Informative ordeals in healthcare: Prior authorization of drugs in Medicaid

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PRELIMINARY: CLICK HERE FOR LATEST VERSION

Abstract

Health insurers frequently impose 'prior authorization' on drugs and services, requiring providers to fill out paperwork before treatment is eligible for coverage. The stated purpose of these policies is to reduce health care spending, ensure treatment complies with established guidelines and target use of treatments to those most likely to benefit. However, critics argue that these policies increase barriers to use of necessary treatment. Using all-payer claims data from Massachusetts in 2009-2013, we estimate the effect of prior authorization on use drugs in MassHealth, the state Medicaid fee-for-service program. We compare Medicaid beneficiaries affected by changes in prior authorization requirements to people in plans of a major commercial insurer not affected by these policy changes. Prior authorizations lead to a 44% drop in patients receiving a prescription. We split prescriptions into 'on-label' and 'off-label' uses of drugs based on FDA indications and we find prior authorization requirements result in large reductions in both on- and off-label uses.

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1 Introduction

Prescription drugs have become an increasingly important part of health care spending in the US and across the world. From 1980 to 2018, real per capita spending on drugs in the US increased more than sevenfold. Over this time, the share of spending on prescription drugs paid by patients has decreased from 57% in 1990 to 15% in 2018 (CBO, 2022). In Medicaid and other US programs aimed at low-income households, as well as in many other public healthcare systems around the world, copayments are deliberately set low in order to reduce financial barriers to access. This increase in costs and reduction in out-of-pocket share has led payers to attempt to control spending through 'utilization management' policies.

One of the most common ways payers try to reduce spending is 'prior authorization', where providers are required to fill out paperwork before an insurer will approve coverage. The stated goal of prior authorization policies is to reduce health care spending by ensuring treatment complies with established guidelines and targets use of treatments to those most likely to benefit (America's Health Insurance Providers, 2020). However, critics argue that these policies prevent patients from accessing necessary treatment, as well as generating unnecessary paperwork for providers (American Medical Association, 2017). Use of prior authorization has been rising over time (Brot-Goldberg et al., 2023; Kyle et al., 2023) and is the second biggest administrative burden for providers behind billing (Casalino et al., 2009). Prior authorization requirements are generally imposed on new, high-cost, on-patent drugs (Kyle and Song, 2023).

In this paper we investigate the effect of prior authorization requirements on prescription drug use in MassHealth, the Massachusetts fee-for-service Medicaid program. We use an event study design to evaluate the effect of adding a new prior authorization requirement on a drug on use of that drug. We compare 'treated' beneficiaries enrolled in MassHealth in the quarter prior to the prior authorization change with 'control' beneficiaries enrolled in Blue Cross Blue Shield of Massachusetts (BCBS MA) plans. We match beneficiaries in Mass Health with beneficiaries in BCBS MA based on age, gender, enrollment duration, and whether someone has had an ER visit or hospitalization in the prior 12 months. We use Massachusetts All Payer Claims Data (APCD) from 2009-2013 combined with formulary data from MassHealth and BCBS MA.

We find that a new prior authorization requirement on a drug reduces use of that drug by 44%. We then investigate heterogeneity by whether the prescribed use is 'on-label' or 'off-label' based on whether the patient has a diagnosis on file at the time of the prescription that matches one of the FDA approved indications for the drug. We find that prior authorization reduces on label use of drugs by 49% and off-label use by 25%, suggesting that prior authorizations are more likely to decrease guideline-consistent use than off-label use.

1.1 Contribution

This paper contributes to a small body of work on prior authorization. The paper closest to this is Brot-Goldberg et al. (2023), which evaluates the effect of prior authorization requirements on drugs in Medicare part D using randomization of a subset of beneficiaries. Dillender (2018) investigates the effect of prior authorization for drugs commonly subject to abuse, finding that prior authorization reduces prescriptions, but does not target the riskiest drug use. Eliason et al. (2021) look at the effect of authorization requirements for ambulance rides in Medicare.

More broadly, we contribute to work on administrative costs in health (Casalino et al., 2009; Cutler and Ly, 2011; Gottlieb et al., 2018) and the effects of provider-facing ordeals, including work by Dunn et al. (2023) showing that claims denials reduce participation in state Medicaid programs. This paper also greater monitoring in health care, including auditing Medicare claims (Shi, 2022), prescription monitoring (Alpert et al., 2020). Prior authorization, and utilization management more generally, can be thought of as an alternative to price-based rationing through copays. There is a huge body of work on the effects of copays on utilization (Brot-Goldberg et al., 2017; Newhouse and the Insurance Experiment Group, 1993). Most of the recent work finds that copayments cause people to cut back on both high and low-value care (Brot-Goldberg et al., 2017; Chandra et al., 2021).

This paper is organized as follows. Section 2 describes the setting, data and construction of the sample. Section 3 describes our empirical approach. Section 4 shows some summary statistics on the beneficiaries and drugs in our sample. Section 5 shows the results, and the final section concludes.

2 Setting and data

2.1 Setting: MassHealth

We focus on prior authorization changes in MassHealth, the Massachusetts' state Medicaid program. Beneficiaries enrolled in MassHealth can choose between a Fee-for-Service (FFS) plan and various managed care plans. In the period we study, managed care plans were responsible for maintaining their own formularies so we restrict to beneficiaries in the FFS plan[1]. MassHealth has common copays. In the period we study copays for most drugs were $2-3.65 per prescription. From July 2010, copays for some classes of drugs, including antihyperglycemics, antihypertensives and antihyperlipidemics were set even lower, at $1 per prescription. There was also a cap on total prescription drug payments of $200 that rose gradually over the period. Because copayment rates are set low and there is little differentiation between drugs ('tiering'), the primary way in which MassHealth can direct drug use is through use of prior authorization requirements, as well

[1] As of 2023, the formularies have been unified between FFS and managed care plans, although they may stuff differ for drugs covered under the medical benefit component of the plan https://www.mass.gov/doc/issue-1-april-2023-0/download

as excluding drugs from the formulary.

2.2 Data

This paper uses the Massachusetts All-Payer Claims Database (APCD) for 2009-2013 to measure patient characteristics and drug utilization. The APCD includes demographic and plan enrollment data such as payer and enrollment dates from all enrollees covered by payers providing insurance coverage for Massachusetts residents and employees. The data also contains enrollees' medical claims (with diagnoses, procedures, physician-administered drugs, and drugs prescribed in a medical setting) and pharmacy claims with drug identifiers. All claims are associated with physician identifiers and include total and out-of-pocket spending.

