne by physicians for inframarginal prescriptions. We calibrate the sludge cost of authorization restrictions from existing accounting measures. Under a variety of assumptions about sludge cost magnitudes, we find that this burden is equal to $4.8-$5.7 per beneficiary-year, roughly one-fifth to one-quarter of the cost savings realized. This implies that prior authorization is an efficient rationing tool as long as the average net value of consumption for the average patient-drug pair induced to switch, relative to the expected alternative, is no greater than $553 per year, i.e., at close to the financial cost of drug procurement.

In the final part of the paper, we assemble a variety of pieces of evidence pointing to the social value of the marginal drug consumption. In a typical product market, an econometrician would use the estimated demand system and revealed preference to estimate social value. In our setting, doing so is impossible given

[1]Note that our evaluation in this way only allows for savings among people who were assigned to plans restricting a given drug, making up only 5% of prescription fills. These policies cover only some drugs, for only some beneficiaries.

the absence of prices and the presence of an agent (the prescribing physician) who may exert their own preferences. Instead, we take indirect approaches towards evaluating the efficiency of restricted consumption. First, we ask whether the effects of prior authorization on consumption are different across race and gender. These demographic indicators should be orthogonal to the likelihood of approval and therefore there should be no difference. In contrast, we find some evidence of a racial gap in relative terms and a gender gap in absolute terms.[2] Second, we ask whether prior authorization restrictions have meaningful effects on patient health, which would serve as a strong proxy for social value. We focus on the case of oral anticoagulants, where formulary variation is simple and health consequences are easily measured. We find that restrictions on a set of novel drugs are estimated to have approximately no effect on the 1-year likelihood of ischemic stroke, internal bleeding, or death, and we can reject large effects.[3]

This paper speaks to three important narratives in the economics literature. First, as mentioned before, we speak to a narrative that bureaucracy in U.S. health care is pure waste imposed on providers, and that removing this bureaucracy would lead to cost savings. This literature has primarily focused on measurement of burdens rather than their effect on economic activity. Our study is one of the few to quantify the role of these bureaucratic hassle costs in affecting behavior (alongside Dunn et al. (2021) on claims denials and Alpert et al. (2020) on opioid monitoring programs), and our results suggest the narrative of bureaucracy as purely wasteful is inaccurate.

Second, we speak to a recent narrative in the literature arguing that bureaucratic reporting requirements reduce the efficacy of means-tested transfer programs. Scholarship in economics and public administration has shown that targeted populations may have more difficulty navigating bureaucracy, thus resulting in these programs going to less-deserving populations (Heinrich, 2016; Herd and Moynihan, 2018; Deshpande and Li, 2019; Finkelstein and Notowidigdo, 2019; Homonoff and Somerville, forthcoming; Shepard and Wagner, 2021). Our results are far less stark, with significant cost reductions, and no strong evidence that the effects are larger for more-deserving populations. This may reflect the fact that prior authorization policies are largely intermediated by experts rather than beneficiaries, although we do not have a direct comparison.[4]

[2]This draft is preliminary. We are currently estimating whether there are also differential effects by 1) Drug type/characteristics; 2) Beneficiary comorbidities; and 3) Characteristics of the prescribing provider. We are also estimating the extent to which marginal patients diverted by authorization restrictions are likely to have shorter tenures on the restricted drug.

[3]Simpler results on health effects are hindered by the fact that our variation is at the beneficiary-drug level, but health is measured at the beneficiary level. Future versions of this paper will test whether health outcomes respond to a measure of beneficiary-level exposure to authorization restrictions akin to that used by Brot-Goldberg et al. (2021).

[4]This literature has also tended to consider only the effect on the margin, rather than the burden placed on the inframarginal recipients. This is sensible given that a change which *reduces* targeting efficiency while also raising inframarginal burdens must be inefficient no matter how large the burden it imposes is. A smaller literature has considered how to design in-kind transfer programs considering both targeting efficiency and the burden on inframarginal recipients, although that literature has not dealt

Finally, we speak to a recent literature expressing pessimism about the ability of insurers to efficiently ration health care. The primary way insurers have sought to do so is via introducing cost-sharing schemes that reduce risk protection in order to screen beneficiaries' access to care by willingness-to-pay. Recent work has argued that this does a poor job, as beneficiaries do not understand the price incentives (Sood et al., 2013; Baicker et al., 2015; Brot-Goldberg et al., 2017). Our results suggest that a (non-pecuniary) pricing system that faces *providers* rather than patients may target more efficiently, in line with recent work on the efficacy of risk-sharing contracts with providers (Ho and Pakes, 2014; Song et al., 2019).

The paper proceeds as follows. In Section I, we describe how prior authorization is used in practice and sketch a simple conceptual model that highlights what quantities need to be estimated to think about the welfare effects of such policies. In Section II, we describe Medicare Part D, the LIS program, and the data we use. We also provide descriptive statistics on the use of prior authorization policies in this setting. In Section III, we estimate reduced-form regressions of drug use on its prior authorization restriction status. In Section IV, we estimate a structural model of drug demand with the goal of characterizing intensive vs. extensive margin substitution patterns. In Section V, we use the results of this model to measure the trade-off between spending reductions and paperwork costs using calibrated measures of provider costs. In Section VI, we measure effects of authorization restrictions across demographics and on patient health to assess the efficiency of conserved care. Section VII concludes.

I. Prior Authorization Restrictions in Theory and Practice

A. Prior Authorization Restrictions in Practice

The vast majority of health insurance is provided by managed care organizations (MCOs), private insurers who provide insurance coverage, but place restrictions on this coverage to keep costs down (Glied, 2000). With the exception of traditional Medicare coverage for non-drug medical services, virtually all insured Americans face managed care policies of some kind. Prior authorization restriction policies are one item in an MCO's toolbox for reducing costs and ensuring appropriate care. In general, MCOs provide insurance coverage for certain medical services and prescription drugs, while excluding others due to cost and/or clinical efficacy. In between these two stances towards coverage is a third option: The MCO will cover the service/drug, but on an *ad hoc* basis, where coverage must be requested explicitly from the insurer *before* the service is rendered or the prescription filled. This contrasts with an MCO's stance towards unrestricted services and drugs, where coverage is implicit in the insurance contract (though sometimes with a modest financial cost to the consumer via a copayment or deductible).

with bureaucratic mechanisms; see, e.g., Lieber and Lockwood (2019) and Waldinger (2021).

To get permission, the patient's medical provider (rather than the patient herself) must fill out a specific form, provided by the MCO. Authorization forms for prescription drugs generally require the provider to answer some yes-or-no questions regarding why they are choosing to prescribe a restricted drug, *particularly when an unrestricted option is available*. Forms almost always require the patient's history of taking drugs in the same class (including the drug itself, if the patient received coverage for it from a previous insurer) to be reported. Generally, the provider will be asked to provide medical documentation of the assertions made in the form. In Appendix B we provide some examples of prior authorization forms used by MCOs. After the form is submitted, the provider and patient must wait until the MCO authorizes it. Authorization requires an administrator at the MCO to review the application and respond accordingly. This generally takes between 1 and 5 business days (American Medical Association, 2017). If the authorization is approved, the patient can then receive the drug or service with coverage. If not, they will not be able to use coverage unless their provider makes another request and receives authorization.

In theory, prior authorization can be required for most medical services and prescription drugs. In practice, since a single hospital stay or physician office visit is comprised of a bundle of many services, requiring prior authorization for some subset of those would be unnecessarily disruptive, forcing providers to deliver care in a piecemeal way. Instead, prior authorization restrictions are generally applied to discrete services.[5] Prescription drugs, especially specialty and high-cost branded drugs, are the most common treatment to face restrictions, which is why we focus on them in this study. Other commonly-restricted services include surgeries, durable medical equipment, genetic testing, and imaging, most of which are also highly discrete services (America's Health Insurance Providers, 2020). In Section II.D we describe how prior authorization is specifically used in our empirical setting.

The stated purpose of prior authorization restrictions is that they allow an MCO to prospectively review potential drugs whose value, for a specific patient, may not be high enough relative to procurement cost, and reject coverage for prescriptions where this is the case. In this way, coverage under authorization restrictions functions similarly to auto insurance, another setting where insurers require extensive documentation by an expert third party as a prerequisite for coverage. A natural question is, if insurers believe they can observe enough information to make a determination about what care is cost-effective and what care is not, why not make coverage directly contingent on this information in a formulaic way, rather than an ambiguous way requiring human review?[6] First, the implicit formula is likely to be quite complex. For example, for anticoagulants (blood-thinners), newer high-cost non-vitamin K antagonists (so-called "novel anti-coagulants") will be

[5]For these other services, MCOs typically use *retrospective* utilization review instead. Dranove and Spier (2003) present a theory of why MCOs might do this and how it disciplines provider moral hazard. Dunn et al. (2021) study the effect of aggressive use of review-induced claims denials.

[6]i.e., the 'tagging' approach of Akerlof (1978).

preferred over the low-cost generic blood-thinner warfarin if the patient is already taking some other drug that has an adverse interaction with warfarin (of which a few exist). Codifying all of these requirements might be possible but would be difficult to communicate to non-expert patients, and embedding them into a form for the expert medical provider to fill out may be an easier enforcement mechanism. Second, the patient's provider may be able to observe important signals of the patient's suitability for a specialty drug that cannot be credibly communicated to the MCO, e.g. their ability to tolerate side effects, or interactions with diet and lifestyle. A provider doing paperwork in support of the patient's prescription can thus serve as a costly signal to the MCO of the prescription's merit. In the terminology of Nichols and Zeckhauser (1982), the paperwork serves as an 'ordeal' that screens out prescriptions that providers think are relatively low-value for a given patient.

B. A Model of Prior Authorization Restrictions

We present a simple model of prior authorization restrictions in the typical setting in which they are applied. Consumers face a discrete choice over a high cost drug H, a low cost drug L, and the outside option of purchasing no drug (0). A consumer i gets (social) value v_i^d from drug $d \in H, L, 0$. Without loss of generality, we normalize $v_i^0 = 0$ for all i such that v_i^H and v_i^L also represent incremental valuation of H and L relative to the outside option. We also define $\Delta v_i = v_i^H - v_i^L$ as the consumer's incremental valuation of H versus L. Similarly, let c^d be the (social) cost of drug d, and again let $c^0 = 0$ and $\Delta c = c^H - c^L$.

The social planner is considering whether to impose a prior authorization requirement on the high cost drug H. The requirement imposes a constant "sludge" cost of a for every consumer whose doctor fills out and submits the authorization paperwork. Not all prior authorization requests are approved, so not every consumer for whom the sludge cost is paid actually consumes the drug. Let θ represent the (exogenously-determined) approval rate.

While the sludge cost imposes a social cost on physicians, insurers, and consumers, it also may affect who ultimately consumes each drug. Let $D_i^H(0)$ represent consumer i's demand for drug H in the absence of the prior authorization requirement, where $D_i^H(0) = 1$ if the consumer gets the drug in the absence of the prior authorization requirement and $D_i^H(0) = 0$ otherwise.[7] Similarly, let $D_i^L(0)$ be consumer i's demand for drug L and $D_i^0(0)$ be consumer i's demand for the outside option. Finally, let $D_i^d(1)$ be consumer i's demand for drug d with the prior authorization requirement in place.

Social welfare without the prior authorization requirement is thus given by

$$SW(0) = \sum_i \left[(v_i^H - c^H) D_i^H(0) + (v_i^L - c^L) D_i^L(0) \right]$$

[7]We remain agnostic on the relationship between D_i^H and valuation so as to allow for a variety of behavioral and institutional factors to result in wedges between demand and value.

And social welfare with the prior authorization requirement is given by

$$SW(1) = \sum_i \left[(v_i^H - c^H - \frac{a}{\theta}) D_i^H(1) + (v_i^L - c^L) D_i^L(1) \right]$$

The two key differences between these expressions are (1) a sludge cost is paid for every consumer requesting authorization to fill a prescription for drug H when the prior authorization requirement is in place and (2) different consumers consume the drugs under prior authorization.

To see how these two key differences affect welfare, and to illustrate when welfare will be higher versus lower under prior authorization, we now difference the two expressions. First, we make the following assumptions, which we think of as fairly benign:

1) "No defiers": There are no consumers who consume L or no drug when H is not subject to prior authorization restrictions, but consume H when it is ($D_i^H(0) = 0$ and $D_i^H(1) = 1$)

2) "Independence of irrelevant alternatives": There are no consumers who consume no drug when H is not subject to prior authorization restrictions, but consume L when H is subject to restrictions, or vice versal ($D_i^0(0) = 1$ and $D_i^L(1) = 1$, or $D_i^L(0) = 1$ and $D_i^0(1) = 1$)

Given these assumptions, there are five types of consumers. First, there are three groups of inframarginal consumers, those always consuming H, those always consuming L, and those always consuming no drug. Second, there are two groups of marginal consumers: (1) the 'intensive margin marginals' who consume H without prior authorization and consume L when prior authorization is required and (2) the 'extensive margin marginals' who consume H without prior authorization and consume nothing when prior authorization is required. Given this, the difference between $SW(0)$ and $SW(1)$ is given by

$$SW(0) - SW(1) = \underbrace{\frac{a}{\theta} \sum_i D_i^H(1)}_{\substack{\text{Sludge cost for} \\ \text{always H inframarginals}}} + \underbrace{\sum_i (\Delta v_i - \Delta c) D_i^H(0) D_i^L(1)}_{\substack{\text{Incremental social benefit of } H \text{ versus } L \\ \text{for intensive margin marginals}}} + \underbrace{\sum_i (v_i^H - c^H) D_i^H(0) D_i^0(1)}_{\substack{\text{Absolute social benefit of } H \\ \text{for extensive margin marginals}}}$$

The difference in social welfare between the cases without and with prior authorization requirements on H (or the welfare "loss" from prior authorization) consists of three components. The first component is the sludge cost paid for each consumer in the "always H" inframarginal group, amplified slightly by a prior authorization approval rate less than one (θ). This is the pure welfare loss that is the sole focus of most of the literature on administrative costs in healthcare.