We collect data on prior authorization (PA) changes in MassHealth drug lists from 2009-2013. MassHealth can implement a PA at the brand-ingredient-dosage-formulation level. For example, one of the changes in MassHealth's formulary requires a PA for the active ingredient methylphenidate, with the brand name Concerta, extended-release formulation, 27mg dosage. However, MassHealth can also impose a PA on any combination of brand name, active ingredient, dosage, or formulation. Examples include a PA implemented on all formulations, dosages, and brands for norfloxacin, a PA placed only on ketoprofen injection, or a PA placed on buspirone 30mg tablet.

We similarly collect data on PA changes from the 2023 Blue Cross Blue Shield (BCBS) of Massachusetts formulary. Unlike MassHealth, we cannot exactly observe the dates at which prior authorizations were implemented in BCBS. However, we observe whether a drug was subject to prior authorization at any time between 2009 and 2023.[2]

Our measures of drug utilization include both pharmacy and physician-administered drugs. We use the Redbook data to map drug names to National Drug Codes (NDCs), which allows us to identify drugs with PA changes in the APCD pharmacy claims. We manually map HCPCS codes to drug names to identify physician-administered drugs in the medical claims.[3]

2.3 Sample

Our APCD data cut includes data from private insurers, MassHealth, and Medicare Advantage, but not traditional Medicare. Since we cannot observe Medicare enrollees' complete enrollment, medical, and prescription history in our data, we exclude patients aged 65 or older from our analysis.[4] Furthermore, for those covered under Medicare Advantage, the same formulary may not

[2]We do not observe drugs that were part of retired prior authorization policies. However, since BCBS defines policies often at the drug class level, a retired policy would mean that prior authorizations were removed from all drugs in a given class, which is rare.

[3]In some cases, over-the-counter drugs and products for compounding (e.g., powders) may be subject to prior authorization. We do not include these drugs in our analysis since their utilization is difficult to track and observe completely.

[4]This implies that we also would exclude those dually eligible under Medicare and MassHealth; however, the primary payer for prescription drug coverage for the dually eligible is typically Medicare, which we do not observe in

apply to those younger than 65, even though the listed payer is the same.[5]

Table 1: Sample selection

	MassHealth (Treated)	BCBS (Control)
Patients with some prescription drug coverage in 2009-2013	2,265,974	2,863,883
Patients younger than 65 in 2009-2013	2,070,213	2,694,489
Patients that lived in MA in 2009-2013	2,048,189	1,809,169
Patients with 12 months of medical enrollment before any period of prescription drug coverage in 2009-2013	1,707,651	1,468,841

Note. Data comes from the Massachusetts All-Payer Claims Database for 2009-2013. BCBS stands for Blue Cross Blue Shield of Massachusetts.

Table 1 shows the steps of our sample selection process and the number of patients included in each step. We begin by finding all patients ever enrolled in prescription drug coverage provided *only* by MassHealth fee-for-service or Blue Cross Blue Shield (BCBS) of Massachusetts during 2009-2013.[6] Approximately 2.3 million MassHealth enrollees and 2.9 million BCBS patients had prescription drug coverage only through MassHealth or BCBS, respectively, at some point during 2009-2013, which covers almost 80% of the MA population in 2013.[7] As discussed earlier, we drop enrollees 65 or older during all periods of prescription drug coverage by MassHealth or BCBS. Furthermore, because payers are not required to report claims to the APCD for enrollees living outside of Massachusetts, we also drop patients who were not Massachusetts residents during all periods of prescription drug coverage by MassHealth or BCBS.

Lastly, and most importantly, we require that every period of prescription drug coverage by MassHealth or BCBS during 2009-2010 be preceded by at least 12 months of medical coverage by any payer. This criterion ensures that we have enough medical history to identify on- and off-label use of drugs and effectively restricts our time period to 2010-2013.

Our final sample contains 1.7 million individuals enrolled in MassHealth and 1.5 million patients individuals enrolled in BCBS at some point during 2009-2013 and satisfying our sample selection criteria. Individuals may have multiple continuous periods of prescription drug coverage that satisfy our sample selection criteria, all of which are included in our analysis.

the data.

[5]For example, the Blue Cross Blue Shield (BCBS) formulary does not apply to "Medicare Advantage, Medex, direct-pay products such as Managed Major Medical, Comprehensive Managed Major Medical, and certain Managed Blue for Seniors plans".

[6]The MassHealth formulary data we collect applies to MassHealth fee-for-service but not necessarily managed care. As a result, our sample excludes those insured through MassHealth managed care. During our sample period, the majority of MassHealth enrollees belonged to fee-for-service.

[7]While some physician-administered drugs may be covered under medical coverage instead of prescription drug coverage, the vast majority of claims for drugs in our sample are prescription drugs.

2.4 Data on approved ages and indications

We use the same methods for determining off-label use as in Ristovska (2023). We map each drug with a prior authorization policy change in MassHealth's formulary to its active ingredient. We then create a crosswalk between active ingredients and all indications and ages approved by the Food and Drug Administration (FDA) as of March 2023 using the MicroMedex database, which is one of the statutorily named medical compendia by Centers for Medicaid and Medicare Services (CMS).[8] We consider all indications approved for an active ingredient as on-label, even if they were approved for a specific formulation, route of administration, or dosage, and not the entire active ingredient. Such a definition may underestimate the actual off-label use; however, such disparate indications based on formulation, dosage, or route of administration are rare. Since MicroMedex does not list dates of approval, following Berger et al. (2021), we manually review the Drugs@FDA records for our sample drugs to determine the indication and dates of approval for each disease and age pair.

Indications can be quite detailed (e.g., use for treatment-naive vs. experienced patients, disease sub-types). We map indications to coarser diseases that can plausibly be mapped to ICD-9-CM diagnosis codes, which we use to identify diseases in the data.[9] Since multiple indications can be mapped to the same disease, and approved age ranges across indications may differ, we take the broadest possible age range as approved for each disease (across indications), which may also lead to an underestimate of off-label use.

2.5 Defining FDA-approved and unapproved (off-label) uses

The APCD pharmacy claims do not list what uses each drug was prescribed for. Thus, to identify uses for which a drug might be prescribed, we use ICD-9-CM diagnosis codes reported in the APCD medical claims for individuals in our sample. Based on our sample selection criteria, each individual has at least 12 months of medical claims data preceding any drug claims included in our analysis. We base our on-label/off-label classification on the medical claims data preceding each drug claim.

For a drug claim to be classified as FDA-approved, it must satisfy the following criteria: (i) the individuals associated with the drug claim must have been diagnosed with an indicated disease *prior to* the date the prescription was filled, and (ii) the drug must be FDA-approved for the indicated disease for the patient's age at the time the drug claim was filled.[10] This implies that there are four types of off-label use that we can observe in the data:

1. Prescriptions to individuals never diagnosed with the indicated disease

[8] For off-label use to be approved by MassHealth, the healthcare provider must list a reference to an academic paper or medical compendium supporting the off-label use.

[9] This method of mapping drugs to indications and dates of approval closely follows methods used by Berger et al. (2021).

[10] While we include both prescription drug claims and medical claims associated with physician-administered drugs in our analysis, for conciseness, we refer to filling a prescription when talking about both pharmacy drugs and physician-administered drugs.

2. Prescriptions to individuals diagnosed with the indicated disease *after* the prescription was filled

3. Prescriptions to individuals diagnosed with an eventually indicated disease before FDA approval for that indication

4. Prescriptions to individuals diagnosed with an indicated disease but associated with an age not approved by the FDA at the time of the prescription

Active ingredients can be indicated for multiple diseases. If a prescription is determined to be on-label for any indication, we classify it as on-label for all indications.

2.6 Prior authorization changes

Table 2 summarizes the prior authorization policy changes in MassHealth and shows the number of drugs and active ingredients affected by each policy change. Drugs are uniquely identified by combinations of active ingredient, brand name, formulation, and dosage. We map around 700 prior authorization policy changes in MassHealth's formulary for 2009-2013 to drug identifiers in the APCD data.[11] These changes affect 2800 unique drugs and 467 unique active ingredients.

Table 2: Prior authorization changes in MassHealth

	Sample events remaining	Sample drugs remaining	Sample active ingredients remaining
PA changes	697	2,205	467
PA added or removed	238	945	191
Drop multiple events per drug	226	924	189
Drop if cannot map to indication	208	777	172
Drop events affecting drugs under PA in BCBS	170	573	140
Count of events	170	573	140
PA removed	23	64	21
PA added on brand only	62	163	50
PA added on formulation/dosage	43	152	36
PA added on active ingredient	42	194	42

Note. Includes data on all changes in prior authorization policies (PA) for MassHealth in 2009-2013 that can be mapped to drug identifiers in the APCD data.

In the MassHealth formulary, a drug can be unrestricted (i.e., not subject to prior authorization) or restricted in several ways. One way is by imposing what we call a "full" prior authorization, meaning that every use of the drug requires the submission of a prior authorization form. Another common way to restrict the use of a drug in the MassHealth formulary is based on quantity prescribed, i.e., require a prior authorization form to be submitted if the quantity prescribed exceeds a certain amount, typically if it exceeds 30, 60, or 90 units for a 30 days' supply. Somewhat rarer are

[11] We could not match 53 changes to drug identifiers in the data. The majority of these are powders used for compounding.

requirements that the health care provider submits a prior authorization form if the drug is used for a specific gender, age, or in a specific setting (e.g., in a hospital vs. outpatient vs. pharmacy setting). Lastly, a drug can be entirely excluded from the MassHealth formulary, in which case MassHealth does not cover it.

The prior authorization policy changes we consider in our analysis include transitions from no prior authorization required to full prior authorization required and vice versa. This excludes most of the MassHealth prior authorization policy changes from our sample. One-third of the exclusions come from dropping new drugs that enter the MassHealth formulary. For these drugs, the policy change of entering the formulary effectively corresponds to a *relaxing* of the prior authorization policy since they go from not being covered at all to requiring prior authorization for coverage. The remaining third of prior authorization policy changes we exclude mainly involve changes in whether a drug is subject to quantity restrictions. We exclude such policy changes for two reasons. First, it is difficult to confidently identify quantities subject to prior authorization in the claims data. Second, cases where the quantities of a drug exceed the threshold imposed by the prior authorization are rare. We further exclude drugs affected by multiple policy changes and drugs that we cannot map to indications, which excludes a small share of sample events.

In the BCBS formulary, we observe whether a drug was subject to any restriction, such as step therapy, prior authorization, or lack of coverage during 2009-2023. However, we cannot observe changes in the details of the restrictions, such as whether only certain ages, genders, or settings were subject to the prior authorization policy. As discussed before, we do not observe when the policy change occurred. In order to obtain a sample of drugs where a prior authorization policy change occurred in MassHealth but not in BCBS, we excluded drugs that were subject to any prior authorization policy in BCBS at any point during 2009-2023. This criterion may over-exclude drugs as we exclude drugs that may have been subject to prior authorization requirements only after our data ends.[12] However, this ensures a clean control group unaffected by prior authorization requirements. As a result, we further exclude approximately 100 prior authorization policy changes affecting drugs that may have been subject to prior authorization in BCBS.

Our final sample of 170 events affects 573 unique drugs (which we refer to as sample drugs moving forward) and 140 active ingredients. In 23 of these events, the drug was subject to a prior authorization, which was removed during the span of our data. For example, ramipril capsule, used to treat hypertension and heart failure, was subject to a prior authorization for any use of the drug but transitioned to no prior authorization required during the span of our data. While these events can be used to examine whether there is a symmetrical response for the removal of prior authorizations as for addition or prior authorization requirements, we focus on the addition of prior authorizations as the results for removal of prior authorizations are too noisy. 62 events include the addition of prior authorization for any use of a branded drug. Typically, these occur when a

[12] We also do not know which drugs have been subject to quantity-based restrictions in BCBS and when. However, as mentioned previously, these account for a small share of claims.

generic becomes available. In 43 events, prior authorization was added on a specific formulation or dosage. For instance, we observe MassHealth add a prior authorization on phenytoin 100 mg/4 ml only, which is used to treat epilepsy. Lastly, 42 events include the addition of prior authorization on all brands, formulations, and dosages for a specific active ingredient, such as ambrisentan, used to treat pulmonary hypertension.

3 Empirical Approach

In our setting, treatment occurs at the drug level, defined as unique combinations of ingredient, brand, dosage, and formulation.[13] We use a dynamic difference-in-difference approach to identify the effect of changes in prior authorization policy on outcomes of interest:

$$Y_{itd} = \alpha_0 MassHealth_{it} + \sum_{k=-4}^{k=6} \alpha_k \mathbb{1}(t - T_d = k) + \sum_{k=-4}^{k=6} \beta_k \mathbb{1}(t - T_d = k) MassHealth_{it} + \delta_d + \delta_t + X_i + \varepsilon_{itd}$$

where i identifies patients, t is calendar time, d identifies drugs. δ_t represents fixed effects for calendar time and δ_d represent drug fixed effects. X_i controls for patient characteristics: fixed effects for 5-year age bins by gender, whether the patient had any emergency room (ER) visit in 12 months prior to t, and whether the patient had any hospitalization in 12 months prior to t. The ER and hospitalization controls capture time-varying differences in disease severity and utilization patterns across enrollees.

$MassHealth_{it}$ is an indicator variable denoting whether patient i was enrolled in MassHealth's prescription drug program at time t (relative to being enrolled in BCBS' prescription drug program). T_d denotes the calendar time the prior authorization policy change occurred for drug d. Thus, α_0 identifies any time-invariant differences in outcomes between MassHealth and BCBS, and α_k identifies trends in BCBS outcomes over time and around the time when the policy change occurred in MassHealth.