The second and third components are the change in welfare due to the shift in social surplus generated by marginals. This is the typical focus of recent papers on administrative burdens in social insurance (Deshpande and Li, 2019; Finkelstein and Notowidigdo, 2019), although our setting contains two margins of substitution rather than one. These components can be either positive (welfareloss due to authorization restrictions) or negative (welfare gain), depending on whether or not incremental or absolute values of drug H for patients on the intensive or extensive margins (respectively) are larger than the incremental or absolute social costs of procuring those drugs.

First, there is a change in welfare due to the shift in the intensive margin marginals from consuming H to consuming L. This component could be positive (welfare loss due to authorization restrictions) or negative (welfare gain due to authorization restrictions), depending on the incremental social value of the marginal consumption relative to the incremental social cost of that consumption. In cases where H is the branded version and L is the generic version of the same drug, $\Delta v_i = 0$, and this component represents a pure welfare gain to offset the welfare loss from the sludge costs. In other cases, where L and H are imperfect substitutes, the welfare consequences are less clear, as the incremental value could exceed the incremental cost. [8]

Second, there is a change in welfare due to the shift in extensive margin marginals from consuming H to consuming nothing. Again, this component could be positive or negative, but for this group the bar for prior authorization requirements to produce a welfare gain is much higher: Here, the *absolute* social value of the marginal consumption must be less than than the absolute social cost. Again, under full insurance we would expect at least some cases where cost exceeds valuation, especially where the cost of the drug is very high, as is often the case with drugs under prior authorization requirements. But again, we would also expect at least some cases where valuation exceeds cost. Once again, it is an empirical question as to which group will dominate among the intensive margin marginals, an empirical question that we attempt to investigate to the best of our ability below.

When Should Policymakers Restrict Drugs? Our model provides several

[8] Under full insurance, we expect there to be some consumers of H for whom incremental cost exceeds incremental value, due to moral hazard (Pauly, 1968). However, the extent to which these consumers make up a large share of drug consumers generally, as well as of the marginals, is an empirical question. In general, we should expect the share of such consumers to be higher in circumstances where the cost difference between L and H is higher.

important insights for where prior authorization is more versus less likely to provide social value. First, prior authorization is more likely to add value in settings where the size of the "always H" inframarginal group is small relative to the size of the marginal groups, since total sludge costs scale with the size of this group. Prior authorization may thus be most useful for "niche" drugs with relatively few users.

Second, prior authorization requirements are likely to be more valuable in settings where the size of the intensive margin marginal group is large relative to the size of the extensive margin marginal group, particularly when a cheaper close substitute exists. As Chandra and Skinner (2012) point out, much of health care spending growth comes from new technologies that have little demonstrated clinical benefit over the status quo. This includes new drugs, and it is thus likely that new, expensive drugs tend to have low incremental value, although they may have large absolute value relative to receiving no treatment.

Rearranging terms, we note that our expression for $SW(0) - SW(1)$ implies that in order for prior authorization to improve welfare it must be the case that:

$$\underbrace{\sum_i \Delta v_i D_i^H(0) D_i^L(0) + \sum_i v_i^H D_i^H(0) D_i^0(1)}_{\text{Social value of all marginal consumption}}$$
$$< \underbrace{\sum_i \Delta c_i D_i^H(0) D_i^L(1) + \sum_i c_i^H D_i^H(0) D_i^0(1)}_{\text{Social cost of all marginal consumption}} - \underbrace{\frac{a}{\theta} \sum_i D_i^H(1)}_{\substack{\text{Sludge cost from} \\ \text{inframarginal} \\ H \text{ consumption}}}$$

This expression realigns our social welfare evaluation into three objects: The drug consumption value effects, drug procurement cost (spending) effects, and sludge cost effects of prior authorization restrictions.

In the following sections of the paper, we estimate the cost of all marginal consumption in the Medicare Part D Low-Income Subsidy Program, as well as the shares of the relevant marginal and inframarginal populations. We then calibrate the per-application sludge costs using cost estimates from the literature.This calibration sets an estimated upper bound on how high the social value of all marginal consumption needs to be in order to make prior authorization as it is currently used in the Part D LIS program welfare-improving. We will then attempt to provide suggestive evidence of the social value of marginal consumption.

II. Setting & Data

A. Medicare Part D and the Low-Income Subsidy

Medicare Part D was introduced in 2006 by the Medicare Modernization Act of 2003 to fill a coverage gap in Medicare, which had previously lacked any outpatient

prescription drug benefit. Under Part D, drug coverage is fully outsourced to privately contracted insurers providing coverage on the government's behalf. The Medicare program organizes a centralized market in which beneficiaries may select from one of these private plans. In 2016, Medicare Part D covered about 41 million beneficiaries and accounted for about $94 billion of annual expenditures, of which 86% was paid for by federal and state governments and the remainder by individual beneficiaries through premium payments and cost-sharing.

Part D plans are required to adopt a standardized benefit design, in terms of their financial as well as non-financial features. Specifically, plans follow a standardized cost-sharing structure and are required to cover at least two drugs in each of 148 therapeutic classes. Nonetheless, plans are given some scope for differentiation, in terms of the specific drugs that they cover on their formulary and the specific cost-sharing levels they assign to different formulary tiers. Similarly, plans are given flexibility in setting non-price rationing mechanisms for formulary-covered drugs, such as authorization restrictions, which constitute a focus of this paper. Meanwhile, consumers enjoy choice among a substantial variety of Part D plans, being free to choose any one of the many Part D plan offered in their service region. In 2016, the average beneficiary had access to 26 stand-alone Part D plans.

While the Part D program is heavily subsidized for all beneficiaries, those with financial need are granted additional subsidies through the low-income subsidy program (LIS), which offers supplemental drug premium and cost-sharing support. Around 30% of Medicare beneficiaries participate in the LIS program. So-called 'dual-eligibles' (those who simultaneously qualify for both Medicare and their state's Medicaid program) are automatically enrolled in the LIS program when they qualify for Medicare, as are beneficiaries in the Medicare Savings Program. Others not automatically eligible for LIS, but who meet income and asset eligibility criteria, can qualify by applying directly.

The generosity of LIS subsidies varies by group, with partial LIS recipients receiving partial premium and cost-sharing support, while the full LIS on which our study focuses receive much more generous subsidies. Specifically, full LIS recipients get a subsidized reduction in their plan premium payments up to the 'benchmark' amount, meaning that those enrolling in a subset of plans (otherwise known as 'benchmark plans') would have no premium responsibility. Multiple benchmark plans are available in a service region; beneficiaries have access to between two and sixteen, with 92% of beneficiaries having at least 5 benchmark plans to choose from (see Appendix Figure A1).

Dual-eligibles in the LIS program additionally receive substantial cost-sharing subsidies: They have all plan deductibles completely waived, under both benchmark and non-benchmark plans. In addition, full LIS beneficiaries in both benchmark and non-benchmark plans are shielded from each plan's drug-specific copayment and coinsurance schedule, which can otherwise be a significant source of out-of-pocket costs for Medicare beneficiaries. Instead, full LIS beneficiaries face

their own custom copayment schedule: In 2020, they were charged a copayment of $1.30 for all formulary-covered generic drugs and $3.90 for all formulary-covered branded drugs, though in most cases these nominal copayments are not actually collected. In addition to substantially reducing out-of-pocket costs, this policy also makes plans effectively uniform in their financial characteristics for dual-eligible beneficiaries, nullifying any variation in cost-sharing determined by the plan sponsor.

Given that the full-LIS population's out-of-pocket expenses are uniform for covered drugs, plans most materially differ in the set of drugs covered by their formularies (the set of drugs that they offer coverage for), along with the utilization management requirements imposed on those drugs that are covered. As a result, this setting is particularly well-suited for isolating the impact of prior authorization and formulary restrictions on different drugs. Note that in this context, formulary exclusion of a drug means a beneficiary would have to pay the full sticker price of that drug out-of-pocket if they opt to purchase the drug. Because Part D regulations require plans to cover at least two drugs in each therapeutic class, beneficiaries will generally have another covered drug that they can switch to as a substitute, although it might be an imperfect substitute given variation in how good

This heterogeneity is important, as it leads to substantial cross-plan variation in the set of drugs covered by plans' formularies, as well as the prior authorization restrictions imposed on covered drugs, all of which we leverage as part of our study. To take the popular anti-cholesterol drug Lipitor as an example, of the nine benchmark plans in New York in 2009, six plans covered the drug on their formulary while three did not. Further, even among the six plans that did cover the drug, two required prior authorization for beneficiaries to obtain coverage, while four did not. As such, if a LIS beneficiary in New York wanted to fill a prescription for Lipitor but was on one of the three plans that did not cover it, they had the option to either pay for its cost 100% out-of-pocket, substitute to another drug, or switch plans entirely. Given that different anti-cholesterol medications (as well as many other classes of important drugs) are not perfect substitutes for one another, these cross-plan differences in drug coverage can be meaningful for beneficiaries and carry real consequences.

B. Data

We make use of several administrative datasets from the Centers for Medicare and Medicaid Services (CMS). These data contain information on beneficiary program enrollment status, medical utilization, and prescription drug utilization within the Medicare program. The data is nationwide in scope and extends from 2007 to 2015, tracking drug utilization for all Medicare beneficiaries and medical utilization for all beneficiaries outside of Medicare Advantage.

Beneficiary Demographics, Enrollment, and Choice Status.

We obtain information on beneficiary demographic characteristics and plan as well as program enrollment from the Medicare Beneficiary Summary File. This file provide important demographic information such as age, gender, and geographic location, including the Part D plan region to which individuals belonged that year. It additionally tracks enrollment status at a person-month level for different Medicare programs, including Part A (the hospital benefit), Part B (outpatient), Part C (Medicare Advantage), and Part D (prescription drugs). These Medicare files also track enrollment in the LIS program at a person-month level, and whether beneficiaries qualify for the full LIS subsidy.

We combine this data with a newly released plan election type file. This file covers all Part D enrollment spells from 2007-2015, and for each spell tracks whether enrollment was initiated through active choice or default auto-assignment. Importantly, in addition to listing the plan a beneficiary was enrolled in during each month, the file also includes the default plan that was assigned to the beneficiary, even if the beneficiary opted out of that default. This allows us to observe the *assigned* plan as well as the *realized* plan for each beneficiary.

Plan Characteristics and Formulary Data.

We obtain information on plan characteristics from publicly available CMS datasets, which cover all Part D plans offered during our sample period. These data track the set of plans offered in each Part D plan region. For each plan in each year it was offered, we are able to observe the monthly premium that the plan charged (both the Medicare-paid portion and the beneficiary-paid portion) and the plan's benchmark status.

We additionally obtain drug-level formulary data for each Part D plan, publicly available from CMS, information which is key to our study design. This data tracks the set of drugs covered by each plan's formulary, at a drug-by-drug. For each covered drug, the data also indicates the type of utilization restrictions imposed by the plan on the covered drug, including prior authorization, step therapy, or quantity limits.

While the original CMS data defines drugs at an NDC level, we revise the drug definition to instead be at the combination of active ingredient and brand/generic status, and then aggregate the data up to this level. In doing so, we effectively treat different doses and different modes of administration as equivalent; if a formulary covers at least one dose or mode of administration, we count every possible dose/mode of administration as covered. Similarly, this approach also means that we treat identical generic substitutes as equivalent, and treat the full set of generic substitutes as covered so long as at least one is by a plan.

Outpatient Prescription Drug Data.

We track outpatient prescription drug usage for a random 20% sample of Part D enrollees using claims-level Medicare data from the Part D Event files. Each claim represents an event where a beneficiary filled a single prescription of a given drug. For each claim, we observe the specific drug prescribed and filled (at the NDC code level), the quantity/days supply for the fill, as well as the date when the prescription was filled, and the cost charged to the beneficiary and to the Medicare program. As with the formulary data, rather than defining unique drugs directly based on NDC codes, we instead define a unique drug based on the combination of active ingredient and brand/generic status. Setting comparable drug definitions across these two data files ensures that we can cleanly link the formulary file to the outpatient drug claims at an individual drug level, to then examine the impact of formulary coverage/prior auth status on a given drug's utilization.

For our main analyses, we restrict only to drugs that were listed as covered by at least one Medicare Part D plan formulary in that calendar year. This is meant to remove uncovered drugs from our sample, for which there would be no coverage variation, and additionally to remove miscellaneous drug types whose coverage status we would not be able to track in formularies whatsoever.[9] As part of our analyses, we aggregate utilization statistics from the drug claims data up to the plan-drug-market-year level, for our main analytic sample of interest. Plan for these purposes is defined based on beneficiaries' originally assigned, rather than actual enrolled, plan in the listed contract year. We then divide the aggregated statistics up by the number of people in a given plan-drug-market-year cell in our analytic sample, to yield per capita utilization statistics. Aggregating this data at a plan-level rather than individual beneficiary level substantially reduces the number of observations in the data, and in doing so makes analysis of the data much more tractable.

C. Sample Selection

For our main analyses, we employ a single subsample of LIS beneficiaries, which is defined to cleanly and maximally exploit natural experiments in exposure to prior authorization. To start, we restrict to those in Medicare Parts A, B, and D, and not enrolled in Medicare Advantage. We further restrict to individuals who qualify for the full rather than partial LIS subsidy, who would qualify for the full premium subsidy and for whom cost-sharing for formulary-covered drugs would be minimal. We generally sample at the beneficiary-year level and require these restrictions to be true for every month in a year in which we include a beneficiary in our sample.

Critically, we additionally restrict to individuals who were randomly re-assigned from their incumbent plan to a new plan; these individuals are made up of previous

[9] For example, formularies generally do not track coverage status for over-the-counter (OTC) drugs.

non-active choosers, whose incumbent plans lost benchmark status. In doing so, we exclude incumbent plan-market combinations where reassignment is expected to be non-random, based on reassignment rules. For example, reassignment will not be randomized if the carrier of the incumbent plan offers another benchmark plan in the market, as all reassignees will simply get funneled to that other plan.[10] Finally, for beneficiaries whose assigned plan retained benchmark status for two full years following the beneficiary's reassignment, we include data for two years post-assignment. For beneficiaries whose assigned plan lost benchmark status in the second year post-assignment, we drop the second year and only keep observations from the first year. Table 1 shows summary statistics for the plans included in our sample. There are 1,444 plan-years in our sample, with an average of 804 beneficiaries per plan. The average plan requires prior authorization for 12% of drugs it covers.