The coefficients of interest are the set of β_k coefficients, which identify the effect of prior authorization policy changes on outcomes in MassHealth relative to BCBS for the same drug and calendar time for 4 quarters before the policy change and 6 quarters after the policy change, controlling for all other individual characteristics. We also report the estimates from the static difference-in-difference specification, where we replace the relative time fixed effects with a single dummy variable for whether the prescription occurred before or after the prior authorization policy change. We cluster standard errors at the drug level.

Our treated group is defined as everyone enrolled in MassHealth's prescription drug program at

[13] This is the definition in both pharmacy and medical claims. Among generics, we ignore brand names, which is equivalent to saying all generics are the same, but for branded drugs, the brand matters.

time t, living in MA at the time, younger than 65 at time t, and with 12 months of medical coverage by any payer at any time prior to t. Similar criteria define the control group, except that it includes everyone enrolled in BCBS's prescription drug program at time t instead of MassHealth. These definitions of our treated and control groups implicitly allow for individuals to switch plans endogenously due to the prior authorization policy change because we allow for the enrollee composition to change across time. To examine whether our results are driven by individuals switching plans as opposed to the direct restrictive effect of prior authorizations, we also estimate the effect of prior authorization policy changes on individuals who remain in the same plan throughout the study period (2009-2013).

A potential concern with the above approach is that MassHealth and BCBS enroll different patients. In addition to examining the pre-trends in our dynamic difference-in-difference specification as a check for differential trends between our treatment and control group, we also use a matched difference-in-difference specification using nearest-neighbor matching to match MassHealth enrollees to similar BCBS enrollees. We match treated individuals to controls based on 5-year age bins by gender, prior medical enrollment duration, and whether the enrollee had any ER or hospitalization visits in the 12 months prior. We do not control for race as it is infrequently reported in the APCD data. We control for prior medical enrollment to capture the fact that prescriptions to individuals with longer medical histories are more likely to be classified as on-label (since there is a longer time horizon for finding diagnosis codes for an indicated disease). We report the results from the unmatched difference-in-difference as a robustness check.

4 Summary statistics

Table 3 shows summary statistics on the use of sample drugs in the APCD data. Almost 800,000 patients have at least one drug claim for a sample drug in the data. More specifically, a quarter of the MassHealth enrollees and a quarter of the BCBS enrollees satisfying our sample criteria have at least one claim for a sample drug, indicating that these are relatively common drugs. We have approximately 8 million claims for sample drugs in our data among MassHealth and BCBS enrollees.

Table 3: Rates of use of sample drugs

	Total	MassHealth (Treated)	BCBS (Control)
Pats with at least one prescription for sample drug	790475	441013	354437
Number of sample drug claims	7586660	4503415	3083245
Number of sample drug claims, medical claims	20321	12116	8205
% off-label	19.3	16.2	23.7
% off-label, never dx	17.2	13.8	22.1
% off-label, dx after rx	1.8	2.1	1.5
% off-label, rx before approval	.1	.1	.1
% off-label, unapproved age	.2	.2	.1

Table 3 also shows that the rate of off-label use among our sample drugs is quite high – almost 1 in every 5 prescriptions is used off-label. The off-label use is particularly high in BCBS, reaching almost 25%. The vast majority of off-label prescriptions are among patients who have never been diagnosed with an indicated disease.

The drugs with the highest number of claims in our sample of prior authorization events are listed in Table 4. The highest-demand sample drug is a combination of buprenorphine and naloxone, which is approved to treat opioid dependence and is mostly used on-label. Four out of the ten most frequent sample drugs are mental health drugs, such as venlafaxine (approved for major depressive disorder, generalized anxiety disorder, panic disorder, and social phobia), quetiapine (approved for bipolar disorder, major depressive disorder, schizophrenia), escitalopram (approved for treatment of generalized anxiety disorder and major depressive disorder), and methylphenidate (approved for attention deficit hyperactivity disorder). The off-label share for these drugs also tends to be quite high. Among the remaining drugs listed in Table 4, doxycycline is an antibiotic, losartan is approved to treat cerebrovascular accidents, diabetic nephropathy, and hypertension, clobetasol is used to treat plaque psoriasis, and tamsulosin is approved for benign prostatic hyperplasia.

Table 4: Top 10 drugs in sample with prior authorization events, by number of claims

Drug	Number of claims	% on-label	% off-label
buprenorphine naloxone	1079915	96.1	3.9
venlafaxine	789788	91.3	8.7
doxycycline	778567	92.1	7.9
quetiapine	709906	86.4	13.6
losartan	512155	95.2	4.8
clobetasol	371441	69.3	30.7
tamsulosin	351443	54.6	45.4
escitalopram	343546	86.5	13.5
methylphenidate	224319	79	21
prednisolone sodium phosphate	215721	90.9	9.1

Table 5 shows the patient characteristics of our matched sample.[14] Patients in our sample are young – the average age in our sample is 24 – because MassHealth mostly enrolls children. Almost a quarter of the patients in our sample have had an ER visit in the past 6 months. While we see some statistically significant differences in prior medical enrollment and ER/hospital utilization between the treated (MassHealth) and control (BCBS), these are small in magnitude.

A vital difference arises when we look at spending, which we discuss now. We do not directly match on spending because MassHealth (and Medicaid more broadly) has almost no cost sharing by design, as compared to BCBS. Table 5 confirms this – out-of-pocket spending is much lower for MassHealth than BCBS, conditional on similar demographics and health care utilization. Additionally, prices for services and drug rebates may differ significantly between MassHealth and BCBS. As a result,

[14] See Appendix Table A1 for summary statistics on the unmatched sample.

Table 5: Summary statistics

Characteristic	Treated mean	Control mean	Difference
Female, %	52.59	52.36	.22
Any ER visit, prior 6 months, %	24.21	20.71	3.5***
Any hospitalization, prior 6 months, %	5.59	4.82	.77***
Any ER visit, prior 12 months, %	37.93	36.94	.98
Any hospitalization, prior 12 months, %	9.90	9.18	.72*
Medical enrollment days at baseline	452.60	464.10	-11.6***
Age	24.20	23.70	.5
Num. ER visits, prior 6 months	0.60	0.40	.3***
Num. hospitalizations, prior 6 months	0.10	0.10	.1***
Num. ER visits, prior 12 months	1.20	0.70	.5***
Num. hospitalizations, prior 12 months	0.20	0.10	.1***
OOP, prior 6 months, $	107	293	-186***
OOP, prior 12 months, $	197	583	-386***
OOP pharmacy, prior 6 months, $	38	126	-88***
OOP pharmacy, prior 12 months, $	85	249	-164***
Spending, prior 6 months, $	3,136	2,829	306**
Spending, prior 12 months, $	6,287	5,612	675***
Spending pharmacy, prior 6 months, $	539	471	68*
Spending pharmacy, prior 12 months, $	971	892	79

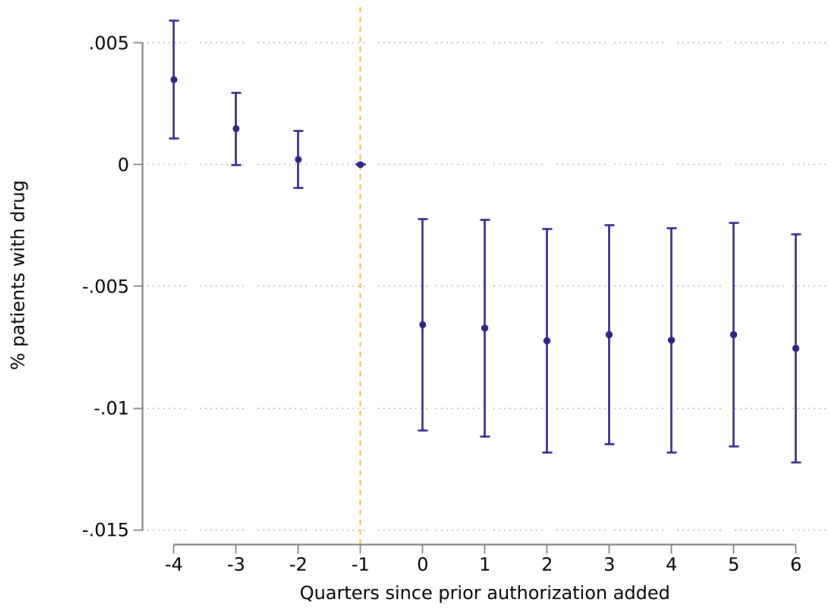
Note. Treated individuals are matched to controls using nearest-neighbor matching based on 5-year age by gender bins, prior medical enrollment duration, and any emergency room (ER) visits or hospitalizations in the 12 months prior. Demographics, utilization, and spending were measured in the Massachusetts All-Payer Claims Database as of January 2010.

we do not consider BCBS a good control group for assessing the effects of prior authorization on spending and focus our analysis on utilization instead.

5 Results

Figure 1 shows that adding a prior authorization requirement on a drug that previously did not have such a requirement causes a significant and persistent decrease in the utilization of the drug. This decrease in utilization is immediate and lasts throughout the entire post-policy period (18 months). Column 1 of Table 6 shows that this decrease is equivalent to a 44% (=0.00729/0.0165) decrease in the focal drug's utilization relative to the pre-period utilization in MassHealth. Since our effects are driven by the sample drugs with the highest demand in the data, this indicates that there is a large decrease in drugs used to treat mental health disorders, opioid dependence, and a few other chronic conditions, as shown in Table 3.

Figure 1: Effect of adding prior authorization on % of enrollees taking focal drug



Appendix Figure A1 shows matched difference-in-difference results if we condition on individuals who have been enrolled in MassHealth or BCBS throughout the entire study period, effectively shutting down the endogenous plan switching channel for decreasing the utilization of drugs. We see slightly larger decreases in drug utilization if we condition on individuals who have never switched in or out of MassHealth and BCBS. However, the difference is only 5 percentage points relative to the case where we allow for endogenous plan switching shown in Figure 1, indicating that endogenous plan switching does not play a large role in the drug utilization reduction; rather, we seem to be picking up the direct effects of prior authorization on drug utilization. We also observe similar results if we use the non-matched sample in the difference-in-difference analysis (Appendix

Figure A2), indicating that our results are not driven by the choice of matching procedure or controls.

Table 6: Effect of adding prior authorization on % of enrollees taking focal drugs

	(1) % taking focal drug	(2) % taking focal drug on-label	(3) % taking focal drug off-label
Post-period	-0.00217**	-0.00130*	-0.000797
	(0.00105)	(0.000783)	(0.000524)
MassHealth	0.00727***	0.00652**	0.000821*
	(0.00271)	(0.00254)	(0.000422)
Post-period * MassHealth	-0.00729**	-0.00661**	-0.000747*
	(0.00285)	(0.00268)	(0.000446)
Observations	11095378769	11095378769	11095378769
R-squared	0.064	0.066	0.010
Pre-period control group mean:	0.0165	0.0136	0.00296

Note. Clustered standard errors in parentheses (clustered at drug level). *** p<0.01, ** p<0.05, * p<0.1

Figure 2 and Figure 3 separate the effect of prior authorizations on on-label vs. off-label uses of a drug. These results suggest that there is a reduction in both guideline-consistent on-label use and guideline-inconsistent off-label use of drugs as a result of prior authorizations. However, the decrease in off-label use is noisier and smaller in absolute magnitude. Columns 2 and 3 in Table 6 suggest that relative to the average drug utilization in MassHealth prior to the policy change, on-label use decreases by roughly 49% and off-label use decreases by 25%, suggesting that prior authorizations are more likely to decrease guideline-consistent use rather than off-label use. Appendix Figure A4–Figure A6 further that we see decreases in almost all types of off-label use, except for the use of drugs for conditions that are eventually approved by the FDA but are not indicated at the time the individual filled the prescription. Since prior authorizations typically require that citations supporting off-label use are included in the documentation submitted with the form, these results suggest that prior authorizations may be an effective way of decreasing off-label use in cases where guidelines may not be supportive of the use since it might be easier to provide supportive evidence for an off-label use of a drug if the off-label use is soon-to-be approved by the FDA.

While separately estimating the effects of prior authorization by type of restriction (on brand name drug, on specific formulation, or on entire active ingredient) yields noisy estimates, Figure 4 shows the effect of prior authorization on drug utilization when we look at restrictions imposed on brands or specific formulations pooled together. In other words, this is the effect of prior authorization on drug utilization when similar alternatives are available. In these cases, the effect of prior authorization on drug utilization is slightly larger, equivalent to a 50% decrease relative to the pre-period average utilization in MassHealth. However, we might have expected a much larger decrease in drug utilization for these cases if drugs with the same active ingredient act as perfect substitutes.