Table 1—: Included plan summary statistics

	Whole sample	First year	Second year
Plan-years	1,444	1,071	723
Mean benes per plan	804.1	655.2	635.3
Mean % of drugs under prior auth	12.0	11.7	12.6
	(4.5)	(4.7)	(4.0)
Mean % of drugs excluded	28.4	27.4	29.6
	(9.8)	(10.6)	(8.3)

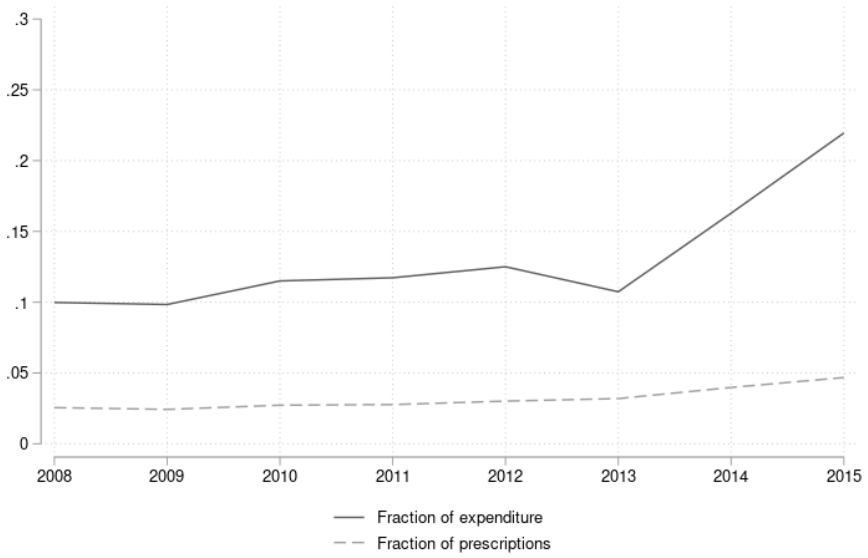
Note: Observations are at the plan-year level. The first column includes all beneficiary-years in our sample. The second column includes all beneficiaries in the first year after being re-randomized to a new plan. The third column includes beneficiaries whose randomized plan retained benchmark status for two full years following initial reassignment.

D. Prior Authorization in Medicare Part D

Before proceeding to our main empirical analysis, we describe the use of prior authorization restrictions in Medicare Part D over time and across drug types. Figure 1 shows the use of prior authorization restrictions for a 20% sample of Medicare Part D claims from 2008-2015. Use of prior authorization increased over this period, and by 2015 5% of all claims under part D involved a prior authorization requirement, accounting for more than 20% of overall spending. Use of prior authorization differs substantially by therapeutic class. Appendix table A1 shows incidence of prior authorization restrictions for the top 30 therapeutic classes by Part D drug expenditure in 2008-2015. These classes together

[10] We perform additional robustness checks to validate that reassignment out of different incumbent plan-market combinations is randomized, and drop combos from the sample from which reassignment does not appear random, based on observables.

Figure 1. : Use of prior authorization in Medicare Part D



make up 83% of all spending. Among the highest spending classes, prior authorization is particularly common for biological response modifiers (affecting 70% of total claims spending), immunosuppressants (66%), and anti-neoplastic drugs (58%).Prior authorization is also used in mental health, affecting 7% of antipsychotic spending and 8% of antidepressant spending. On the other hand, prior authorization is less common for important classes like the antihyperlipidemic drugs (including well-known 'blockbuster drugs' like Lipitor and Crestor) and insulins. Table 2 shows use of prior authorization restrictions for all drugs in our sample. The average drug is under prior authorization restriction for 13% of plan-years. Branded drugs without generic equivalents are under prior authorization restrictions for 24% of plan-years, much higher than either generics or branded drugs with generic equivalents. Branded drugs with generic substitutes are on average excluded by more than half of plan-years, and exclusion is also common for branded drugs without generics. The price of branded drugs[11] without generic equivalents is higher than for branded drugs with generics or generics. Figure 2 shows that higher cost drugs are more likely to have prior authorization restrictions. This pattern is observed for both branded and generic drugs, but is more pronounced for branded drugs with a full 60% of drugs in the top ventile of price under prior authorization.

[11]'Price' is defined as claim total cost divided by days supply of the drug. This ignores any rebates the insurer may receive from drug manufacturers

Table 2—: Formulary restrictions by drug type

	All	% Drug type		
		Branded without generic	Branded with generic	Generic
Number of drug-years	12,727	4,457	3,443	4,736
Number of unique drugs	2,017	847	609	742
% of plan-years under prior auth	12.6	23.5	5.9	7.8
	(23.9)	(30.4)	(15.0)	(18.6)
% of plan-years excluded	29.8	27.5	57.4	10.2
	(34.9)	(30.7)	(37.7)	(18.2)
Price per day supply (USD)	26.0	61.2	16.1	5.6
	(128.4)	(218.6)	(44.1)	(22.3)
% of benes with any use	0.8	0.3	0.2	1.7
	(2.9)	(1.1)	(1.0)	(4.4)
Cost per enrolled bene (USD)	2.6	5.0	1.3	1.4
	(10.3)	(16.0)	(5.9)	(3.5)

Note: A 'drug' is defined as a combination of active-ingredient and whether the product is branded/generic. Products containing different doses of the same active ingredient and with different modes of administration are all counted as the same drug.

III. The Effect of Authorization Restrictions on Prescribing

We begin by estimating the effect of prior authorization restrictions on drug utilization at the person-drug level. We specify that as estimating the treatment effect of moving a drug from having coverage with no restrictions to having coverage with restrictions on the utilization of that same drug, all else equal. Our initial analysis seeks to estimate the average treatment effect, averaged over beneficiary-drug pairs, $E_{id}[Y_{id}(1) - Y_{id}(0)]$.

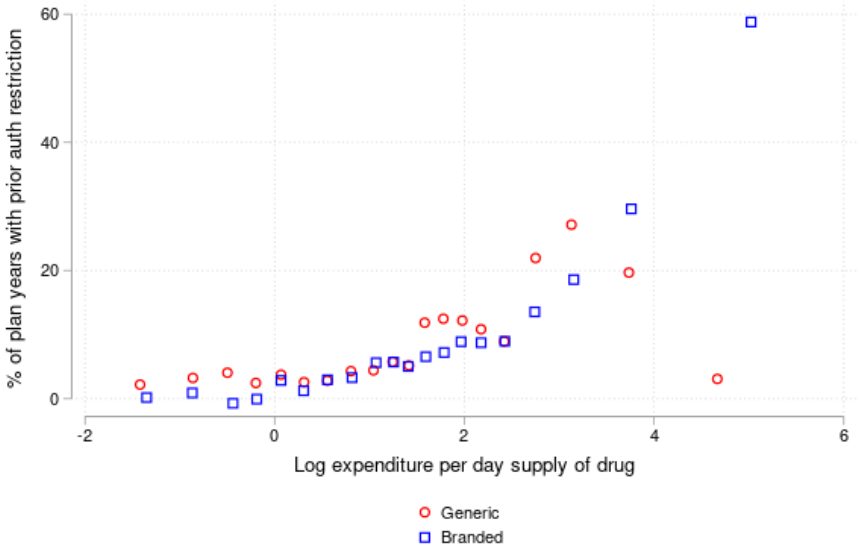
A. Research Design

Before delving into our research design, it is worth highlighting what the ideal experiment would look like. Ideally, beneficiaries would be uniformly-randomly assigned to a formulary where any given drug could either be covered with restrictions or without restrictions, with all possible formulary arrangements available for assignment. We would then be able to estimate the simple regression of utilization on restriction status,

$$Y_{id} = \beta \text{Auth}_{id} + \epsilon_{id}$$

and β would represent an unbiased estimator of the average treatment effect. Unfortunately, this is not a proper representation of our setting. Our setting has

Figure 2. : Prior authorization restrictions by drug price



random assignment to default auto-enrollment into one of a handful of insurance plan options. This creates five complications.

First, drugs can be unrestricted and restricted as well as fully excluded by the plan, a third category. Because we are interested in the effects of prior authorization restrictions relative to the counterfactual where the drug is included on the formulary and not restricted, comparing restricted drugs to all other drugs would not provide an estimate of our parameter of interest because it would improperly conflate unrestricted and excluded drugs. There are thus two possible treatments, restriction and exclusion, and we must control for whether a drug receives the excluded treatment in order to cover the independent effect of prior authorization requirements relative to unrestricted formulary inclusion.

Second, not every formulary is available for assignment. Because there are 3 potential treatments and approximately 2000 unique drugs, this would require $3^{2000} = 1.7 \times 10^{954}$ unique formularies to be available, which is larger than our sample size. Moreover, as shown in Section II.D, drugs facing authorization restrictions are non-randomly chosen, and tend to be expensive on-patent branded drugs. Therefore we need to control for drug fixed effects, or else our treatment effect will be biased by differences in counterfactually-unrestricted levels of use among frequently-restricted drugs.

Third, the random assignment we use is not to *formularies* but instead to *plans*. As we describe in Section II.A, for LIS beneficiaries, plans have limited scope to differentiate on dimensions other than their formulary. However, we need not

assume this is true. Instead, we absorb differences across plans that secularly affect drug utilization, using plan fixed effects.[12]

Fourth, the randomization we use is across plans within a specific market (defined by region and year), with the formularies available varying across markets. If this variation reflects the tastes of the market (e.g., drugs are less likely to be restricted by plans in a given market if beneficiaries prefer them in that market), this will introduce correlation between treatment assignment and unobservable preferences for a drug. We therefore perform all of our analysis within-market, interacting all fixed effects with fixed effects for the market. That is, instead of controlling for drug and plan fixed effects, we control for drug-market and plan-market pair fixed effects.

Fifth, we need to account for spillovers across drugs. Since some drugs are substitutes, restrictions on one drug may have positive effects on the consumption of another. While this fact alone would not lead to bias, it will if prior authorization restriction status is correlated across substitute drugs. For example, take a situation in which three drugs can be used to treat a condition: Drug A, Drug B, and Drug C (ordered by increasing price). Generally, restriction status is reserved for the most expensive drugs. If an MCO restricts Drug B, they are likely to also restrict (or exclude) Drug C. Therefore, if we didn't control for the status of Drug C, we would underestimate the effect of prior authorization applied to B alone on consumption of B, which would be confounded by the (positive) effect of restricting access to C. In other words, we want to compare the use of a drug for beneficiaries assigned to a formulary where that drug is under prior authorization restriction versus beneficiaries assigned to a formulary where that drugs has no restriction, *holding fixed the formulary status for all substitute drugs.* Since there are roughly 2000 drugs, controlling richly for all drugs' substitution effects on others would require us to estimate approximately 4 million parameters, which is infeasible given our limited number of unique formularies. Instead, we construct a single control for prior authorization status of substitute drugs, $\text{Auth}_{id}^{Sub} = \sum_{k \in \mathcal{C}(d)} s_k \text{Auth}_{ik}$, i.e., the share of drugs k within the same class $\mathcal{C}(d)$ that face authorization restrictions, weighted by their market shares s_k in the entire sample.[13] We also control for a similar measure for formulary exclusion of substitute drugs.

Incorporating these issues, our primary estimating equation is

[12] In later analyses, identification requires us to drop these plan fixed effects. In Appendix Table A6, we show that our results are robust to excluding them, implying that drug exclusion and restriction fully capture the effect of plans on drug consumption.

[13] This weighting scheme is exactly appropriate if demand is logit or nested logit, under which $\frac{\partial Y_{id}}{\partial \text{Auth}_{ik}} \propto s_{ik}$

$$
\begin{aligned}
(1) \qquad Y_{id} &= \beta \text{Auth}_{id}^{\text{Assigned}} + \delta \text{Excl}_{id}^{\text{Assigned}} + \alpha_{dm(i)} + \eta_{p(i)m(i)} \\
&+ \beta^{Sub} \text{Auth}_{id}^{\text{Sub,Assigned}} + \delta^{Sub} \text{Excl}_{id}^{\text{Sub,Assigned}} \\
&+ \alpha_{dm(i)} + \eta_{p(i)m(i)} + \epsilon_{id}
\end{aligned}
$$

Our approach, which relies on two-way fixed effects, is similar in spirit to difference-in-differences designs used in the literature (de Chaisemartin and D'Haultfœuille, 2020). β is identified off of many two-drug, two-plan comparisons, comparing utilization differences across plans for a drug whose formulary status varies across the two plans to one whose formulary status does not vary.

Our approach is valid under a handful of assumptions. First, since we are leveraging the auto-assignment mechanism, it must be that assignment to authorization restrictions is truly random (within a market), i.e., for a given drug d, the formulary status of that drug in the plan beneficiary i is assigned to must be independent of their unobserved propensity to use the drug, ϵ_{id}. In the next section we provide a number of balance tests which support this assumption. Second, we require an approach akin to the 'parallel trends' assumption in difference-in-differences research designs: Since we identify our treatment effect using two-way drug and plan fixed effects, it must be that plans that restrict a drug do not engage in other, unobservable actions that encourage or dissuade beneficiaries from using that drug (relative to plans that do not restrict the same drug). Plans can have secular effects on drugs overall (e.g. having restrictive pharmacy networks that make it difficult to pick up drugs), which will be absorbed by the plan fixed effects, but are assumed to not *differentially* affect drugs (e.g. by instituting other drug-specific coverage policies) in ways that are correlated with use of prior authorization restrictions. For LIS beneficiaries, plans have limited capacity to affect drug utilization beyond formulary design, so we feel comfortable making this assumption.