Figure 2: Effect of adding prior authorization on % of enrollees taking focal drug as **on-label**

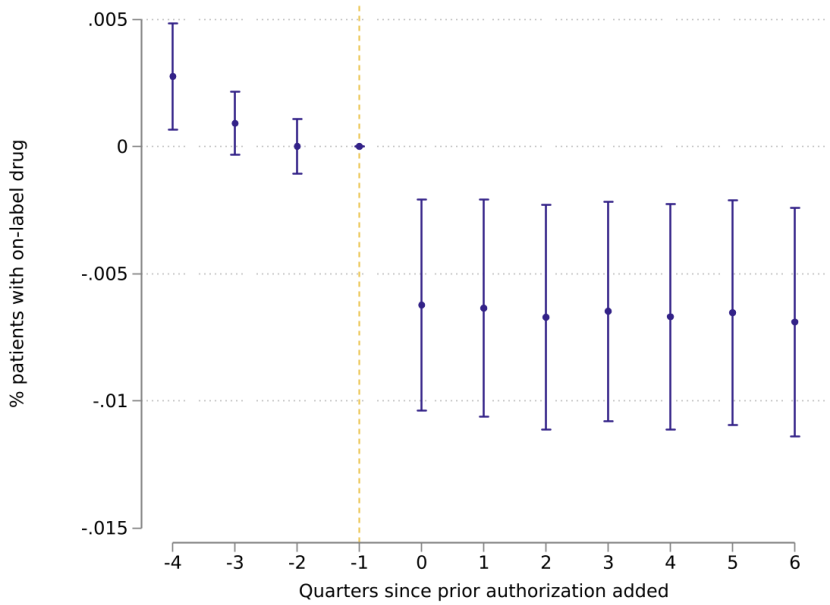


Figure 3: Effect of adding prior authorization on % of enrollees taking focal drug as **off-label**

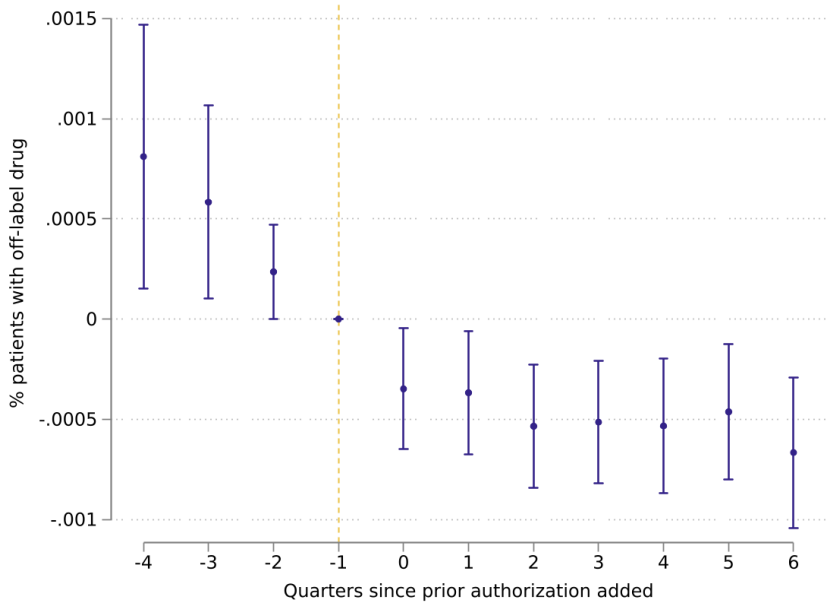
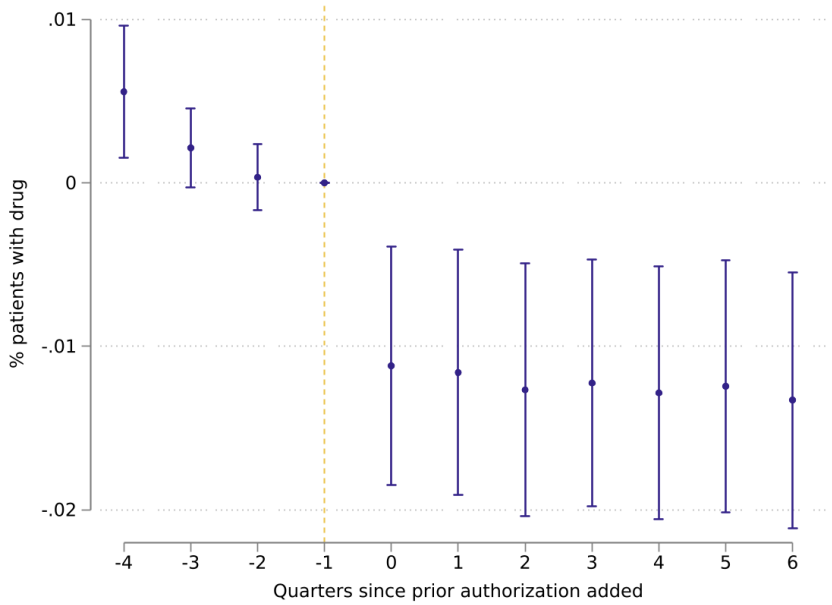


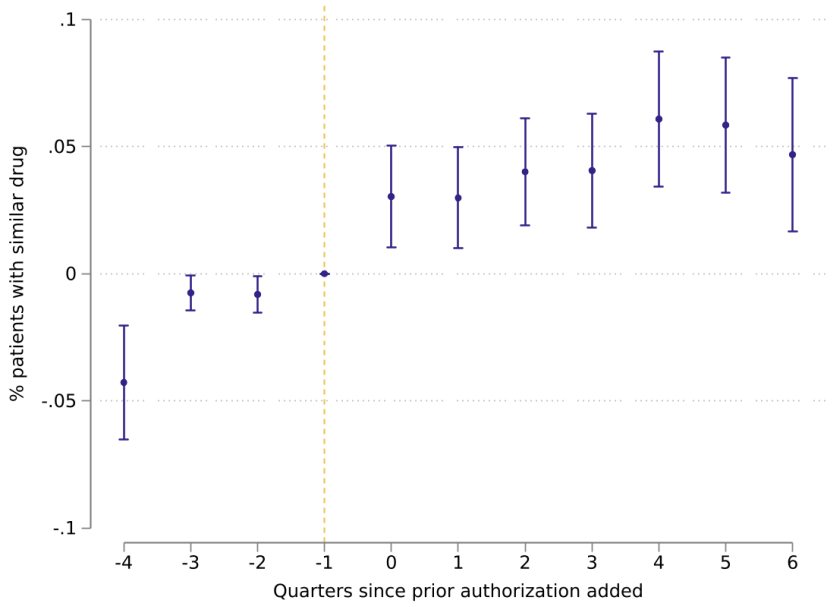
Figure 4: Effect of adding prior authorization on % of enrollees taking drug where other drugs with same active ingredient are not restricted



Note. Includes prior authorizations imposed only on brands or on specific formulations. Similar alternatives are defined as other drugs with the same active ingredient.

The prior authorizations where the brand name drug or an alternative formulation is restricted allow us to assess the substitution to drugs that may have the same active ingredient but be in a generic form (and thus cheaper) or alternative formulation (e.g., tablet instead of injection, which tends to be more expensive since it must be administered by a health care professional). Figure 5 shows the effect of imposing a prior authorization on a specific brand or formulation on the utilization of drugs which may have the same active ingredient but are in a generic form or alternative formulation. This figure shows that substitution to similar drugs when a focal drug is restricted is twice as high as the comparable decrease in drug utilization of the focal drug in the initial months after the policy change. Importantly, this effect increases over time. We theorize two reasons for this effect. One, prior authorizations on brand name drugs or formulations are often imposed when a cheaper generic drug or cheaper formulation newly enters the market. Thus, the results shown in Figure 5 reflect a differential adoption of a new drug in MassHealth relative to BCBS, indicating that prior authorizations may also direct the adoption of new drugs. Second, these results may also pick up substitution patterns from multiple prior authorization changes on different brands and formulations of the same active ingredient occurring at the same time, leading to larger substitution than the decrease of the focal drug's utilization in Figure 1. However, the fact that Figure 5 looks like a drug adoption curve suggests that the first explanation is more likely.

Figure 5: Effect of adding prior authorization on % of enrollees taking another drug with the same active ingredient



Note. Includes prior authorizations imposed only on brands or on specific formulations. Similar alternatives are defined as other drugs with the same active ingredient.

6 Conclusion and discussion

We find large and persistent effects of prior authorizations on drug utilization in MassHealth, where prior authorizations are the only means available to the payer for regulating health care spending. Our findings indicate that prior authorizations decrease drug utilization by almost a half relative to no prior authorization. Furthermore, we find that guideline-consistent use is the one driving this decrease (as opposed to guideline inconsistent use).

As discussed earlier, our comparison of MassHealth to BCBS enrollees as a control prohibits us from estimating the effect of prior authorizations on spending since prices and drug rebates might differ between MassHealth and BCBS. Future work includes trying to estimate spending impacts by comparing MassHealth fee-for-service to MassHealth managed care enrollees, as well as assessing substitution patterns in more detail. Finally, we will also tackle outcomes in future work, such as health care utilization from the emergency room and hospitalizations, as well as delays in treatment, defined as differences between the date of filling a prescription and the date the prescription was written.

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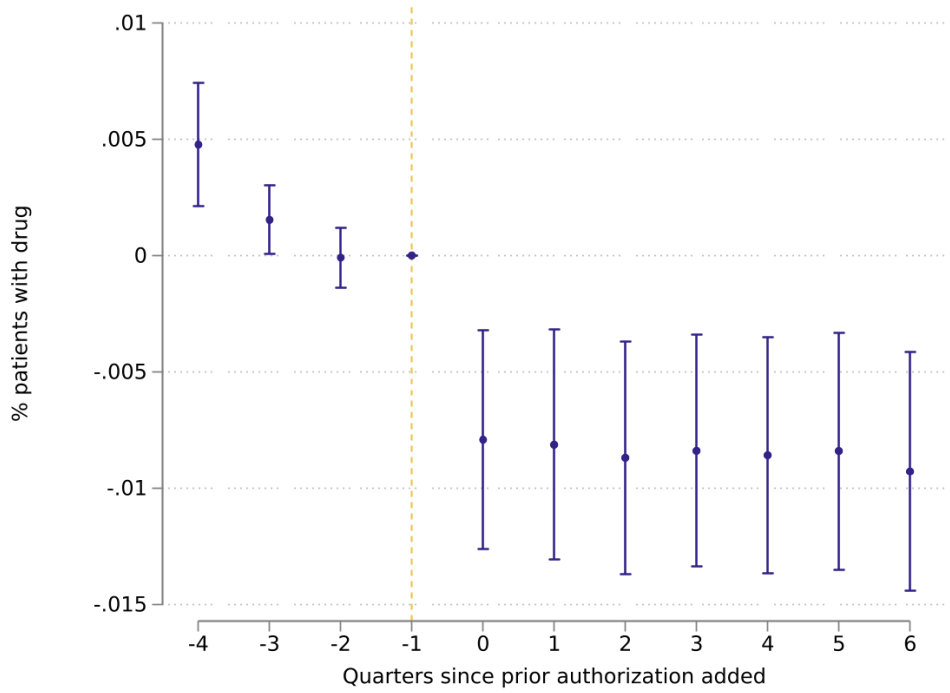
Appendix Tables and Figures

Appendix Table A1: Summary statistics, unmatched sample

Characteristic	Treated mean	Control mean	Difference
Female, %	52.59	49.68	2.9***
Any ER visit, prior 6 months, %	24.21	9.31	14.9***
Any hospitalization, prior 6 months, %	5.59	2.08	3.51***
Any ER visit, prior 12 months, %	37.93	16.75	21.17***
Any hospitalization, prior 12 months, %	9.90	3.98	5.92***
Medical enrollment days at baseline	452.60	503.70	-51.2***
Age	24.20	33.10	-8.9***
Num. ER visits, prior 6 months	0.60	0.20	.5***
Num. hospitalizations, prior 6 months	0.10	0.00	.1***
Num. ER visits, prior 12 months	1.20	0.30	.9***
Num. hospitalizations, prior 12 months	0.20	0.10	.2***
OOP, prior 6 months, $	107	280	-173***
OOP, prior 12 months, $	197	568	-372***
OOP pharmacy, prior 6 months, $	38	147	-109***
OOP pharmacy, prior 12 months, $	85	298	-213***
Spending, prior 6 months, $	3,136	2,054	1082***
Spending, prior 12 months, $	6,287	4,104	2183***
Spending pharmacy, prior 6 months, $	539	484	55***
Spending pharmacy, prior 12 months, $	971	962	9

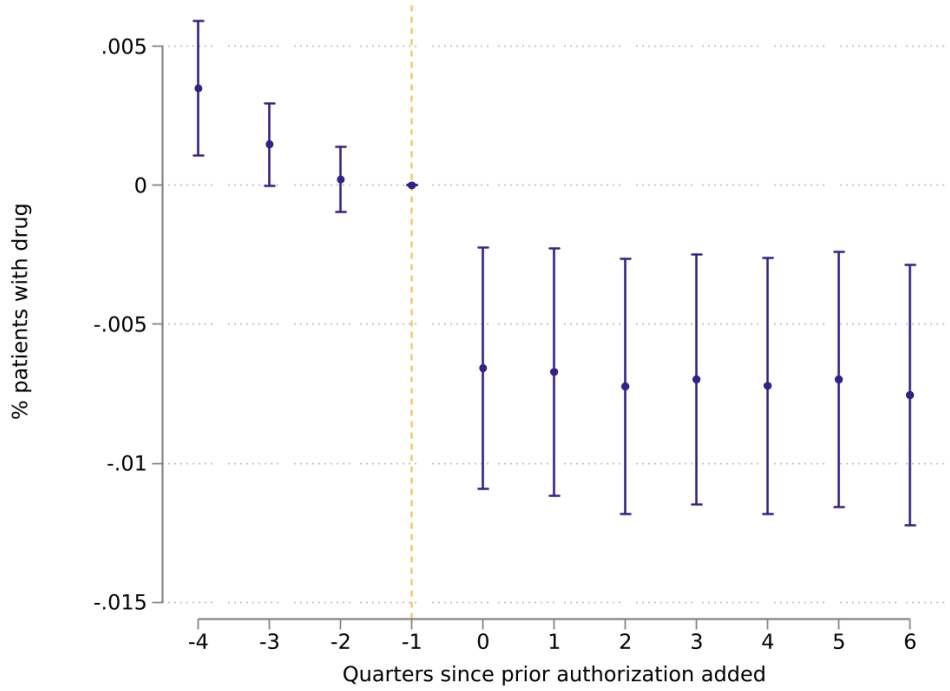
Demographics, utilization, and spending were measured in the Massachusetts All-Payer Claims Database as of January 2010.