B. First Stage

Before we estimate our primary regression, we first estimate a 'first-stage' regression to show that compliance is extremely high. We perform basic checks of compliance and balance. For more detail on when and why beneficiaries comply with default assignments in this setting, see Brot-Goldberg et al. (2021).

We estimate the following regression to determine compliance with the assigned default:

$$
\begin{aligned}
(2) \qquad \left\{ \begin{array}{c} \text{Auth}_{id}^{Enrolled} \\ \text{Excl}_{id}^{Enrolled} \end{array} \right\} &= \vec{\gamma_1}\text{Auth}_{id}^{Assigned} + \vec{\gamma_2}\text{Excl}_{id}^{Assigned} \\
&+ \vec{\gamma_3}\text{Auth}_{id}^{Sub,Assigned} + \vec{\gamma_4}\text{Excl}_{id}^{Sub,Assigned} \\
&+ \alpha_{dm(i)} + \eta_{p(i)m(i)} + + u_{id}
\end{aligned}
$$

where the coefficients $\vec{\gamma_1}, \vec{\gamma_2}$ measure compliance with assignment at the drug level. In practice, the input dataset into this regression as well as our main regression contain approximately 1.6 billion observations, since each observation is an individual-drug-year tuple. Estimating such a model with high-dimensional fixed effects is computationally burdensome. To ease computation, we collapse our dataset down to the drug-plan-market (the assigned treatment unit) level and measure averages of outcomes over these aggregates. This is equivalent to clustering our standard errors at the drug-plan-market level. Indeed, we eventually cluster at the plan-market level, so we do not lose any information through this shortcut. We weight plan-market observations by the number of assigned beneficiaries.

Estimates from Equation 2 are given in Table 3. Our first stage is extremely strong, with F-statistics of over 67 million, well above the usual threshold of 10. Approximately 97% of beneficiaries comply with their default assignments. One worry is that, although this result is strong for the general population, most individuals do not use most drugs. If compliance is primarily centered around beneficiary-drug pairs where the beneficiary is unlikely to use the focal drug, our instrument will only be strong for an irrelevant population. To try to address this, we re-estimate the first stage on a subset of beneficiary-drug pairs where the beneficiary took the drug at least once in the prior year. These beneficiaries should be especially likely to take the drug again in the following year. We present results from these regressions in Appendix Table A3, which line up well with those in Table 3. This is unsurprising given that Brot-Goldberg et al. (2021) show that beneficiaries in this setting do not actively choose plans in response to defaults that exclude their previously-used drugs.

Another worry is that the default assignment we leverage is not truly random. We perform a series of balance tests, where we replace the dependent variables in Equation 2 with a series of variables which should be independent of default assignment: Restriction and exclusion status for the drug d in the beneficiary i's plan in the prior year, their utilization of that drug in the prior year, and demographics (age, whether they are female, whether they are white). We display the results from this exercise in Appendix Table A4. Reassuringly, our estimated differences from these regressions are substantively small.

Table 3—: First Stage Regressions

	$\text{Auth}^{\text{Enrolled}}$	$\text{Excluded}^{\text{Enrolled}}$
$\text{Auth}^{\text{Assigned}}$	0.968	< 0.001
	(< 0.001)	(< 0.001)
$\text{Excluded}^{\text{Assigned}}$	< 0.001	0.968
	(< 0.001)	(< 0.001)
F-statistic	73,076,468	67,775,444
R^2	0.972	0.974
Number of drug × plan × plan years	10,376,842	
Number of market years	210	
Number of drug × bene years	1,622,630,894	
Average plans per market year	6.9	
Average benes per plan	749	

Note: Observations are at level of drug × assigned plan × enrolled plan × year. Column (1) shows estimates from regressions of prior authorization of drug d in enrolled plan on prior authorization and exclusion status of drug d in assigned plan.

C. Main Estimates

We now estimate the effect of prior authorization restrictions on utilization by estimating the regression in Equation 1. We focus on two outcomes: Total spending by that beneficiary on the drug in that year, and a binary indicator for whether the beneficiary filled the drug at least once in that year.[14] We estimate two versions of these regressions: One without the controls for restrictions on substitutes (in the first and third columns), and one with those controls (in the second and fourth columns). For all regressions, we continue to cluster standard errors at the plan-market-year level. We present these results in Table 4.

While our results seem small in magnitude, this is because the overwhelming majority of beneficiary-drug-year tuples result in zero utilization. Therefore, we need to reference a control mean to properly situate the results. We construct a control mean by estimating a regression of $Y_{idt} = \alpha_{dm(it)} + \eta_{p(it)m(it)} + \epsilon_{idt}$ only on control observations. We then average over the α_{dm} values to construct an appropriate mean spending/utilization level estimate for untreated beneficiaries and list this as "Control Mean" in Table 4. However, this is still the wrong reference mean, since our treatment effect is, implicitly, a weighted average treatment effect where weights are proportional to treatment variance in assigned plans. Therefore, we reweight the α_{dm} values by $\text{Var}[\text{Auth}_{id}|d, m]$, the variance of authorization restriction status for a given drug in a given market across beneficiaries. Since drugs with lower baseline utilization are weighted more heavily in our regression, we must account for that appropriately.

[14] Again, we measure these outcomes, then average over them at the plan-market-year level.

Table 4—: Main Regressions

	Spending		% Ever filled	
$\text{Auth}^{\text{Assigned}}$	-0.748	-0.769	-0.090	-0.097
	(0.035)	(0.036)	(0.003)	(0.003)
$\text{Excluded}^{\text{Assigned}}$	-0.978	-0.994	-0.117	-0.122
	(0.0305)	(0.031)	(0.0031)	(0.0031)
Auth^{sub}		0.149		0.048
		(0.030)		(0.004)
$\text{Excluded}^{\text{sub}}$		0.536		0.127
		(0.040)		(0.008)
F-statistic	617	325	832	500
R^2	0.837	0.837	0.978	0.978
Control Mean	3.486		1.320	
Reweighted Control Mean	3.991		0.446	
Number of drug × plan years	2,164,653			
Number of market years	210			
Number of drug × bene years	1,740,683,902			
Average plans per market-yr	6.9			
Average benes per plan	804			

Note: This table presents estimates from regressions of utilization measures on prior authorization and exclusion of a given drug and other drugs within the class. Each observation is a drug-plan-year. Regressions include plan-market-year and drug-market-year fixed effects. Prior authorization of substitute drugs is mean prior authorization status of all other drugs within the class, where drugs are weighted by their average expenditure across all plans in the sample.

Given this re-weighted control mean, our results indicate that prior authorization restrictions reduce spending on the focal drug by 20%, and reduce the share of beneficiaries who ever use that drug by 22%.[15] Restrictions on substitute drugs, as expected, raise utilization of the focal drug by an economically meaningful amount. Despite the high unconditional correlation between restrictions on the focal drug and its substitutes, including these controls has a minimal effect on our estimated coefficients, due to us conditioning on drug and plan fixed effects. This result is robust to other utilization measures. In Appendix Table A5 we estimate the same regression using two other measures of utilization: The number of fills during the year (reduced by 25%), and the total days supply for the year (reduced by 28%).

Taking our regression results and scaling them up to the full sample, the regime of authorization restrictions imposed between 2008 and 2015 reduced spending by $66 million (roughly $57.6 per beneficiary-year) compared to a regime where all

[15]The "% ever filled" indicator is the number of beneficiaries per 100 who ever fill a prescription in a year for the focal drug. The reweighted control mean of 0.446 indicates that the (weighted) average drug is ever used by 0.446% of the population.

of the same drugs are covered without restriction. However, this is potentially an overestimate. Our estimator implicitly compares untreated drugs to treated drugs (via the plan fixed effect). However, as our regressions show, restrictions on one drug causally increase utilization of other drugs. While our estimates are valid for the focal drug, computing the savings from using authorization restrictions require us to account for spending on substitute drugs.

IV. Estimating Drug Substitution

Understanding the extent of savings generated by authorization restrictions, as well as the effects on drug consumption, requires us to model the extent to which patients who are deterred from using a restricted drug substitute to an unrestricted drug or to no drug at all. Further, as we discuss in more detail in Section V, our model in Section I.B also showed that understanding the extent to which the overall effect on the focal drug reflects intensive versus extensive margin effects is critical for determining the welfare consequences of prior authorization. Determining the importance of substitution versus extensive margin effects in a reduced-form way is challenging: It would require us to estimate the effect of prior authorization for a given drug on every other drug. As mentioned in Section III.A, our setting has too many drug options and not enough unique formularies for this to be a viable option. Therefore we must enforce some structural restrictions on drug demand to properly estimate substitution patterns and perform this decomposition.

We assume that beneficiaries and their prescribing medical providers choose a drug by maximizing a utility function representing their joint decision-making process (c.f. Ho and Pakes (2014); Brot-Goldberg and de Vaan (2018) for similar approaches to joint decision-making). We follow recent work by Dubois et al. (2019) and Ganapati and McKibbin (2019) and assume that the pair chooses a single drug (or no drug) to consume each year from a therapeutic class. That is, by this assumption, we assume that drugs in *different* therapeutic classes are neither substitutes nor complements and we assume that drugs in the *same* therapeutic class are potentially substitutes *but are never complements*. We assume that the utility function to maximize is:

$$u_{id} = \beta_{c(d)}\text{Auth}_{id} + \delta_{c(d)}\text{Excl}_{id} + \alpha_{dm(i)} + \epsilon_{id}$$

We allow beneficiary-provider pairs to have preferences that vary in mean terms across drugs, and allow pairs in different markets to have different preferences across drugs ($\alpha_{dm(i)}$). Pairs face a constant barrier (β and δ, which vary across therapeutic classes) to getting a drug depending on its formulary status. We normalize u_{i0}, the mean utility of the outside option of getting no drug, to zero.

Finally, we assume that unobserved preferences for options ϵ are Type 1 Extreme Value, independent and identically distributed across beneficiaries, but correlated across drug options for a beneficiary, with correlation $1 - \lambda$. This structure gives rise to a nested logit demand system, with a nest for all 'inside

goods' (the choice to take a drug within the class rather than take no drug). That is, the probability of taking a drug d is

$$P_{id} = \frac{\exp \frac{V_{id}}{\lambda} \left(\sum_{k \in D} \exp \frac{V_{ik}}{\lambda} \right)^{\lambda - 1}}{1 + \left(\sum_{k \in D} \exp \frac{V_{ik}}{\lambda} \right)^{\lambda}}$$

and the probability of taking no drug is

$$P_{i0} = \frac{1}{1 + \left(\sum_{k \in D} \exp \frac{V_{ik}}{\lambda} \right)^{\lambda}}$$

where $V_{id} = \beta_{c(d)} \text{Auth}_{id} + \delta_{c(d)} \text{Excl}_{id} + \alpha_{dm(i)}$ and D is the set of drugs (i.e., choices other than the outside option).

This nesting structure is essential, because the standard conditional logit substitution effects depend on the share of relevant beneficiaries taking each option. Since most beneficiaries take no drug, this would lead us to incorrectly predict substantial extensive-margin substitution in response to authorization restrictions. Instead, the extent to which beneficiaries substitute on the intensive margin (to another drug) or the extensive margin (to no drug) depends on $\lambda \in (0, 1)$, to be estimated. Lower (higher) λ values imply that relatively more substitution is on the intensive (extensive) margin.

We note that, in contrast to our earlier reduced-form regressions, our drug choice model omits plan fixed effects. This is due to identification constraints in the nested logit. As Berry (1994) and Berry and Haile (2016) note, in the nested logit, an econometrician needs two instruments for each product: One for the price (in this case the presence of prior authorization restrictions), and one for the quantity of use across the nest (i.e., the total share of beneficiaries who use *any* drug). Our implicit instrument for a drug's own authorization restriction for a beneficiary is whether the beneficiary was assigned to a plan with a restriction; our instrument for the group share is the full regime of prior authorization restrictions facing the beneficiary, including both the drug in question and all other drugs. For example, in a simplified setting with two drugs, H and L, where only H ever faces prior authorization restrictions, both the coefficient on prior authorization and the nesting parameter are identified from changes in outcomes in response to H facing restrictions; the coefficient on prior authorization is determined from changes in H's market share; whereas the nesting parameter is determined from changes in L's market share. Since a plan is defined by its formulary, we would only be able to identify differences across plans *within a formulary*, which is arbitrarily defined across classes. We instead simply omit these fixed effects. In Appendix Table A6 we show that our reduced-form results are the same without plan fixed effects, alleviating any worries about omitted variable bias.[16]

[16]The irrelevance of plan fixed effects is not too surprising here, given that plans are unlikely to differ

To construct the relevant data set, we define a beneficiary as taking a drug within a class if they ever filled it during the year. For beneficiaries who took multiple drugs within a class, we assign them to the drug they filled with the highest days supply during the year, and break ties randomly. We restrict to classes where drugs under prior authorization made up at least 3% of spending, and where the average spending on the drug per beneficiary-year in our data exceeded $1. This left approximately 60 therapeutic classes. We estimate the model using maximum likelihood estimation, and do so separately for each therapeutic class. The parameters themselves are largely uninterpretable . Instead, we focus on interpreting them through the lens of counterfactual exercises.

With the model estimated, we can then use it to ask how the current use of authorization restrictions affects spending and utilization. Using our model, we simulate demand for drugs under 1) the status quo assigned formularies; and 2) an alternative arrangement where we remove all uses of authorization restrictions (but otherwise leave formulary exclusion as it is).[17] We then compute the differences between these two simulations and display them in Table 5. We compute spending by assuming that beneficiaries who consume a drug spend an amount equal to the empirical average amount spent on that drug by beneficiaries who consumed it in the same region-year pair.

Our results suggest that prior authorization reduced drug spending by 1.5%, approximately $23.7 per beneficiary-year.[18] This spending reduction is composed of a 15% reduction in utilization of restricted drugs ($37.4 reduction in spending per beneficiary-year), and an 0.9% increase in the utilization of unrestricted drugs ($13.7 increase in spending per beneficiary-year). Our current estimates show that the vast majority of beneficiaries switch to another drug rather than substitute away from drugs altogether.[19] This stands in stark contrast to results on the substitution margins of cost-sharing, where e.g. Brot-Goldberg et al. (2017) find that patients facing cost-sharing tend to substitute to no service rather than a cheaper one.

in ways not captured by the formulary, and we fully control for all relevant dimensions of the formulary for the LIS population (prior authorization restrictions and exclusion).