Appendix Figure A1: Effect of adding prior authorization on % of enrollees taking focal drug



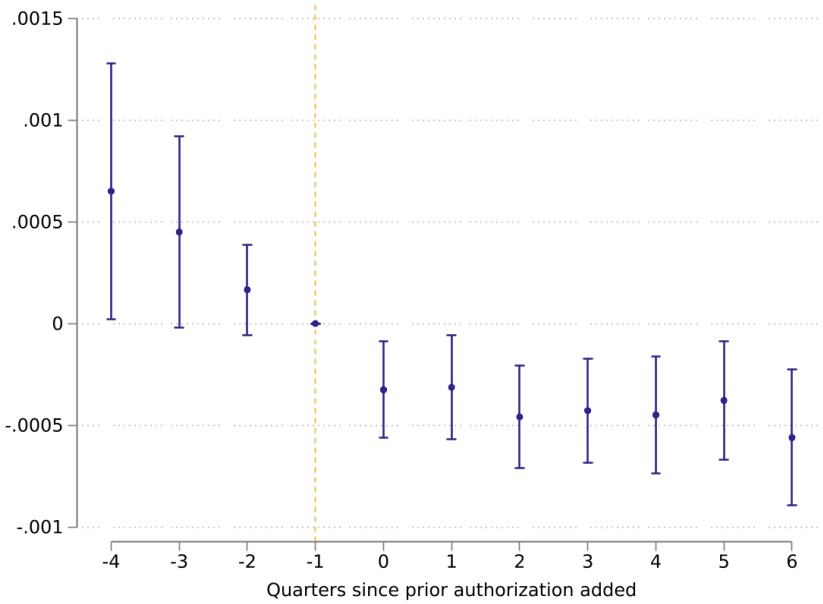
Includes everyone enrolled in MassHealth or BCBS for the entire data period (2009-2013). Treated (MassHealth) individuals are matched to control (BCBS) individuals using nearest neighbor matching.

Appendix Figure A2: Effect of adding prior authorization on % of enrollees taking focal drug

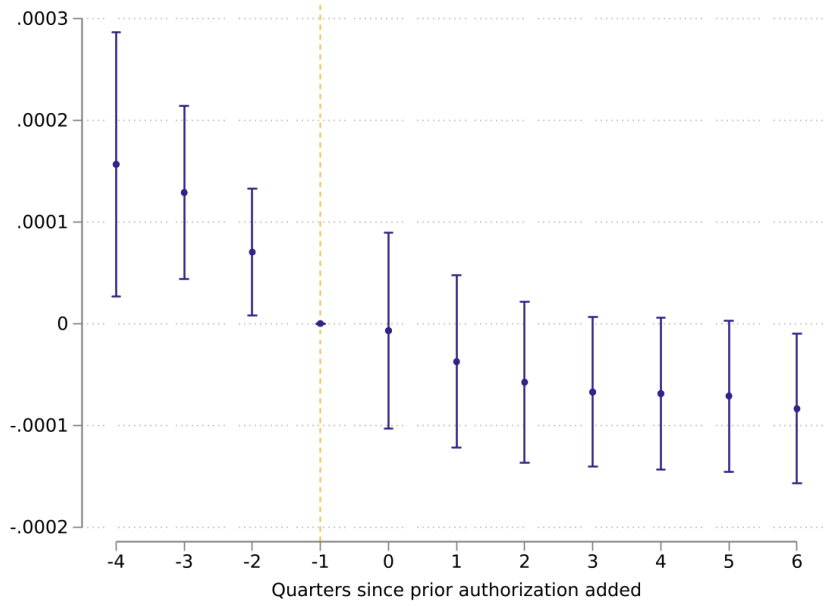


Includes everyone enrolled in MassHealth or BCBS at any point during the study period (2009-2013).

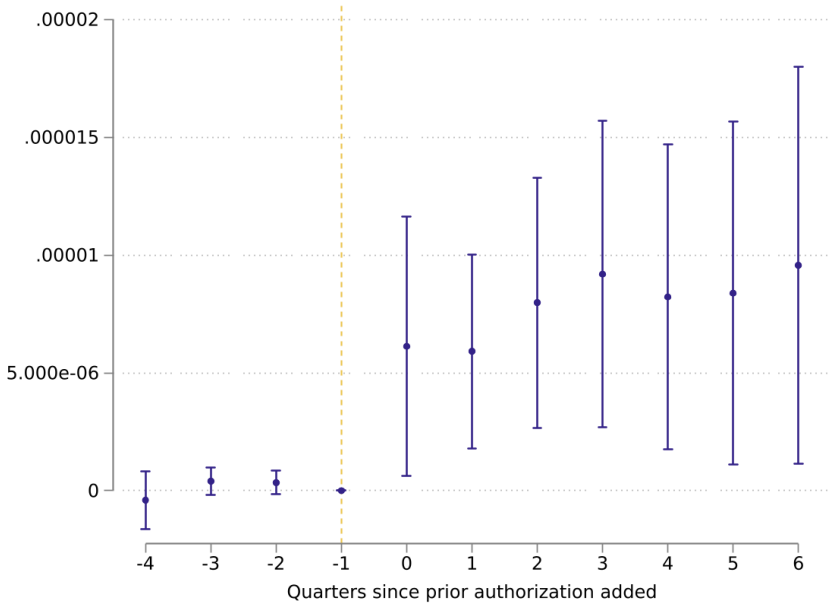
Appendix Figure A3: Effect of adding prior authorization on % of enrollees taking focal drug as **off-label**, never diagnosed



Appendix Figure A4: Effect of adding prior authorization on % of enrollees taking focal drug as **off-label**, diagnosed after prescription



Appendix Figure A5: Effect of adding prior authorization on % of enrollees taking focal drug as **off-label**, prescribed before FDA approval



Appendix Figure A6: Effect of adding prior authorization on % of enrollees taking focal drug as **off-label**, prescribed for an unapproved age