[17]Note that, for beneficiaries assigned to plans that used no authorization restrictions, they will not have differences in spending across the two simulations.

[18]This is far less than our estimate in Section III, but this largely reflects the restriction on classes imposes in this exercise, as we can see by the fact that the reduction in only restricted drugs is also less than results from Section III.

[19]This version is still preliminary. We think this may be an underestimate of the true margin of substitution.

Table 5—: Counterfactual Simulations

	Total	Restricted Drugs	Unrestricted Drugs
Change in Spending	-1.5%	-11.5%	+1.1%
	-$23.7	-$37.4	+$13.7
Change in Utilization	0%	-15.0%	+0.9%

Note: This tables presents results from an exercise where we switch beneficiaries from facing no authorization restrictions to facing the status quo for 60 classes, chosen as described in this section. We detail the change in spending and utilization of all drug, restricted drugs (those drug-plan-region-year observations where an authorization restriction was in place in the status quo), and unrestricted drugs. In the spending panel, the upper row gives the percent change in these quantities, while the lower row presents the absolute change per beneficiary-year.

V. Characterizing Trade-Offs of Drug Restrictions

From Section IV, we now have estimates of the effect of authorization restrictions on utilization and spending. We can use these estimates, as well as some calibrations we introduce in this section, to think about the trade-offs policymakers face when introducing restrictions on drugs. As presented in Section I.B, a policymaker should be willing to do so for a given drug H when

$$\underbrace{\sum_i \Delta v_i D_i^H(0) D_i^L(0) + \sum_i v_i^H D_i^H(0) D_i^0(1)}_{\text{Social value of all marginal consumption}} < \underbrace{\sum_i \Delta c_i D_i^H(0) D_i^L(1) + \sum_i c_i^H D_i^H(0) D_i^0(1)}_{\text{Social cost of all marginal consumption}} - \underbrace{\frac{a}{\theta} \sum_i D_i^H(1)}_{\substack{\text{Sludge cost from} \\ \text{inframarginal} \\ H \text{ consumption}}} \tag{3}$$

where H is the restricted drug and L represents the unrestricted drug(s).

Our results from Section IV provide us with estimates of $D_i^j(T)$ for all drugs j and restriction regimes T, allowing us to characterize the relative size of the inframarginal and marginal groups. We take c_i^j to be the (average) transacted price of the drug, observed within our claims data.[20] This leaves three parameters still unknown: a, the paperwork cost of an application; θ, the authorization request approval rate; and v_i^j, the value of drugs to consumers.

As we discuss below, we calibrate a and θ from reports in the health policy

[20]This means we do not account for rebate agreements between manufacturers and insurers/pharmacy benefit managers, which Kakani et al. (2020) show are prevalent, since we do not have access to data on these agreements. We will overstate social costs savings to the extent of rebates.

literature. However, we cannot do this for v_i^j. Instead, taking the above trade-off as given, we compute the lower part of it, the net fiscal cost of prior authorization restrictions, which serves as an upper bound on the total valuation of foregone drugs to marginal consumers such that prior authorization restrictions are welfare improving. We then try to assess, in Section VI, outcomes that proxy for these values.

Calibrating Application Costs

Our data only include fulfilled prescriptions, i.e. those whose authorization applications are approved. We do not directly observe the application process, nor the costs borne by physicians in submitting applications and insurers in processing them. Therefore we must calibrate these costs externally.

First, comporting with our equation above, we assume that beneficiaries require authorization for a drug once every year.[21] At this time, they file a single application, which costs the physician a constant amount a. Of applicants, a share $1-\theta$ are rejected, and rejectees do not reapply and instead choose another option. Therefore, if we take the number of patients who successfully fill a restricted drug, and multiply that number by $\frac{1}{\theta}$, we have an estimate of the total number of applications. Multiplying this by a gives us the total paperwork costs.

When considering costs of prior authorization, there are two parties who incur costs for each authorization request: Medical providers, who need to submit requests, and insurers, who need to process and respond to them. We draw from case studies and industry reports to calibrate a measure of both costs. There are three sources that we are aware of that have estimated provider-side costs: Raper et al. (2010), who do so for a single HIV clinic in Alabama between March 2006 and February 2008, Bukstein et al. (2006), who do the same in an allergist clinic in Madison, WI, in August to October 2003, and Council for Affordable Quality Healthcare (2014), who field an annual survey of providers to solicit their costs. Raper et al. compute both direct and opportunity costs (i.e., the revenue that could have been earned by the nurse practitioner who filed the request instead seeing patients), whereas CAQH only measure direct costs.[22] Raper et al.'s direct estimate (which includes nurse practitioner and administrative staff time at their wage levels, as well as materials cost) is \$14.24, whereas their opportunity cost estimate comes out to \$27.35. Bukstein et al. (2006) estimate direct costs only, estimating them at \$17.77 per request. The CAQH estimate ranges from year to year, but their 2013 report (the earliest we were able to find, using a survey fielded in 2012, report completed in 2014) estimates direct costs at \$18.53.[23] To

[21] In truth, beneficiaries generally require authorization once for every regimen for a drug, which may extend more than a year. However, we do not observe discrete regimens.

[22] Raper et al. incorrectly add these two cost measures together, which double-counts the value of the nurse practitioner's time.

[23] We use their estimate for manually-submitted requests. Costs for doing so through an IT system were estimated at only \$5.20, but the majority of requests (110 million out of 130 million) were filed manually. Their cost estimates for manual filing decreased in later reports, with \$14.07 for calendar year

compute insurer costs, we use a similar insurer-facing survey from CAQH, which estimated manual processing costs of $3.95 for insurers in 2012.[24] Added together, that gives us total cost per application estimates of $18.19, $21.72, $22.48, and $31.30. We also experiment with a handful of more extreme values: $50, $100, and $200.

The literature provides many more estimates of prior authorization request rejection rates, although not all of them are directly comparable, and none precisely get at the exact quantity of interest–the number of (unobserved) requests per (observed) successful fill. Nonetheless, we take a handful of measures from this literature. We report the rates from the universe of studies we found in Appendix Table A2. Unfortunately, none of them are directly comparable to our setting. The majority cover either a single, potentially unrepresentative clinic, or have extensive coverage that includes unrelated products (e.g. hospital services). We use five values: 1.5%, 4%, 7.5%, and 15%, which cover the range of estimates found in the literature, as well as 0%.

Computing Net Fiscal Savings from Authorization Restrictions

Now, we can evaluate the lower portion of Equation 3, the net fiscal savings from prior authorization restrictions. As in Section IV, we consider the effects of moving between the historical status quo, and an alternative where prior authorization was removed but exclusion was left intact. We measure the total net effect per beneficiary-year. We measure this for every pair of calibrated a and θ values, and report the resulting calculation in Table 6. We also report the measure when $a = 0$, which is equivalent to simply measuring the cost savings, $23.70 per beneficiary-year. Unsurprisingly, at higher calibrated values of a (application costs) and $1 - \theta$ (rejection rates) rise, our estimates of fiscal savings diminish. However, net fiscal savings remain positive unless we calibrate unit per-application paperwork costs well beyond those documented in the health policy literature. Even at paperwork costs of $100, the historical prior authorization regime still resulted in net fiscal saving unless the request rejection rate was 15%.

Our preferred calibrated measure of paperwork costs is the CAQH measure of $22.48, which is the most comprehensive. For this measure, cost savings are calibrated at between $18 and $19 per beneficiary-year (paperwork costs of roughly $4.9 to $5.7 per beneficiary), implying that the savings to insurers and the government is roughly 4-5 times the cost imposed on providers.

We can now use this to bound how large patient valuations must be for authorization restrictions to be beneficial for welfare. Substituting calibrated values into Equation 3, we have

2013, $7.17 for 2014, and $7.50 for 2015.

[24] Manual insurer-facing costs are stable across time in the CAQH survey and never exceed $3.95 per request. Bukstein et al. (2006) claim that insurer costs for processing nonformulary drug requests are $20-$25 based on personal communication with a pharmacy manager at a major PBM, but since the methodology of estimating these costs is unclear we discard this estimate.

Table 6—: Net Fiscal Savings From Authorization Restrictions

		Request Rejection Rate				
		0%	1.5%	4%	7.5%	15%
Paperwork Cost	\$0			23.7		
	\$18.19	19.8	19.7	19.6	19.4	19.1
	\$21.72	19.0	18.9	18.8	18.6	18.2
	\$22.48	18.8	18.8	18.6	18.4	18.0
	\$31.3	16.9	16.8	16.6	16.4	15.7
	\$50	12.9	12.7	12.4	12.0	10.9
	\$100	2.0	1.7	1.1	0.3	-1.8
	\$200	-19.7	-20.3	-21.5	-23.2	-27.3

Note: This table reports estimates of the per-beneficiary-year net fiscal savings from authorization restrictions, i.e., the reduction in spending on drugs net of the calibrated cost for physicians and insurers, for different calibrated values of application costs a and rejection rates $1-\theta$. Positive outcomes indicate savings, while negative numbers indicate total costs. When costs are \$0, the rejection rate does not impact net fiscal savings.

$$\sum_i \Delta v_i D_i^H(0) D_i^L(0) + \sum_i v_i^H D_i^H(0) D_i^0(1) < \$18$$

as our condition. In our current estimates, there are no marginal switchers to no drug. Our prior estimates showed that, of those using restricted drugs in the absence of prior authorization, 15% are marginal, in that they switch to another drug when facing restrictions. The average beneficiary consumes around 0.22 of a restricted drug, so this requirement becomes

$$\Delta v_i \times 0.22 \times 0.15 < \$18$$

or $\Delta v_i < \$553$. That is, the average beneficiary who marginally substitutes must value the average deterred drug by \$553 per year relative to the alternative drug they substitute to. Given that paperwork costs are between $\frac{1}{5}$ to $\frac{1}{4}$ of savings, this means that marginal beneficiaries must value this consumption at $\frac{3}{4}$ to $\frac{4}{5}$ of the procurement cost, a substantial bar for top-up consumption. In our final section below, we try to assess the value of this deterred consumption.

VI. Are Prior Authorization Restrictions Efficient?

Our results in Section V suggest that, as long as equilibrium application-per-approved drug rates/paperwork costs are low enough, authorization restrictions need to destroy a significant amount of drug consumption value for their use to be harmful. While we cannot test this directly, we take a number of approaches that test for whether the effects of authorization restrictions are relatively inefficient. We explore this on two dimensions: First, we explore heterogeneity in the effects

of prior authorization policies based on characteristics of patients that should not be expected to have differential effects. Second, we explore health effects in a specific case, anticoagulation, where prior authorization is common and health effects are easily measured.[25]

A. *Heterogeneous Effects by Patient Characteristics*

An optimal implementation of a screening mechanism should, ideally, screen on relevant characteristics and *not* screen on irrelevant characteristics. We test for the latter by asking whether the effects of authorization restrictions are stronger by gender and race. In this context, this is a particular worry. Authorization is intermediated by medical providers and their willingness to exert effort on behalf of their patients. Prior research has shown that providers exert less effort for women and non-white patients, meaning that such patients may be more affected by provider-facing bureaucracy.

We test this by re-estimating our model from Equation 1 separately for white vs. non-white patients, and male vs. female patients. This is effectively the same as allowing all of our covariates to interact with race or gender (not just the treatment, but also all drug-region-year and plan-region-year fixed effects). Life expectancy is different across race and gender, which may affect the composition of the two samples. We therefore weight observations in our regressions for male and non-white patients to match female and white patients, i.e., proportional to $\frac{P[X_i|\text{Female}]}{P[X_i|\text{Male}]}$ for our male regression and proportional to $\frac{P[X_i|\text{White}]}{P[X_i|\text{Non-White}]}$ for our non-white regression, where X_i are cells of age (in 5-year buckets) and health status (in Elixhauser quintiles).

We report the results in Table 7. Table 7a displays our results segmented by gender and Table 7b displays our results segmented by race. We find level differences in the effects of restrictions by gender, with women facing a (statistically significantly) larger burden than men both in terms of spending and in terms of extensive margin drug take-up. While there are some level differences in the extensive margin of use for nonwhite patients, these are not statistically significant.

However, it is important to note that baseline utilization in the absence of restrictions also differs across these groups. If we rescale the treatment effects by baseline utilization (i.e., compute the percent change induced by authorization restrictions rather than the levels), we see a surprising reversal. A substantial racial gap emerges, with extensive margin effects for white patients being a reduction of 20%, whereas nonwhite patients see reductions of 25%. Conversely, the gender gap shrinks, considerably such that we can no longer reject differences by gender, with both genders seeing roughly 22% reductions in extensive margin use. This is due to the fact that non-white patients have substantially lower baseline drug use

[25]This draft is incomplete. We are currently exploring four more angles: 1) Heterogeneous effects by value of drug; 2) Heterogeneous effects by provider characteristics; 3) The extent to which deterred consumption is by patients who are less likely to stay on the drug, as an indicator of their match value; 4) Effects on mortality.

than white patients, whereas women have substantially *higher* baseline use than men. There is no clear guideline as to whether absolute or relative effects should be given more credence when considering disparate effects (especially if the baseline already suffers from disparity), but it is clear that authorization restrictions have some undesirable disparate impacts.

B. Health Effects

One of the clearest ways that authorization restrictions could harm patients is if their reduction in drug utilization harms patient health. The American Medical Association's public documents on prior authorization make strong claims about potential health harms, claiming restrictions might lead to "hospitalization, disability, or even death," although these claims are based on a survey of physicians' opinions rather than measured outcomes.[26] Our primary research design does not permit measurements of health effects, since health is defined at the patient level, whereas our research design is identified at the patient-drug level. To estimate health effects, we either need drug-specific measures of health, or an alternative design that induces variation at the patient level. We start by using the former.

As a measure of drug-specific health, we measure the effects of prior authorization on a specific class of drug: Oral anticoagulants, often referred to as blood thinners. Anticoagulants reduce the extent of blood clotting, therefore reducing the risk of strokes (blood clots that occur in the brain), as well as other clot-driven health issues such as heart attacks and pulmonary embolisms, and are used regularly over a long period of time. The standard anticoagulant from 1954 until the 2010s was warfarin, which, by the time our sample period had begun, existed primarily as a cheap generic, costing approximately $0.30 per pill. In the 2010s, however, a series of drugs called non-Vitamin K oral anticoagulants (NOACs) were approved by the FDA and introduced into usage. There are two main advantages of these new drugs over warfarin: required dose varies less, so there is less need for frequent monitoring of blood clotting, and there are fewer food and drug-interactions. By 2015, NOACs represented around one-eighth of anticoagulant prescriptions, but two-thirds of spending (see Figures A2 and A3). Total anticoagulation spending rose substantially over this period, exemplary of the hypothesis by Chandra and Skinner (2012) that technological change drives spending increases.

We restrict to a subsample of individuals with a medical history of atrial fibrillation, deep vein thrombosis, or pulmonary embolism, the typical conditions treated by anticoagulants. Most plans put authorization restrictions on all NOACs when they are available, or cover them without restriction. Therefore we run the regression

$$Y_i = \beta \text{AuthAllNOACs}_i + \gamma \text{OtherFormulary}_i + \delta_{m(i)} + \epsilon_i$$

[26] c.f. `https://www.fixpriorauth.org/patients`.

Table 7—: Regressions with Patient Heterogeneity

(a) Gender

	Spending		% Ever filled	
	Female	Male	Female	Male
$\text{Auth}^{\text{Assigned}}$	-0.865	-0.634	-0.089	-0.065
	(0.042)	(0.044)	(0.003)	(0.003)
$\text{Excluded}^{\text{Assigned}}$	-1.093	-0.854	-0.113	-0.081
	(0.032)	(0.032)	(0.003)	(0.002)
Auth^{sub}	0.185	0.098	0.041	0.029
	(0.038)	(0.039)	(0.003)	(0.003)
$\text{Excluded}^{\text{sub}}$	0.583	0.473	0.112	0.075
	(0.046)	(0.048)	(0.006)	(0.005)
% Effect of $\text{Auth}^{\text{Assigned}}$	-29.0	-22.5	-12.3	-12.0
	(1.4)	(1.5)	(0.4)	(0.5)
Control Mean	3.481	3.493	1.098	0.836
Reweighted Control Mean	4.127	3.800	0.400	0.290
N (plan-drug-market-years)	2,164,653	2,164,653	2,164,653	2,164,653

(b) Race

	Spending		% Ever filled	
	White	Non-White	White	Non-White
$\text{Auth}^{\text{Assigned}}$	-0.754	-0.795	-0.076	-0.084
	(0.040)	(0.045)	(0.003)	(0.004)
$\text{Excluded}^{\text{Assigned}}$	-0.979	-1.015	-0.094	-0.108
	(0.029)	(0.037)	(0.002)	(0.003)
Auth^{sub}	0.186	0.090	0.039	0.032
	(0.033)	(0.045)	(0.003)	(0.004)
$\text{Excluded}^{\text{sub}}$	0.537	0.537	0.094	0.100
	(0.046)	(0.050)	(0.005)	(0.007)
% Effect of $\text{Auth}^{\text{Assigned}}$	-24.6	-29.6	-11.5	-13.3
	(1.3)	(1.6)	(0.4)	(0.6)
Control Mean	3.662	3.214	1.009	0.958
Reweighted Control Mean	4.324	3.464	0.371	0.328
N (plan-drug-market-years)	2,164,653	2,164,653	2,164,653	2,164,653

Note: This table presents estimates from regressions of utilization measures for each demographic group on prior authorization and exclusion of a given drug and other drugs within the class.

where OtherFormulary_i includes any formulary other than restricting all NOACs or unrestrictedly covering all NOACs (all plans fully cover warfarin), so β mea-

sures the difference between restriction and unrestriction. We omit plan fixed effects since we estimate this regression for a single set of drugs at a time, and thus plan identifiers are colinear with the treatment.

We estimate β values for utilization of any anticoagulant, utilization of warfarin, and utilization of any NOAC, and report them in Table 8. As in our prior analysis, authorization restrictions reduce overall spending on anticoagulants, but do not significantly imapct the total use of anticoagulants, instead reallocating around 25% of patients from NOACs to warfarin. We then estimate the effect on health outcomes: The probability of death during the year, the probability of a stroke, and the probability of a bleeding event. We report the results from these regressions in Table 9. We find small, insignificant effects for all three, and can reject large effect sizes in either direction. This is consistent with meta-analyses in the medical literature finding limited differences in clinical outcomes between warfarin and NOACs, with most of the differences coming through side effects and ease of use.

Table 8—: Effects of anticoagulant prior authorization restrictions on outcomes

	Spending			Any prescription		
	All	NOACs	Warfarin	All	NOACs	Warfarin
All NOACs PA	-16.6	-18.3	1.7	-0.0003	-0.0097	0.0069
	(6.41)	(6.61)	(0.70)	(0.0033)	(0.0028)	(0.0035)
Other restrictions	-16.1	-12.4	-3.7	-0.0011	-0.0100	0.0058
	(5.51)	(5.14)	(2.51)	(0.0086)	(0.0035)	(0.0085)
R^2	0.026	0.032	0.019	0.014	0.030	0.024
Mean	111.6	77.4	34.2	0.291	0.043	0.260
N bene years	134,182					
N market years	160					

Note: This table presents estimates from a set of regressions of health outcome of individual i on dummies for whether their plan has prior authorization restrictions on all NOACs. Regressions include market-year fixed effects.

While this is one example, we think it is generally representative: In oral anticoagulants, as in many other classes, substitution is largely to another drug, rather than to no drugs. While, again, this is not fully representative of patient value for the change in their drug regimen, these results suggest that, in contrast to recent work finding that cost-sharing for drugs in Medicare Part D increases patient mortality (**?**), prior authorization restrictions are a managed care tool that does not have such an effect.

VII. Conclusion

We have found that prior authorization policies, applied to drugs in Medicare Part D, lower program spending by an amount that exceeds the administrative

Table 9—: Effects of anticoagulant prior authorization restrictions on outcomes

	Died	Stroke	Bleed
All NOACs under prior auth	-0.00032	0.00067	-0.00124
	(0.00090)	(0.00143)	(0.00172)
Other restrictions on NOACs	-0.00152	0.00569	0.00480
	(0.00189)	(0.00275)	(0.00497)
R^2	0.002	0.002	0.002
Mean of health variable	0.014	0.032	0.054
Number of bene years		134,182	
Number of market years		160	

Note: This table presents estimates from a set of regressions of health outcome of individual i on dummies for whether their plan has prior authorization restrictions on all NOACs. Regressions include market-year fixed effects.

costs of prior auth to physicians. While the effect of prior authorization is not necessarily efficiently allocated, with potentially larger deterrence of use for non-white and female patients, the reduction in consumption seems to have a minimal impact on patient health.

To conclude, we would like to emphasize two broader points that arise from our work. First, although these policies reduce net social costs, they *raise* costs for physician and other health care providers, by increasing their paperwork burdens. These policies are Kaldor-Hicks efficient in the sense that providers could be transferred a portion of the savings to be made at least indifferent between being the stewards of these policies and not. However, much of the gains are realized by insurers, and, in particular in our setting, drug insurers who have no direct interaction with providers. Finding a way to efficiently share the gains with providers is a serious political economy issue, particularly in the light of the American Medical Association's strong opposition to paperwork burdens.

Second, our results have important implications for the broader discourse around international health care spending comparisons and U.S. health care reform. This paper shows that, although managed care rationing mechanisms introduce seemingly-wasteful administrative costs, they carry the net benefit of reducing overall costs. However, because the costs are largely incurred by providers and insurers, they show up in accounting measures of costs. In contrast, using queueing more aggressively, as is the case in other OECD health systems, imposes costs on patients that are not captured in accounting measures. More research is needed to both characterize the costs *and* benefits of other sources of administrative cost burden, as well as to compare how other rationing mechanisms induce administrative costs, both those that show up in accounting data and those that do not.

REFERENCES

Akerlof, George A., "The Economics of "Tagging" as Applied to the Optimal Income Tax, Welfare Programs, and Manpower Planning," *American Economic Review*, 1978, *68* (1), 8–19.

Alpert, Abby E., Sarah E. Dykstra, and Mireille Jacobson, "How Do Prescription Drug Monitoring Programs Reduce Opioid Prescribing? The Role of Hassle Costs versus Information," 2020. NBER Working Paper No. 27584.

American Medical Association, "2017 AMA Prior Authorization Physician Survey," 2017.

America's Health Insurance Providers, "Key Results of Industry Survey on Prior Authorization," 2020. https://www.ahip.org/wp-content/uploads/Prior-Authorization-Survey-Results.pdf.

Archer, Diane, "Medicare Is More Efficient Than Private Insurance," *Health Affairs Blog*, 2011. https://www.healthaffairs.org/do/10.1377/hblog20110920.013390/full/.

Baicker, Katherine, Sendhil Mullainathan, and Joshua Schwartzstein, "Behavioral Hazard in Health Insurance," *Quarterly Journal of Economics*, 2015, *130*, 1623–1667.

Berry, Steven and Philip Haile, "Identification in Differentiated Products Markets," *Annual Review of Economics*, 2016, *8*, 27–52.

Berry, Steven T., "Estimating Discrete-Choice Models of Product Differentiation," *RAND Journal of Economics*, 1994, pp. 242–262.

Birdsall, Ashley D., Ashley M. Kappenman, Bryce T. Covey, and Matthew H. Rim, "Implementation and impact assessment of integrated electronic prior authorization in an academic health system," *Journal of the American Pharmacists Association*, 2020, *60* (4), e93–e99.

Brot-Goldberg, Zarek C., Amitabh Chandra, Benjamin R. Handel, and Jonathan T. Kolstad, "What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics," *Quarterly Journal of Economics*, 2017, *132* (3), 1261–1318.

_ **and Mathijs de Vaan**, "Intermediation and Vertical Integration in the Market for Surgeons," 2018.

_ **, Timothy Layton, Boris Vabson, and Adelina Yanyue Wang**, "The Behavioral Foundations of Default Effects: Theory and Evidence from Medicare Part D," 2021. NBER Working Paper No. 28331.

Bukstein, Don A., Greeta A. Cherayil, Adam D. Gepner, Allan T. Luskin, J. Brent Kooistra, and Reid M. Olson, "The economic burden associated with prior authorizations in an allergist office," *Allergy & Asthma Proceedings*, 2006, *27* (2), 119–122.

Casalino, Lawrence P., Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, and Wendy Levinson, "What Does It Cost Physician Practices To Interact With Health Insurance Plans?," *Health Affairs*, 2009, *28* (4), w533–w543.

Chandra, Amitabh and Jonathan Skinner, "Technology Growth and Expenditure Growth in Health Care," *Journal of Economic Literature*, 2012, *50* (3), 645–680.

Council for Affordable Quality Healthcare, "2013 U.S. Healthcare Efficiency Index: Electronic Administrative Transaction Adoption and Savings," 2014.

Cutler, David M., "Reducing Administrative Costs in U.S. Health Care," 2020. The Hamilton Project.

_ **and Dan P. Ly**, "The (Paper)Work of Medicine: Understanding International Medical Costs," *Journal of Economic Perspectives*, 2011, *25* (2), 3–25.

_ **, Elizabeth Wikler, and Peter Basch**, "Reducing Administrative Costs and Improving the Health Care System," *New England Journal of Medicine*, 2012, pp. 1875–1878.

de Chaisemartin, Clement and Xavier D'Haultfœuille, "Two-Way Fixed Effects Estimators with Heterogeneous Treatment Effects," *American Economic Review*, 2020, *110* (9), 2964–96.

Deshpande, Manasi and Yue Li, "Who Is Screened Out? Application Costs and the Targeting of Disability Programs," *American Economic Journal: Economic Policy*, 2019, *11* (4), 213–248.

Dranove, David and Kathryn E. Spier, "A Theory of Utilization Review," *Contributions in Economic Analysis & Policy*, 2003, *2* (1), 1–19.

Dubois, Pierre, Ashvin Gandhi, and Shoshana Vasserman, "Bargaining and international reference pricing in the pharmaceutical industry," 2019.

Dunn, Abe, Joshua D. Gottlieb, Adam Shapiro, Daniel J. Sonnenstuhl, and Pietro Tebaldi, "A Denial a Day Keeps the Doctor Away," 2021.

_ **,** _ **, and Adam Hale Shapiro**, "Administration Above Administrators: The Changing Technology of Health Care Management," *AEA Papers and Proceedings*, 2020, *110*, 274–278.

Finkelstein, Amy and Matthew J. Notowidigdo, "Take-up and Targeting: Experimental Evidence from SNAP," *The Quarterly Journal of Economics*, 2019, *134* (3), 1505–1556.

Frakt, Austin, "Is Medicare for All the Answer to Sky-High Administrative Costs?," *The New York Times*, 2018.

Ganapati, Sharat and Rebecca McKibbin, "Non-tariff barriers and bargaining in generic and off-patent pharmaceuticals," 2019.

Glied, Sherry, "Managed Care," in "Handbook of Health Economics," Vol. 1, Elsevier, 2000, pp. 707–753.

Heinrich, Carolyn J., "The Bite of Administrative Burden: A Theoretical and Empirical Investigation," *Journal of Public Administration Research and Theory*, 2016, *26* (3), 403–420.

Herd, Pamela and Donald P. Moynihan, *Administrative Burden: Policymaking By Other Means*, Russell Sage Foundation, 2018.

Himmelstein, David U., Terry Campbell, and Steffie Woolhandler, "Health Care Administrative Costs in the United States and Canada, 2017," *Annals of Internal Medicine*, 2020, *172* (2), 134–142.

Ho, Kate and Ariel Pakes, "Hospital Choices, Hospital Prices and Financial Incentives to Physicians," *American Economic Review*, 2014, *104* (12), 3841–3884.

Homonoff, Tatiana and Jason Somerville, "Program Recertification Costs: Evidence from SNAP," *American Economic Journal: Economic Policy*, forthcoming.

Kahan, Natan R., David P. Chinitz, Dan-Andrei Waitman, and Ernesto Kahan, "When gatekeepers meet the sentinel: the impact of a prior authorization requirement for cefuroxime on the prescribing behaviour of community-based physicians," *British Journal of Clinical Pharmacology*, 2006, *61* (3), 341–344.

Kakani, Pragya, Michael Chernew, and Amitabh Chandra, "Rebates in the Pharmaceutical Industry: Evidence from Medicines Sold in Retail Pharmacies in the U.S.," 2020. NBER Working Paper No. 26846.

LaPensee, Kenneth, "Analysis of a Prescription Drug Prior Authorization Program in a Medicaid Health Maintenance Organization," *Journal of Managed Care Pharmacy*, 2003, *9* (1), 36–44.

Lieber, Ethan M.J. and Lee M. Lockwood, "Targeting with In-Kind Transfers: Evidence from Medicaid Home Care," *American Economic Review*, 2019, *109* (4), 1461–1485.

Nichols, Albert L. and Richard J. Zeckhauser, "Targeting Transfers through Restrictions on Recipients," *American Economic Review*, 1982, *72* (2), 372–377.

Pauly, Mark V., "The Economics of Moral Hazard: Comment," *American Economic Review*, 1968, *58* (3), 531–537.

Raper, James L., James H. Willig, Hui-Yi Lin, Jeroan J. Allison, M. Bennet Broner, Michael J. Mugavero, and Michael S. Saag, "Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic," *Clinical Infectious Diseases*, 2010, *51* (6), 718–724.

Schwartz, Aaron L., Troyen A. Brennan, Dorothea J. Verbrugge, and Joseph P. Newhouse, "Measuring the Scope of Prior Authorization Policies: Applying Private Insurer Rules to Medicare Part B," *JAMA Health Forum*, 2021, *2* (5), e210859–e210859.

Shepard, Mark and Myles Wagner, "Reducing Ordeals through Automatic Enrollment: Evidence from a Subsidized Health Insurance Exchange," 2021.

Song, Zirui, Yunan Ji, Dana G. Safran, and Michael E. Chernew, "Health Care Spending, Utilization, and Quality 8 Years into Global Payment," *New England Journal of Medicine*, 2019, *381* (3), 252–263.

Sood, Neeraj, Zachary Wagner, Peter J. Huckfeldt, and Amelia M. Haviland, "Price Shopping in Consumer Directed Health Plans," *Forum for Health Economics & Policy*, 2013, *16* (1), 35–53.

U.S. Department of Health and Human Services Office of Inspector General, "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials," 2018. Report OEI-09-16-00410.

Waldinger, Daniel, "Targeting In-Kind Transfers Through Market Design: A Revealed Preference Analysis of Public Housing Allocation," *American Economic Review*, 2021, *111* (8), 2660–2696.

Wallace, Zachary S., Tyler Harkness, Xiaoqing Fu, John H. Stone, Hyon K. Choi, and Rochelle P. Walensky, "Treatment Delays Associated With Prior Authorization for Infusible Medications: A Cohort Study," *Arthritis Care & Research*, 2020, *72* (11), 1543–1549.

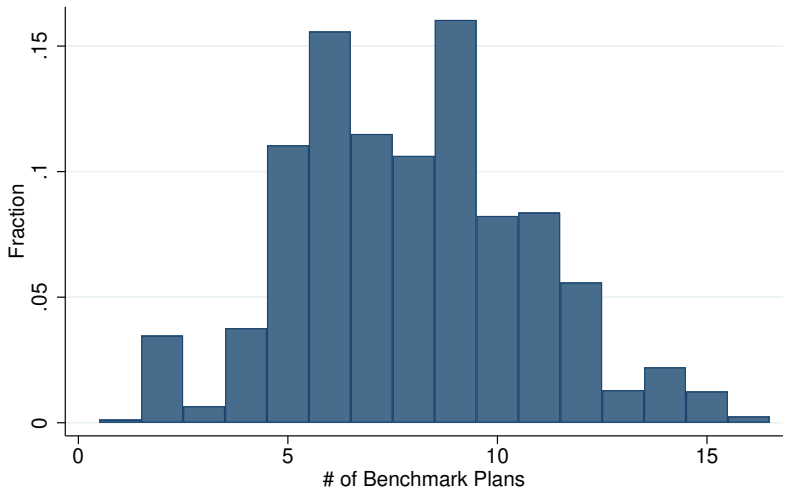
_ , _ , _ , _ , _ , and _ , "Treatment Delays Associated With Prior Authorization for Infusible Medications: A Cohort Study," *Arthritis Care & Research*, 2020, *72* (11), 1543–1549.

Woolhandler, Steffie, Terry Campbell, and David U. Himmelstein, "Costs of Health Care Administration in the United States and Canada," *New England Journal of Medicine*, 2003, *349* (8), 768–775.

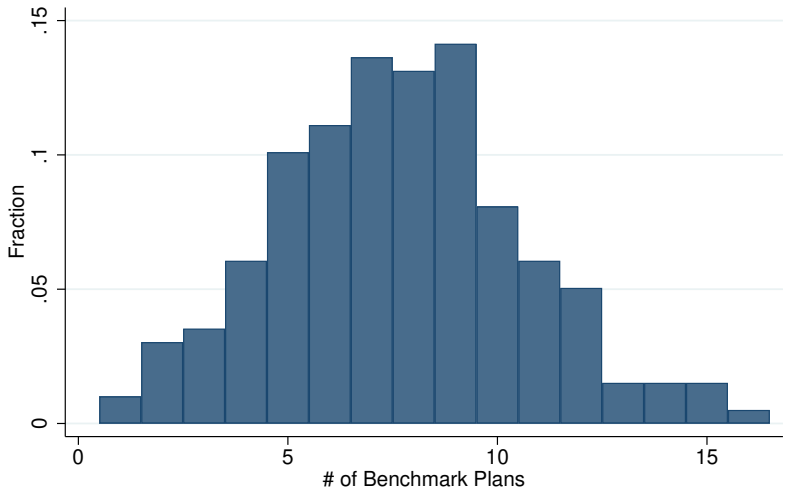
Additional Tables and Figures

Appendix Figure A1. : Distribution of Number of Benchmark Plans in Market-Year

(a) Weighted by Number of Beneficiaries



(b) Unweighted



Notes: This set of figures plots the distribution in the number of benchmark plans across the combination of Part D market region-years. The top figure presents this distribution weighing all Part D market region-years equally, while the bottom weighs Part D market region-years by the number of beneficiaries in our sample enrolled under each.

Appendix Table A1—: Prior authorization use for top drug classes by Medicare Part D spending

	Spending per person-year (USD)	% spending with prior auth	% fills with prior auth
Relatively High Prior Auth			
Tranq/Antipsychotic	185	6.9	3.6
Antivirals	120	14.6	2.1
Antidiabetic Agents, Misc	110	15.0	5.7
Antineoplastic Agents	99	57.7	13.9
CNS Agents, Misc	94	17.6	6.9
Biological Response Modifiers	94	69.6	68.1
Antidepressants	93	7.7	3.3
Cardiac Drugs	88	12.4	5.9
Immunosuppressants	65	66.3	54.7
Anticonvulsants, Misc	60	4.4	1.6
Misc Therapeutic Agents	58	15.0	4.0
Anticoagulants	47	14.5	2.8
NSAIDs	37	10.0	1.6
Vasodilating Agents	27	44.6	1.5
Bone Resorption Inhibitors	22	9.0	4.8
Relatively Low Prior Auth			
Antihyperlipidemic Drugs	212	2.7	1.1
Antidiabetic Agents, Insulins	158	0.6	0.9
Gastrointestinal Drug, Misc	132	2.8	3.2
Opiate Agonists	92	3.5	0.7
Adrenals & Comb	86	3.0	11.6
Antiplatelet Agents	70	0.6	1.4
Cardiac, Calcium Channel	49	1.5	1.0
Anticholinergic	47	0.1	0.2
Cardiac, Beta Blockers	45	0.5	0.5
Eye/Ear/Nose/Throat Misc	44	1.2	0.6
Parasympathomimetic	42	3.2	1.5
Muscle Relaxants	36	1.9	2.3
Antiinflam Agents EENT	29	0.1	0.2
Sympathomimetic Agents	27	2.1	3.4
Estrogens & Comb	25	1.2	5.4

Appendix Table A2—: Estimates of Prior Authorization Request Rejection Rates

Study	Setting	Services	Estimate
Raper et al. (2010)	One HIV clinic, all payers	All drugs	33%
Initial application[a]			
Schwartz et al. (2021)	Large private insurer	Hosp. services and drugs	4.2%
Birdsall et al. (2020)	Academic health system	All drugs	
Initial application			15%
Final application			7.4%
Wallace et al. (2020b)	Rheumatology clinic	Infusable drugs	
Initial application			21%
Final application			4%
Kahan et al. (2006)	Israeli MCO	Cefuroxime	8.5%
LaPensee (2003)	One Medicaid MCO	All drugs	4.4%
		Non-formulary drugs	3.7%
		Formulary drugs	7.1%
OEI (2018)	All Medicare Advantage MCOs	All services and drugs	4.1%
AthenaHealth	Physician clients	All drugs	1.5%

Note: This table presents estimates from the literature on the rejection rates associated with requests made for services and drugs restricted under prior authorization. All studies are in U.S. settings unless otherwise noted.
[a] This study does not report final application approval rates in a way that maps on to what we have here.

Appendix Table A3—: First stage regressions restricted to existing users

	$\text{Auth}^{\text{Enrolled}}$	$\text{Excluded}^{\text{Enrolled}}$
$\text{Auth}^{\text{Assigned}}$	0.979	< 0.001
	(0.001)	(0.001)
$\text{Excluded}^{\text{Assigned}}$	< 0.001	0.975
	(< 0.001)	(0.001)
F-statistic	1,681,253	1,429,394
R^2	0.978	0.977
Number of drug × plan × plan years	173,431	
Number of market years	102	
Number of drug × bene years	254,994,624	
Average plans per market year	6.3	
Average benes per plan	12’	

Note: This table presents estimates from a set of regressions of prior authorization and exclusion status of drug d in the plan enrolled in by beneficiary i on the status of the plan that they were assigned to. The sample of beneficiaries is restricted only to those who took the drug in the prior year

Appendix Table A4—: Balance Tests

Note: ...

Appendix Table A5—: Main Regressions with alternate utilization variables

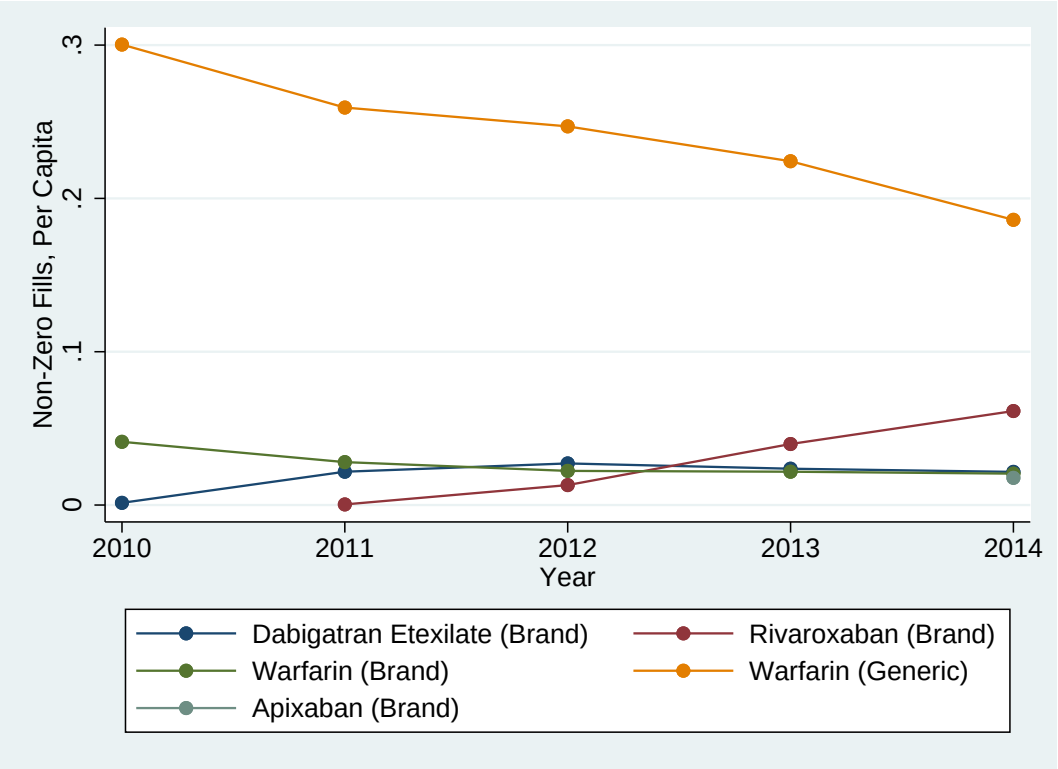
	Days supply per bene		Number of prescriptions per 100 benes	
$\text{Auth}^{\text{Assigned}}$	-0.152	-0.159	-0.459	-0.479
	(0.006)	(0.007)	(0.019)	(0.019)
$\text{Excluded}^{\text{Assigned}}$	-0.210	-0.214	-0.672	-0.686
	(0.0060)	(0.006)	(0.0169)	(0.0169)
Auth^{sub}		0.072		0.223
		(0.007)		(0.024)
$\text{Excluded}^{\text{sub}}$		0.184		0.561
		(0.010)		(0.030)
F-statistic	770	400	979	505
R^2	0.969	0.969	0.966	0.966
Control Mean	1.545		5.126	
Reweighted Control Mean	0.572		1.917	
Number of drug × plan years	2,164,653			
Number of market years	210			
Number of drug × bene years	1,740,683,902			
Average plans per market-yr	6.9			
Average benes per plan	804			

Note: This table presents estimates from regressions of utilization measures on prior authorization and exclusion of a given drug and other drugs within the class. Each observation is a drug-plan-year. Prior authorization of substitute drugs is mean prior authorization status of all other drugs within the class, where drugs are weighted by their average expenditure across all plans in the sample.

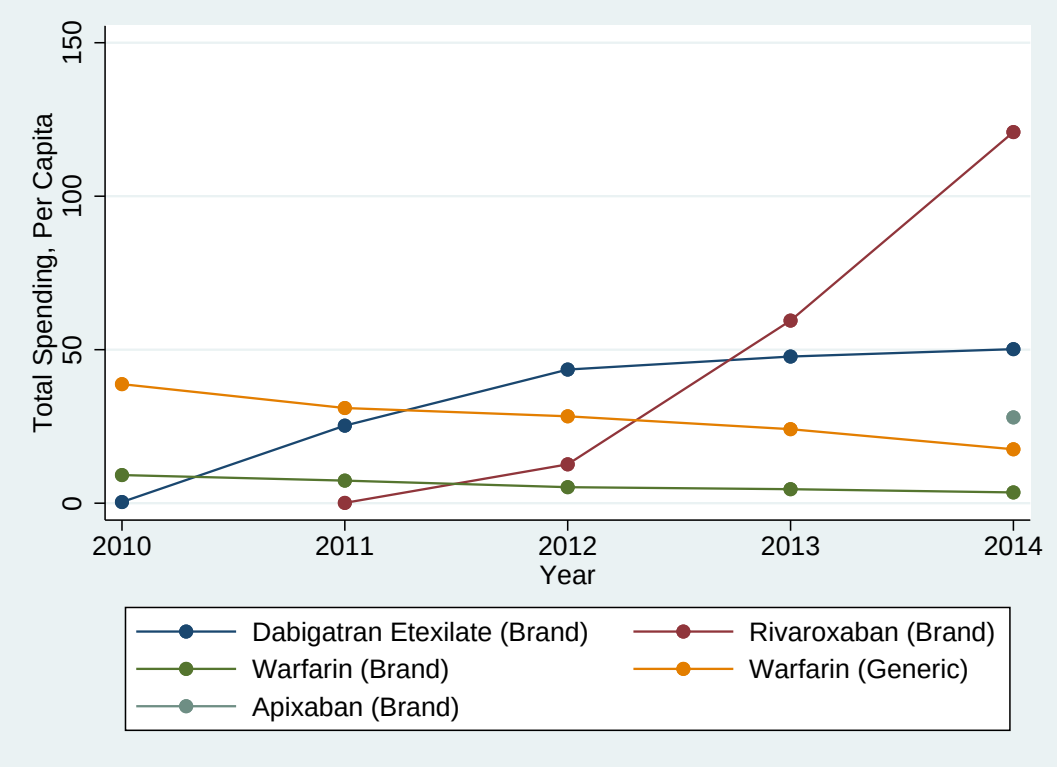
Appendix Table A6—: Main Regressions without plan-region-year fixed effects

	Spending		% Ever filled	
$\text{Auth}^{\text{Assigned}}$	-0.748	-0.769	-0.089	-0.097
	(0.032)	(0.036)	(0.003)	(0.003)
$\text{Excluded}^{\text{Assigned}}$	-0.925	-0.994	-0.109	-0.122
	(0.0269)	(0.031)	(0.0025)	(0.0025)
Auth^{sub}		0.149		0.048
		(0.030)		(0.004)
$\text{Excluded}^{\text{sub}}$		0.536		0.127
		(0.040)		(0.008)
F-statistic	609	325	991	500
R^2	0.837	0.837	0.978	0.978
Control Mean	3.486		1.320	
Reweighted Control Mean	3.991		0.446	
Number of drug × plan years	2,164,653			
Number of market years	210			
Number of drug × bene years	1,740,683,902			
Average plans per market-yr	6.9			
Average benes per plan	804			

Note: This table presents estimates from regressions of utilization measures on prior authorization and exclusion of a given drug and other drugs within the class. Each observation is a drug-plan-year. Prior authorization of substitute drugs is mean prior authorization status of all other drugs within the class, where drugs are weighted by their average expenditure across all plans in the sample.



Appendix Figure A2. : This figure presents the share of patients filling each of these oral anticoagulants at least once during the year, across time.



Appendix Figure A3. : This figure presents the per-patient yearly spending on each of these oral anticoagulants, across time.

Appendix: Prior Authorization Form Examples

Hawki | ia health link | Amerigroup An Anthem Company

https://providers.amerigroup.com

Novel Oral Anticoagulants Prior Authorization of Benefits Form

CONTAINS CONFIDENTIAL PATIENT INFORMATION
Complete form in its entirety and fax to: Prior Authorization of Benefits Center at 1-844-512-9004.
Provider Help Desk: 1-800-454-3730

1. Patient information	**2. Physician information**
Patient name:_____	Prescribing physician:_____
Patient ID #: _____	Physician address: _____
Patient DOB:_____	Physician phone #: _____
Date of Rx: _____	Physician fax #:_____
Patient phone #:_____	Physician specialty: _____
Patient email address: _____	Physician DEA: _____
	Physician NPI #: _____
	Physician email address: _____

3. Medication	**4. Strength**	**5. Directions**	**6. Quantity per 30 days**
_____	_____	_____	Specify: _____

7. Diagnosis:_____

8. Approval criteria: (Check all boxes that apply. Note: Any areas not filled out are considered not applicable to your patient and may affect the outcome of this request.)

Prior authorization (PA) is not required for preferred novel oral anticoagulants (NOACs). PA is required for nonpreferred NOACs. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions:

1. Patient does not have a mechanical heart valve.
2. Patient does not have active bleeding.
3. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least 1 additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1.
4. A recent creatinine clearance (CrCl) is provided.
5. A recent Child-Pugh score is provided.
6. Patient's current body weight is provided.
7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.
8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin). The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Preferred (no PA required if within established quantity limits)
☐ Eliquis ☐ Xarelto
☐ Pradaxa

Nonpreferred
☐ Savaysa

OptumRx has partnered with CoverMyMeds to receive prior authorization requests, saving you time and often delivering real-time determinations.
Visit go.covermymeds.com/OptumRx to begin using this free service.
Please note: All information below is required to process this request.
Mon-Fri: 5am to 10pm Pacific / Sat: 6am to 3pm Pacific

Zetia® (ezetimibe) Prior Authorization Request Form

DO NOT COPY FOR FUTURE USE. FORMS ARE UPDATED FREQUENTLY AND MAY BE BARCODED

Member Information (required)			**Provider Information** (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:	Specialty:	
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:

Medication Information (required)		
Medication Name:	Strength:	Dosage Form:
❑ Check if requesting **brand**	Directions for Use:	
❑ Check if request is for **continuation of therapy**		

Clinical Information (required)

Select the diagnosis below:
- ❑ Homozygous Familial Hypercholesterolemia (HoFH)
- ❑ Homozygous Sitosterolemia
- ❑ Primary Hypercholesterolemia
- ❑ Other diagnosis: _____ ICD-10 Code(s):_____

Clinical information:
Has the patient's diagnosis been confirmed? ❑ **Yes** ❑ **No**

Select the medications the patient has a failure, contraindication, or intolerance to:
- ❑ Ezetimibe-simvastatin
- ❑ Lovastatin
- ❑ Simvastatin
- ❑ Other statin or statin combination product. Please specify all: _____

Quantity limit requests:
What is the quantity requested per DAY? _____

What is the reason for exceeding the plan limitations?
- ❑ Titration or loading dose purposes
- ❑ Patient is on a dose-alternating schedule (e.g., one tablet in the morning and two tablets at night, one to two tablets at bedtime)
- ❑ Requested strength/dose is not commercially available
- ❑ Other: _____

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-800-711-4555.
This form may be used for non-urgent requests and faxed to 1-800-527-0531.

ANTIPSYCHOTICS
PRIOR AUTHORIZATION FORM
(form effective 1/5/21)

Keystone First | PERFORMRX℠ Next Generation Pharmacy Benefits

Fax to PerformRx℠ at **1-215-937-5018**, or to speak to a representative call **1-800-588-6767**.

PRIOR AUTHORIZATION REQUEST INFORMATION

☐ New request ☐ Renewal request	Total pages:	Office contact/phone:	LTC facility contact/phone:

PATIENT INFORMATION

Patient name:	Patient ID#:	DOB:
Street address:	Apt #:	City/state/zip:

PRESCRIBER INFORMATION

Prescriber name:		
Specialty:	NPI:	State license #:
Street address:	Suite #:	City/state/zip:
Phone:	Fax:	

MEDICATION REQUESTED

Preferred Agents

☐ Abilify Maintena	☐ fluphenazine elixir	☐ haloperidol tablet	☐ Invega Sustenna	☐ Perseris ER injection	☐ risperidone tablet
☐ aripiprazole tablet	☐ fluphenazine oral concentrate	☐ haloperidol decanoate inj	☐ Invega Trinza	☐ quetiapine tablet	☐ trifluoperazine tablet
☐ Aristada ER injection	☐ fluphenazine tablet	☐ haloperidol lactate inj.	☐ loxapine capsule	☐ quetiapine ER tablet	☐ ziprasidone capsule
☐ Aristada Initio injection	☐ fluphenazine decan. inj.	☐ haloperidol lactate oral concentrate	☐ olanzapine tablet	☐ Risperdal Consta	☐ Zyprexa Relprevv
☐ clozapine tablet	☐ Haldol injection		☐ perphenazine tablet	☐ risperidone solution	

Non-Preferred Agents

☐ Abilify Mycite	☐ chlorpromazine tablet	☐ Geodon injection	☐ olanzapine inj/ODT	☐ Saphris SL tablet	☐ Versacloz suspension
☐ Abilify tablet	☐ clozapine ODT	☐ Haldol decanoate inj.	☐ olanzapine/fluoxetine cap	☐ Secuado patch	☐ Vraylar capsule
☐ Adasuve inhalation	☐ Clozaril tablet	☐ Invega ER tablet	☐ paliperidone ER tab	☐ Seroquel tablet	☐ Zyprexa tablet/injection
☐ amitriptyline/perphenazine	☐ Fanapt tablet	☐ Latuda tablet	☐ pimozide tablet	☐ Seroquel XR tablet	☐ Zyprexa Zydis
☐ aripiprazole ODT	☐ Fazaclo dispersible tablet	☐ molindone tablet	☐ Rexulti tablet	☐ Symbyax capsule	☐ other:
☐ aripiprazole solution	☐ fluphenazine HCl injection	☐ Nuplazid capsule	☐ Risperdal solution/tablet	☐ thioridazine tablet	
☐ Caplyta capsules	☐ Geodon capsule	☐ Nuplazid tablet	☐ risperidone ODT	☐ thiothixene capsule	

Strength:	Dosage form:	Directions:	Quantity:	Refills:
Diagnosis:			Diagnosis code (required):	

PHARMACY INFORMATION (Prescriber to identify the pharmacy that is to dispense the medication):

Deliver to: ☐ Patient's Home ☐ Physician's Office ☐ Patient's Preferred Pharmacy Name:	
Pharmacy Phone #:	Pharmacy Fax #:
☐ I acknowledge that the patient agrees with the pharmacy chosen for delivery of this medication.	

REQUEST FOR A NON-PREFERRED AGENT

1. Has the patient taken the requested non-preferred antipsychotic in the past 90 days?
   ☐ Yes – *Submit documentation.* ☐ No
2. Has the patient tried and failed the preferred medications (listed above)?
   ☐ Yes – List medications tried: ☐ No
3. Does the patient have a contraindication or intolerance to the preferred medications?
   ☐ Yes – *Submit documentation of contraindication/intolerance.* ☐ No
4. **For oral Invega/paliperidone ER requests, does the patient have active liver disease with elevated LFTs or is the patient at risk for active liver disease?**
   ☐ Yes – *Submit documentation and lab values.* ☐ No

REQUEST FOR A PATIENT LESS THAN 18 YEARS OF AGE

5. Is this request for a dose increase of a previously approved medication? ☐ Yes – *Submit recent chart documentation supporting the increased dose.* ☐ No
6. Is the requested agent prescribed by, or in consultation with, one of the following physician specialists? ☐ Yes ☐ No *Submit documentation of consultation, if applicable.*
   ☐ child development pediatrician ☐ child & adolescent psychiatrist ☐ general psychiatrist (only if patient is ≥ 14 years of age) ☐ pediatric neurologist
7. Does the patient have severe behavioral problems related to a psychotic or neuro-developmental disorder? ☐ Yes – *Submit medical record documentation.* ☐ No
8. Has the patient tried non-drug therapies? ☐ Yes – *Submit medical record documentation.* ☐ No
9. Has the patient had the following baseline and/or follow-up monitoring? Check all that apply. ☐ BMI (or weight/height) ☐ blood pressure ☐ fasting glucose level ☐ fasting lipid panel
   ☐ presence of extrapyramidal symptoms (EPS) using the Abnormal Involuntary Movement Scale (AIMS)
   Submit documentation of all monitoring/test results.

REQUEST FOR A LOW-DOSE ORAL ANTIPSYCHOTIC FOR A PATIENT 18 YEARS OF AGE OR OLDER

10. What is the TOTAL daily dose of the requested medication? _____mg/day
    Submit documentation of complete medication regimen.
11. Is the low dose prescribed as part of a plan to titrate up to a therapeutic dose? ☐ Yes – *Submit documentation of titration plan.* ☐ No

REQUEST FOR THERAPEUTIC DUPLICATION OF AN ATYPICAL OR TYPICAL ANTIPSYCHOTIC

12. Does the patient have a medical reason for concomitant use of the requested medications? ☐ Yes – *Submit documentation with justification.* ☐ No
13. Is this request for a drug that is being titrated to, or tapered from, a drug in the same class? ☐ Yes – *List medication.* ☐ No

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber signature:	Date: