Constraints on Formulary Design Under the Affordable Care Act

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Abstract:

I study the effect of prescription drug essential health benefits (EHB) requirements from the Affordable Care Act on prescription drug formularies of health insurance marketplace plans. The EHB regulates the number of drugs covered but leaves other dimensions (cost sharing and utilization management) of the formulary unregulated. Using data on almost all formularies in the country, I demonstrate that requiring insurers to cover one additional drug adds 0.22 drugs (3.3%) to the average formulary, mostly owing to firms increasing the number of drugs covered to comply with the EHB requirement. The EHB requirement also increases the probability that a drug is subject to utilization management and is assigned to a higher (more costly) formulary tier. My results suggest that newly covered drugs are 22.3 percentage points more likely to be subject to utilization management, compared to 36.7% for the average covered drug. Using formularies for Medicare Advantage plans, which are subject to uniform, nationwide benefit design standards, and the formulary status of newly approved drugs that do not satisfy the EHB requirement, I reject the hypotheses that consumer demand or effects on plan entry can explain my results.

Keywords: Affordable Care Act | benefit design | insurance | mandates

Article:

1 Introduction

The Affordable Care Act (ACA) provides significant new health insurance benefits to millions of Americans and mandates that insurance plans provide several 'essential health benefits' (EHBs). 1 These EHBs are based on coverage offered by a benchmark plan offered in the state in 2012 (Institute of Medicine, 2011) and are intended to ensure that consumers purchase 'high-quality' insurance plans, minimize the ability of insurers to discriminate between different types of

consumers, and facilitate competition on the health insurance marketplaces. 2 However, these goals may be undermined if insurers alter unregulated margins of the insurance benefit in response to the EHB.

The prescription drug EHB, which is the focus of this paper, defines generosity as the number of drugs covered by a plan in each of the 158 drug classes defined by the US Pharmacopeia for use with Medicare Part D plans. However, the EHB does not regulate two other aspects of drug benefit design: (1) the formulary tier assignment of a drug, which is a measure of the cost to the consumer to use a drug, and (2) the use of utilization management techniques, such as a prior authorization requirement, that provide a non-financial barrier to drug utilization. These unregulated margins leave plans with considerable discretion to increase costs and limit access to drugs through tier assignment and utilization management (see Jacobs and Sommers, (2015), for an example).

In this paper, using unique data on 47 of the 158 drug classes included in the EHB requirement, I make four contributions to the literature. First, I provide what is, to my knowledge, the first quantitative assessment of the effect of the EHB regulations on benefit design in plans offered through health insurance marketplaces.

Second, I show that insurers respond to EHB regulations. Using within-drug-class variation in the minimum number of drugs that an insurance plan must cover, I find that increasing this threshold by 10 percentage points, relative to the size of the drug class, results in insurers covering an additional 1.4% of the drugs in a class or 0.22 additional drugs per additional drug required, with the bulk of the increase arising from plans that need to increase coverage to comply with the mandate.

Third, I demonstrate that insurers respond to benefit regulations on one margin by modifying other margins of the same benefit. More stringent EHB requirements increase the probability that a drug is assigned to a higher formulary tier, making the drug more expensive to the consumer or subject to utilization management. While this effect was stronger for marginal than for inframarginal drugs, the increase in utilization management was too large, relative to the increase in coverage, to be explained solely by covering marginal drugs less generously, indicating that inframarginal drugs were also more likely to be covered by utilization management as a result of the mandate.

Fourth, my results imply that insurers are endogenously choosing benefit generosity in response to the EHB regulation. There is a small literature looking at prescription drug benefit design, which finds that insurers respond to financial incentives (Carey, 2015; Lavetti & Simon, 2016). However, this is, to my knowledge, the first paper to document responses to regulatory incentives by demonstrating that regulations governing the breadth of prescription drug coverage (the number of drugs a plan must cover in a class) affects benefit design as well.

I also rule out two alternative explanations. First, I consider the possibility that the EHB rule is proxying for consumer preferences by examining the correlation between the EHB rule and formularies for Medicare Advantage plans, which are not subject to the EHB rule. If consumer preferences for drugs are correlated for marketplace and Medicare Advantage enrollees and the EHB rule reflects consumer preference, then the EHB rule should be correlated with formulary size, coverage, and utilization management in Medicare Advantage plans. I am able to reject all of these comparisons with precise null findings. Second, I consider the possibility that the EHB rule is discouraging entry by less generous plans, where I assume that a less generous plan is also likely to be less generous on unregulated margins, that is, drugs that cannot be used to meet the EHB requirement. Hence, I test if the EHB rule affects coverage of new drugs, which should not be

affected by the EHB rule. I find no evidence that the EHB rule affects coverage of new drugs but rather only affects coverage of older drugs that can be used to satisfy the EHB rule.

Section 2 discusses the EHB requirements. Section 3 describes the unique data on formulary design that I use and presents my empirical methods for identifying the effect of EHBs on formulary design. Section 4 presents my findings on the effect of the EHB on coverage, utilization management, and tier assignment. Section 5 discusses the welfare implications of my results, their implications for regulation of formulary design in the ACA, and concludes. The supporting information provides additional results and develops a theoretical model of benefit design in a regulated, monopolistically competitive setting.

2 Essential Health Benefit Requirements and Formulary Placement in the Affordable Care Act

2.1 Prescription drug benefits and formularies

Prescription drug benefits are a common part of many health insurance plans among employer-sponsored plans (Kaiser Family Foundation, 2013). The typical plan uses a combination of formularies (lists of drugs the consumer may purchase through the plan), benefit tiers (different levels of out-of-pocket costs), and utilization management (non-financial restrictions on drug utilization) to constrain drug costs, with multi-tiered formularies being the dominant formulary design since the year 2000, at the latest, when 76% of covered workers had a formulary with two or more tiers and three or more tiers covered the majority of workers after 2002 (Kaiser Family Foundation, 2013).

Utilization management covers a broad array of techniques that serve as non-financial barriers to drug utilization. Prior authorization requires that consumers obtain approval from the insurer before purchasing a drug. Quantity limits restrict the number of pills of a drug that may be dispensed at a time. Step therapy can be thought of as a weaker form of prior authorization in that patients are required to try to use a series of drugs before they are permitted to use other, presumably more expensive, drugs. All three methods are intended to reduce utilization of a covered drug, but the effect on consumer costs and social welfare is ambiguous and depends on how consumers respond to utilization management. 3 Previous work has found that insurers reject as few as 5% or as many as 19% of claims for some drugs, with three-quarters of these rejections due to utilization management policies (Stevenson et al. 2012; Delate et al. 2005), with higher claims rejection rates consistent with firms using utilization management policies as a substitute for cost sharing.

Both tiering and utilization management can be used to shift market share between different drugs within the same class (Huskamp et al., (2005), (2007); Smalley et al., (1995); Fischer et al., (2004); Delate et al., (2005); Soumerai et al., (2008); Law et al., (2010); Zhang et al., (2009); Dunn et al., (2006); Mark et al., (2010)), provided that there are lower-cost substitutes available (Law et al. 2008). The result is to increase the elasticity of substitution between drugs (hence bargaining power of the insurer), which may allow the insurer to negotiate lower prices with drug manufacturers. However, tiering and utilization management can also have adverse consequences by increasing rates of non-adherence (Dusetzina et al. 2014; Domino et al. 2011), treatment discontinuation (Dusetzina et al. 2014; Soumerai et al. 2008), and non-drug spending and utilization (Chandra et al. 2010; Soumerai et al. 1994; Mark et al. 2010).

2.2 Essential health benefits

The ACA mandated the EHB requirements in order to facilitate competition between plans, limit the opportunity for cream skimming by plans, and establish a floor on plan quality. The Center for Consumer Information and Insurance Oversight (CCIIO), which is a branch of the Center for Medicare and Medicaid Services, is principally responsible for oversight of the health insurance marketplaces and the administration of the EHB requirement. The EHB policy applies to all plans except those that serve the Medicare, self-insured, or large-group markets and those plans that existed prior to March 2010 and did not make significant changes to benefit design (so-called grandfathered plans). The EHB requirements, which were developed by the Institute of Medicine, span 10 service categories and were based on the services covered by a benchmark plan in each state (Institute of Medicine, 2011; Bagley & Levy, 2014), where the benchmark plan was one of the largest small-group plan, large-group plan, federal employee plan, or non-Medicaid HMO offered in the state in 2012. 4 As a result of this state flexibility, there is wide variation in mandated coverage across states (RWJF/LDI, (2014); Grace et al., (2014)).

The prescription drug EHB requires plans to cover the greater of one drug or the number of drugs covered by the benchmark plan in each of 158 therapeutic classes defined by the US Pharmacopeia (USP) for use in the Medicare Part D program (version 5.0), where two drugs are considered to be equivalent if they have the same active ingredient(s), regardless of dose or method of delivery. The counting formula allows a drug to count in each therapeutic class to which it is assigned in the USP classification and excludes either drugs that are not assigned a class, which are typically combination products, or drugs that were not on the market in November of 2012, which is when the counting methodology was finalized for the 2014 plan year; hence, new drugs cannot be used to satisfy the EHB requirement.

Table 1 lists, for each of the 47 drug classes in my data, the number of drugs in my formulary data (Managed Markets Insight and Technology (‘MMIT’)), described later; the average number of drugs covered; the fraction of plans that comply with the EHB requirement; and the maximum, median, average, and standard deviation numbers of drugs a plan must cover in a class. Within a drug class, for example, among blood glucose regulators, there are 21 antidiabetic agents—distinct ingredients to treat diabetes—in my data, and the average plan will cover 19.6 of these drugs, implying that only three-quarters of plans are in technical compliance with the EHB rule. Across states, there is some variation in the number of drugs required, although over half of the states require plans to cover all 21 antidiabetic agents. In other classes, such as molecular target inhibitors, the most stringent requirement is for a plan to cover 13 out of a possible 21 drugs and on average plans chose to cover 18.8 different molecular target inhibitors—substantially more than required by the EHB rules.

Table 1. EHB regulations

	MMIT data			EHB requirement			
Category/class	No. drugs	No. covered	% compliant	Max	Median	Mean	Standard deviation
Antidepressants							
Antidepressants, other	8	7.8	95.4	8	8	7.6	0.9
MAOIs	4	3.7	90.6	4	4	3.7	0.7
SSRIs/SNRIs	13	12.8	99.3	9	9	8.7	0.9
Tricycles	9	8.4	61.2	9	9	8.8	0.7
Antiemetics							
Antiemetics, other	11	10.4	91.5	10	10	9.4	0.9
Emetogenic therapy	8	6.8	80.8	8	7	6.5	1.7
Antineoplastics							
Alkylating agents	8	6.6	67.4	8	6	6.5	1.8
Antiangiogenics agents	2	2.0	98.4	2	2	1.9	0.3
Antiestrogens	3	2.8	92.8	3	3	2.7	0.6
Antimetabolites	5	4.7	99.7	3	2	2.0	0.5
Antineoplastics, other	10	8.1	96.4	6	4	3.8	1.9
Aromatase inhibitors	3	3.0	98.4	3	3	3.0	0.3
Enzyme inhibitors	5	4.5	98.4	3	3	2.1	1.0
Molecular target inhibitors	21	18.8	98.7	13	12	10.6	3.0
Monoclonal antibodies	3	2.1	77.5	3	2	1.9	1.0
Retinoids	2	1.9	25.7	3	3	2.6	0.7
Antipsychotics							
Antipsychotic, typical	10	9.8	91.2	10	10	9.8	0.6
Antipsychotic, atypical	9	8.4	76.9	9	9	8.4	1.4
Antipsychotic, resistant	1	1.0	99.7	1	1	1.0	0.0
Antivirals							
Anti-CMV agents	4	3.4	89.6	4	3	2.9	1.1
Anti-HIV agents, NNRTIs	7	6.7	99.0	5	5	4.8	0.6
Anti-HIV agents, NRTIs	11	10.8	9..8	11	11	10.8	1.0
Anti-HIV agents, other	4	3.8	96.7	4	3	2.9	0.5
Anti-HIV agents, PIs	9	8.9	97.7	9	9	8.8	0.9
Anti-influenza agents	4	3.9	94.5	4	4	3.8	0.6
Antihepatitis agents	11	10.6	32.2	12	12	10.6	2.6
Antiherpetic agents	6	5.6	91.9	6	5	5.3	0.8
Blood glucose regulators							
Antidiabetic agents	21	19.6	75.2	21	21	19.4	3.8
Glycemic agents	2	1.8	91.5	2	2	1.8	0.4
Insulins	12	9.5	90.9	10	10	8.6	2.1
CNS agents							
ADHD, amphetamines	4	3.7	88.3	4	4	3.8	0.4
ADHD, non-amphetamines	5	4.4	9..8	4	4	3.7	0.8
CNS, other	5	4.5	94.1	4	4	3.5	1.0
Fibromyalgia agents	3	2.5	62.2	3	3	2.8	0.7
MS agents	8	6.7	86.3	7	6	5.5	1.7
Immunological agents							
Immune suppressants	25	10.9	77.5	24	20	18.0	5.6
Immunizing agents, passive	4	1.6	91.3	4	1	2.1	1.4
Immunomodulators	17	14.0	97.7	11	8	7.8	2.7
Respiratory tract agents							
Inhaled corticosteroids	7	6.8	97.1	6	6	5.8	0.7
Antihistamines	11	10.1	84.7	11	11	9.7	2.0
Antileukotrienes	3	2.8	91.5	3	3	2.8	0.6
Anticholinergic	3	2.7	97.1	3	2	2.0	0.2
Phosphodiesterase inhibitors	4	3.4	93.2	3	3	2.5	0.7
Sympathomimetic	9	8.4	28.0	10	10	9.2	1.5
Mast cell stabilizers	1	1.0	99.7	1	1	1.0	0.0
Pulmonary antihypertensives	6	5.4	90.6	6	5	4.8	1.7
Respiratory tract agents, other	10	7.9	95.1	5	5	4.0	1.3

Source: Author's analysis of MMIT data for November 2014 and CCIIO EHB rules for 2014. ADHD, attention deficit hyperactivity disorder; CMV, cytomegalovirus; CNS, central nervous system; EHB, essential health benefit; MAOIs, monoamine oxidase inhibitors; MMIT, Managed Markets Insight and Technology; MS, multiple sclerosis; NNRTIs, non-nucleoside reverse-transcriptase inhibitors; NRTIs, nucleoside reverse-transcriptase inhibitors; PIs, protease inhibitors; SNRIs, serotonin–norepinephrine reuptake inhibitors; SSRIs, selective serotonin reuptake inhibitors.

In most drug classes, I am able to identify at least as many unique drugs in the formulary data as are required by the EHB requirement. 4, 5

Table 1 also indicates that there is non-trivial variation in the EHB requirement across all drug classes with more than one drug, even if many states may have similar EHB requirements for some drug classes (e.g., classes where the max and the median are the same imply that at least 26 states have adopted the same, high, threshold). I use both within-state and within-drug-class variation in the EHB rule to identify the effect of the EHB rule.

While no studies have yet examined the impact of the EHBs on availability of drugs or implications for premiums, economic theory suggests that the EHBs should weakly increase insurer costs, relative to the insurer's preferred, profit-maximizing benefit package, holding all else equal. In the supporting information, I develop a formal model of the EHB requirement and demonstrate that an increase in the EHB requirement increases the number of drugs covered but reduces the generosity of coverage.

3 Data and Empirical Approach

3.1 Data

Measuring the EHB regulation: Data on the EHB came from CCIIO and lists the number of drugs covered by the benchmark plan in 2012 in each drug class. In some cases, the EHB requirements specified more drugs than I was able to find in my data, which means that I will tend to overestimate the rate of noncompliance with the EHB rule. I take two approaches to dealing with this problem: first, I limit the EHB requirement to be no greater than the number of drugs I identify in a class; second, as a specification check, I restrict my sample to drug classes where I do observe a sufficient number of drugs to satisfy the most restrictive EHB requirement for the class. Prescription drug formulary data: I obtained a single November 2014 snapshot of data on prescription drug formularies from MMIT. 6 The MMIT data are sourced directly from health plans and prescription benefit managers and are widely used by pharmacies, insurers, and drug manufacturers to monitor formulary coverage of drug products. The data cover almost all formularies in the USA. I use a subsample of these data that covers marketplace plans, all of which are subject to the EHB requirement, and Medicare Advantage plans, none of which are subject to the EHB requirement. I exclude other plans that are offered in the individual, commercial, and employer-sponsored markets because I cannot identify which plans are, and are not, subject to the EHB requirement—specifically, I cannot identify self-insured and grandfathered plans.

The data span nine therapeutic categories and contain 47 therapeutic classes (see Table S2 for the list of categories and classes). These categories include both commonly used and costly drug classes and several ‘protected’ drug classes under the Medicare Part D rules, which require plans to include ‘substantially all’ drugs in the class on the formulary; I omit these classes in my analyses of Medicare Advantage plans. I define a plan as a distinct combination of formulary, insurer, state, and channel (e.g., marketplace), which yields 307 unique marketplace plans and 2796 Medicare Advantage plans. Each of the marketplace plans may be used by numerous health insurance plans.

I constructed a mapping, described in the supporting information, between the MMIT data and ingredients. My final list of unique drugs includes 330 unique drugs, of which 308 can be used to satisfy the EHB requirement, and 378 drug-by-therapeutic class combinations (351 combinations can be used for the EHB) due to drugs being assigned to multiple classes. 7 For each

Table 2. Summary statistics

	Marketplace plans		Medicare Advantage plans	
	Existing	New	Existing	New
Panel A: plan by class				
% drugs required	0.78 (0.25)	0.73 (0.25)	0.78 (0.24)	0.75 (0.25)
No. of drugs required	5.61 (4.25)	7.13 (5.50)	5.48 (4.13)	7.72 (4.96)
% of drugs covered in any form	0.91 (0.19)	0.91 (0.17)	0.82 (0.18)	0.83 (0.16)
No. of drugs covered in any form	6.72 (4.90)	9.17 (6.38)	5.80 (3.95)	8.49 (4.35)
% of plan-class pairs compliant	0.90 (0.30)	0.92 (0.28)	0.69 (0.46)	0.68 (0.47)
# Plan-class tuples	14,429	5,219	69,900	27,960
Panel B: plan by class by drug				
All drugs				
% covered	0.81 (0.39)	0.56 (0.50)	0.68 (0.47)	0.50 (0.50)
% any utilization management	0.30 (0.46)	0.24 (0.43)	0.35 (0.48)	0.39 (0.49)
% prior authorization	0.19 (0.39)	0.19 (0.39)	0.20 (0.40)	0.25 (0.43)
% step therapy	0.04 (0.19)	0.03 (0.18)	0.06 (0.23)	0.08 (0.26)
% prior authorization or step therapy	0.22 (0.41)	0.21 (0.41)	0.21 (0.41)	0.27 (0.44)
% quantity limits	0.15 (0.36)	0.10 (0.31)	0.21 (0.41)	0.25 (0.43)
No. of plan-class-drug tuples	107,757	10,131	500,484	50,328
Conditional on coverage				
% any utilization management	0.36 (0.48)	0.43 (0.50)	0.50 (0.50)	0.77 (0.42)
% prior authorization	0.22 (0.42)	0.34 (0.47)	0.27 (0.44)	0.49 (0.50)
% step therapy	0.05 (0.21)	0.06 (0.24)	0.08 (0.27)	0.15 (0.36)
% prior authorization or step therapy	0.26 (0.44)	0.38 (0.49)	0.29 (0.45)	0.53 (0.50)
% quantity limits	0.19 (0.39)	0.19 (0.39)	0.31 (0.46)	0.50 (0.50)
No. of plan-class-drug tuples	96,968	5,696	405,626	25,474
Census region of plan (% in parentheses)				
Northeast	51 (16.6)		493 (17.6)	
Midwest	86 (28.0)		638 (22.8)	
South	88 (28.7)		944 (33.8)	
West	82 (26.7)		721 (25.8)	

Source: Author's analysis of MMIT data for November 2014.Medicare Advantage Plans exclude 'protected' drug classes (see text for details). 'Existing' drugs were approved before December 2012, and 'new' drugs were approved after November 2012. Standard deviation in parentheses.

MMIT drug product, I defined indicators for being covered, utilization management status, and coverage tier and at the ingredient level defined an indicator for any form of a drug product that is covered by a given plan. Because few drugs were assigned to tier 5 or higher and few plans used more than five tiers, I pooled these tier assignments. Summary statistics: Table 2 presents summary statistics for marketplace and Medicare Advantage plans. Data for Medicare Advantage plans exclude 'protected classes'. The average plan was required to cover 81% of the drugs or 5.6 drugs in a class. Newer drugs were in larger classes but had smaller EHB requirements. On average,

marketplace plans covered more drugs in a class than Medicare Advantage plans (91% vs 82%), and this holds even for the 'non-protected' drug classes (89% vs 82%, not shown). The higher rate of coverage translates into more marketplace plans satisfying the EHB requirement. However, among covered drugs, Medicare Advantage plans are more likely to apply utilization management, principally quantity limits.

Figure 1 plots the distribution of formulary sizes relative to the required number of drugs (truncated at plus or minus five drugs from the threshold) for states and classes that require two or fewer drugs than the highest requirement in the class, require one fewer, or require the highest number of drugs in the class. The fourth panel graphs the distribution of formulary sizes for all plan–classes combined. There are four notable features of the histograms. First, the lower right pane, which uses all plan–classes, indicates that there is substantial mass at the EHB threshold but that there are also some plans that do not comply with the mandate (10.3% of plan–class pairs do not cover enough drugs). Second, with relatively low EHB requirements (top left pane), the distribution of formulary sizes is relatively diffuse with a small increase in fraction of plans at the EHB rule, relative to the number of plans just above and below the requirement. Third, as the EHB rule becomes tighter, the mass at zero increases substantially from requiring one less drug than the highest rule (top right) to having the most stringent rule (lower left). Fourth, comparing the mass at one drug over the threshold in the top right pane and the mass at the threshold in the lower left pane, which correspond to plans covering the same number of drugs in a class, suggests that increasing the threshold induces firms to cover more drugs.

3.2 Empirical approach

3.2.1 Effects on formulary size

I analyze the reduced-form effect of the EHB rule on formulary size (number of covered drugs), using the regression

$$FormularySize_{csp} = \beta EHB_{cs} + \sigma_s + \chi_s + \varepsilon$$

where c,s, and p indicate drug class, state, and plan, respectively. EHBcs is the EHB rule that I define as either the share of drugs or the number of drugs in a class that a plan must cover. I define formulary size as either the share or number of drugs covered in a class.

To analyze the effect of the EHB rule on the distribution of formulary sizes, I test if the distribution of number of drugs covered on the formulary differs in a manner that is correlated with the EHB requirement. Specifically, I consider the probability that plan p includes t drugs more, or less, than the EHB requirement on its formulary in state s and class c. If the EHB rule is effective at increasing the number of drugs covered by a plan, then the probability that a plan covers t drugs more or less than the EHB rule should be lower when t is negative, holding the total number of drugs (EHBcs+t) fixed. I implement two different versions of this test based on changes in the density of plans (Eq. 2a) and differences in the cumulative distribution of plan sizes (Eq. 2b):

$$\mathbf{1}_{[FormularySize_{csp} - EHB_{cs} = t]} = \gamma + \sum_{\tau=-5}^{\tau=4} \alpha_\tau \mathbf{1}_{[t=\tau]} + \sigma_s + \chi_{csk} + \varepsilon$$

$$\mathbf{1}_{[FormularySize_{csp}-EHB_{cs}\leq t]} = \gamma + \sum_{\tau=-5}^{\tau=4} \alpha_\tau \mathbf{1}_{[t=\tau]} + \sigma_s + \chi_{cst} + \varepsilon$$

where χcsk is a set of fixed effects for each state–class–number of covered drugs combination so that the ατs are identified from differences in the probability of observing a given number of covered drugs in a given class in states that require more, versus less, drugs to be covered. As a result, the ατs estimate the causal effect of the EHB rule on the density and distribution of plans.

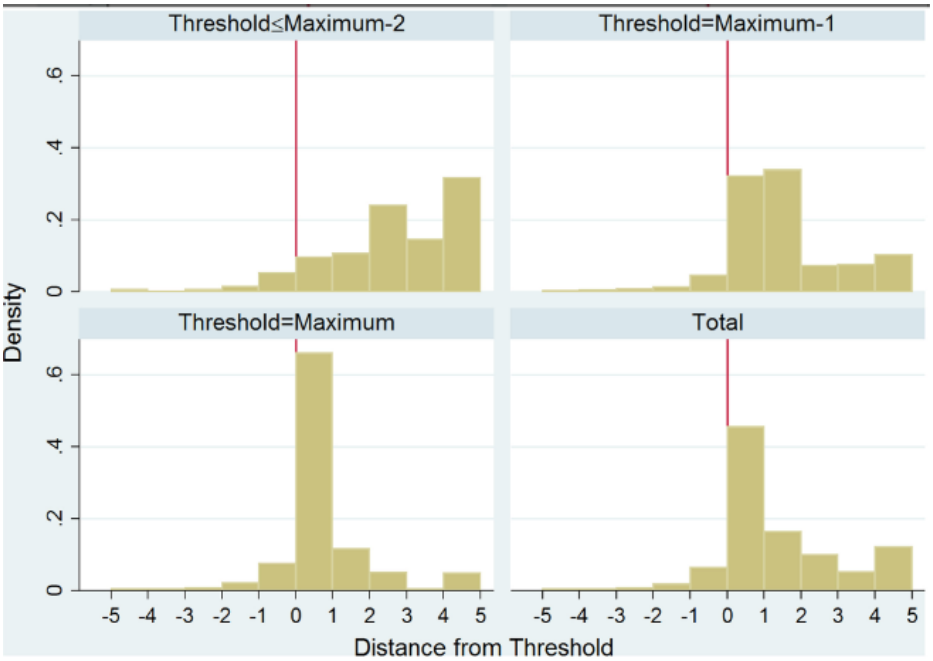


Figure 1. Histograms of formulary sizes, relative to EHB requirement. EHB, essential health benefit; MMIT, Managed Markets Insight and Technology
Source – Author's analysis of MMIT Data from November 2014.
Note – Distances have been truncated at 5 below and 5 above the state- and class-specific EHB threshold. Top left pane graphs the density of plan-classes in states and classes that have an EHB threshold that is two or more drugs smaller than the highest EHB threshold in data. Top right pane uses plan-classes in which the EHB threshold is one less than the maximum. Lower left pane uses plan-classes with the highest EHB threshold for the drug class. Lower right pane uses all plan-classes.

3.2.2 Effects on coverage, utilization management, and tier assignment

At the plan–class–drug level, I estimate reduced-form models of the effect of the EHB requirement on coverage, utilization management, and tier assignment:

$$Outcome_{dcsp} = \beta EHB_{cs} + \chi_c + \sigma_s + \varepsilon$$

I estimate a linear probability model (LPMs) and a probit model for coverage and utilization management and a multinomial logit model for tier assignment, where the multinomial logit is

estimated separately by the number of tiers included in the formulary and uses plan fixed effects to account for further differences in definition of tiers across plan types. In the interpretation of the LPM and probit estimates from this equation, it is important to note that for most outcomes β reflects the combined causal effect of the EHB rule on coverage and the presence of a utilization management provision. However, the multinomial logit results cannot be given a causal interpretation because plans are choosing the number of tiers to use in light of the EHB rule.

I also look at the effect of distance to the EHB threshold on drug-level outcomes using the model

$$Outcome_{dcsp} = \beta_{-1} BelowEHB_{cs} + \beta_0 AtEHB_{cs} + \beta_1 1OverEHB_{cs} + \chi_{ck} + \varepsilon$$

where χck are drug class by number of covered drugs fixed effects so that the β coefficients are identified from differences between formularies that cover the same number of drugs in a given class but are in states with different EHB requirements in the class. The reference group is formularies that cover two or more drugs more than the EHB requirement. The estimated differences in these outcomes do not reflect causal estimates because they are conditional on the number of drugs a plan chooses to cover in a class.

3.2.3 Identifying effects on marginal drugs

I identify the effect of the EHB rules on marginally covered drugs by regressing the number of drugs with a given form of utilization management divided by the percentage of drugs covered in the class on the log percentage of drugs covered in the class, 7 which identifies the difference between the marginal and average covered drug (Batata, 2004; Gruber et al. 1999):

$$\frac{O_{cp}}{CovPct_{cp}} = \alpha_1 + \alpha_2 \ln CovPct_{cp} + \chi_c + \sigma_s + \varepsilon$$

I interpret the coefficient α2 as the difference in the marginal and average probability that a covered drug is subject to some form of utilization management. 8Because $CovPct_{cp}$ is endogenous, I instrument for $CovPct_{cp}$

using the log percentage of drugs a plan is required to cover in a class. Because of a small number of cases in which $CovPct_{cp}=0$, I replace $CovPct_{cp}$ with 0.1 if it equals 0. I convert the marginal average difference into an 'implied effect on the mean' by multiplying α2 by the coefficient on EHB_{cs} in Eq. 3 when the dependent variable is covered and define the 'implied inframarginal effect' as the difference between coefficient on EHB_{cs} in Eq. 3 when the dependent variable is the same as in Eq. 5 and the implied effect on the mean. I compute standard errors for these values using a block bootstrap with drug class for the blocks and 200 replications.

In the supporting information, I provide reduced-form class and drug-level estimates of Eq. 5. These models are scaled by the elasticity of the number of drugs covered in a class with respect to the number of drugs a plan is required to cover. To control for multiple comparisons, I report adjusted p-values using the Holm–Bonferroni procedure, which guarantees a family-wise error rate of 0.05 (Holm, 1979).

4 Effects of Essential Health Benefit Requirements

4.1 Formulary size

The EHB requirement was effective at increasing the number of drugs covered by marketplace plans, with no effect on Medicare Advantage plans (Table 3). On average, a 10% increase in the EHB requirement resulted in a 1.6% increase in the average formulary size for marketplace plans. The fact that the elasticity of formulary size with respect to the EHB requirement is less than 1 implies that plans did not simply match the EHB requirement but rather affected plans that covered less, but not more, than the required number of drugs.

Figure 2a indicates that there was a reduction in the number of plans that covered fewer than the required number of plans, with an eight percentage point increase in the number of plans covering exactly the mandated number of drugs, relative to plans in other states that required fewer drugs in the class. There is also a statistically and economically significant increase in the density of plans covering exactly one more drug than required. Figure 2b plots the difference in the distribution of plans, which indicates that the EHB rule decreased the share of plans covering fewer than the required number of drugs and, using the base sample, there was no significant difference in the share of plans that cover less than one drug more than the EHB rule, implying that the bulk of the effect of the EHB rule was to shift plans towards covering either the required number or one more than the required number of drugs. Restricting to the compliant plans, that is those plans that cover at least as many drugs as required, yields comparable, although typically slightly larger in magnitude, estimates. In results that are not shown, I find qualitatively similar results when I compare marketplace and Medicare Advantage plans (Figure S4 in the supporting information).

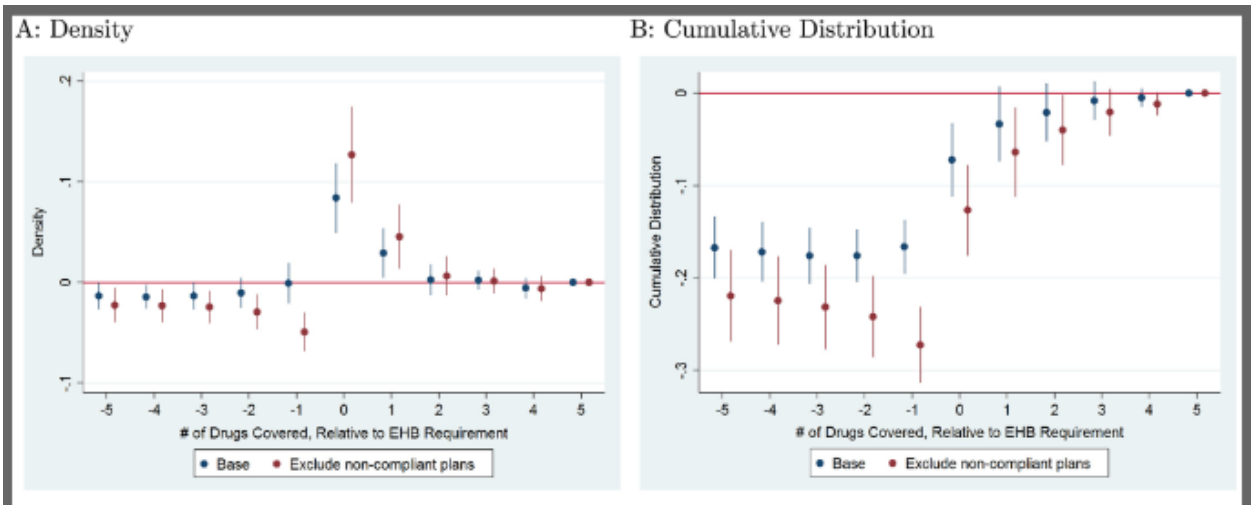


Figure 2 Formulary size, relative to EHB requirement. EHB, essential health benefit; MMIT, Managed Markets Insight and Technology

Source – Author's analysis of MMIT Data from November 2014.

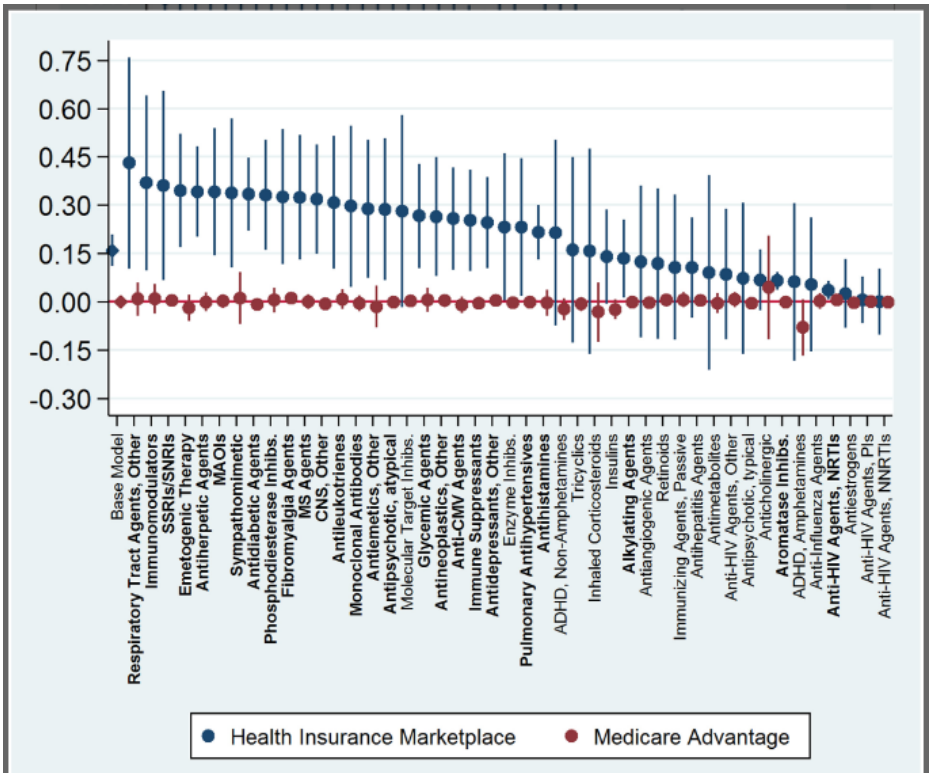
Notes – Points are α_r's from equations (2a) (panel A) and (2b) (panel B), see text for details. 95% confidence interval based on standard errors clustered on drug class.

Table 3. Essential health benefit requirements and number of drugs covered

	Marketplace plans				Medicare Advantage plans	
	(1)	(2)	(3)	(4)	(5)	(6)
Panel A: dependent variable is no. of drugs covered						
% drugs required	−1.160 (1.957)	−1.679*** (0.285)	1.121*** (0.239)		0.001 (0.026)	
No. of drugs required				0.219*** (0.022)		−0.003 (0.004)
No. of plan-class tupels	14,429	14,429	14,429	14,429	69,900	69,900
Mean	6.72	6.72	6.72	6.72	5.80	5.80
Panel B: dependent variable is % of drugs covered						
% drugs required	0.246*** (0.030)	0.223*** (0.018)	0.160*** (0.017)		0.001 (0.003)	
No. of drugs required				0.012*** (0.002)		−0.000 (0.000)
Drug class fixed effects	No	Yes	Yes	Yes	Yes	Yes
State fixed effects	No	No	Yes	Yes	Yes	Yes
No. of plan-class tuples	14,429	14,429	14,429	14,429	69,900	69,900
Mean	0.91	0.91	0.91	0.91	0.82	0.82

Source: Author's analysis of Managed Markets Insight and Technology data for November 2014.The dependent variable is the number of ingredients covered by a plan in a therapeutic class in panel A and the percentage of ingredients covered in a therapeutic class in panel B. Models for the Medicare Advantage sample exclude 'protected' drug classes. Standard errors clustered on drug class in parentheses.*p<0.1, **p<0.05, ***p<0.01.

The effect of the EHB rule on formulary size differed by drug class (Figure 3), with economically and statistically significant elasticities of formulary size for most drug classes, even after accounting for 47 comparisons using the Holm–Bonferroni correction. However, there are also several drug classes where there is no statistically significant effect of the EHB rule (although in some cases the elasticity remains economically significant). Five of these drug classes—molecular target inhibitors, three classes of drugs to treat HIV, and antihepatitis agents—are of particular interest because they contain costly drugs and, in many cases, users of these drugs will have high non-drug spending as well. The implication is that insurers would have covered large numbers of drugs in these formularies, regardless of the EHB rule, which contradicts the conventional wisdom that insurers use prescription drug coverage as a selection tool because then the EHB requirement should be binding in these costly drug categories.



Source—Author's analysis of MMIT Data from November 2014.
Notes—Diamonds correspond to point estimates in columns (3) and (4) of panel B of table III. Dots are class-specific estimates of association between the percentage of drugs a plan must cover in that therapeutic class and the percentage of drugs covered by the plan. Base model reports 95% confidence intervals that are robust to two way clustering by plan and therapeutic class. Confidence intervals for the remaining coefficients are at the Bonferroni corrected $1 - \frac{0.05}{47} \approx 99.9\%$ level based on standard errors clustered at the state level. Bolded labels indicate that the estimate is statistically significant at the Holm-Bonferroni adjusted 0.05 level.

Figure 3. Heterogeneous effects of formulary requirements on coverage. ADHD, attention deficit hyperactivity disorder; CMV, cytomegalovirus; CNS, central nervous system; MAOIs, monoamine oxidase inhibitors; MMIT, Managed Markets Insight and Technology; MS, multiple sclerosis; NNRTIs, non-nucleoside reverse-transcriptase inhibitors; NRTIs, nucleoside reverse-transcriptase inhibitors; PIs, protease inhibitors; SNRIs, serotonin–norepinephrine reuptake inhibitors; SSRIs, selective serotonin reuptake inhibito

Table 4. Effect of EHB on drug coverage and utilization management

			Utilization management				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Covered	Covered in any form	Any	Prior authorization	Step therapy	Prior authorization or step therapy	Quantity limits
Panel A: reduced-form estimates							
OLS	0.151***	0.159***	0.111***	0.084***	0.022**	0.094***	0.029**
	(0.015)	(0.015)	(0.016)	(0.014)	(0.009)	(0.015)	(0.014)
Probit	0.111***	0.0897***	0.104***	0.0638***	0.0321**	0.0747***	0.0233
	(0.0127)	(0.0130)	(0.0144)	(0.0116)	(0.0128)	(0.0123)	(0.0171)
Mean	0.813	0.900	0.299	0.192	0.039	0.220	0.154
Plan–drug–classes	107,757	107,757	107,757	107,757	107,757	107,757	107,757
Panel B: bunching at EHB threshold							
OLS							
Distance from EHB threshold (≥2 reference)							
<0			0.018	0.011	0.002	0.014	0.012
			(0.012)	(0.010)	(0.008)	(0.011)	(0.011)
0			0.041***	0.025***	0.005	0.031***	0.022**
			(0.009)	(0.007)	(0.005)	(0.008)	(0.009)
1			0.021*	0.019**	-0.000	0.018**	0.004
			(0.011)	(0.007)	(0.004)	(0.007)	(0.009)
Probit							
Distance from EHB threshold (≥2 reference)							
<0			0.019	0.011	0.004	0.013	0.013
			(0.013)	(0.013)	(0.011)	(0.012)	(0.014)
0			0.039***	0.029***	0.005	0.032***	0.016
			(0.009)	(0.008)	(0.005)	(0.009)	(0.011)
1			0.017	0.014	−0.001	0.014	−0.000
			(0.013)	(0.009)	(0.004)	(0.009)	(0.010)
Plan–drug–classes			107,757	107,757	107,757	107,757	107,757
Panel C: marginal drugs							
OLS			0.074***	0.051***	0.005*	0.056***	0.037***
			(0.011)	(0.012)	(0.003)	(0.011)	(0.010)
IV			0.223***	0.214***	0.047	0.215***	0.010
			(0.035)	(0.041)	(0.039)	(0.042)	(0.037)
Implied effect on the mean			0.034	0.032*	0.007	0.032*	0.002
			(0.021)	(0.018)	(0.012)	(0.019)	(0.013)
Implied inframarginal effect			0.077***	0.052***	0.015**	0.062***	0.027**
			(0.018)	(0.017)	(0.007)	(0.018)	(0.011)
F on instrument			31.7	31.7	31.7	31.7	31.7
Plan–classes			14,429	14,429	14,429	14,429	14,429

Source: Author's analysis of Managed Markets Insight and Technology data for November 2014.The dependent variable is indicated by column title. Coefficients in panel A are for the percentage of drugs in a class that a plan must cover; coefficients in panel B are for the difference between plans that either are at the EHB requirement or cover one drug more than required, relative to plans covering two or more drugs more than the EHB requirement; coefficients in panel C are for the log percentage of drugs covered in a class. Models in panels A and C include state and drug class fixed effects, while those in panel B include state and class by number of covered drug fixed effects. Instrument for the log percentage of drugs covered in panel C is the log percentage of drugs a plan is required to cover. Coefficients for probit models are average marginal effects. Estimates in panels A and B are at the plan–class–drug level, while panel C is at the plan–class level. Models in panel C are weighted by the number of drugs in each class. Analytic standard errors clustered on drug class in parentheses in all panels except for the implied effects, which use block bootstrap standard errors from 200 replications.EHB, essential health benefit; OLS, ordinary least squares.

*p<0.1, **p<0.05, ***p<0.01.

4.2 Coverage and utilization management

Plan-by-class-by-drug level models demonstrate that a 10 percentage point increase in the fraction of drugs in a class that a plan must cover increases the share of all eligible drugs that are covered by 1.1 to 1.5 percentage points and increased the probability that any form of a drug is covered by 0.9 to 1.6 percentage points (Table 4, panel A, columns 1 and 2). The EHB requirement also increased the probability that a drug is covered with a prior authorization requirement or step therapy and may increase the fraction of drugs subject to a quantity limit, although that estimate is sensitive to estimation method. The effect of the EHB requirement comes from both a change in the probability of coverage and a change in the probability of utilization management, conditional on coverage.

Relative to other plans covering the same number of drugs in a class, but in states with lower EHB thresholds, plans that are exactly at the EHB threshold are significantly more likely to apply some form of utilization management, particularly prior authorization and, depending on functional form, quantity limits, than plans covering the same number of drugs in a class in a state with a lower EHB requirement (Table 4, panel B). These results are consistent with a model in which utilization management substitutes for coverage. However, because these models are estimated conditional on the number of drugs a plan chose to cover, these relationships are not causal because plans are choosing how many drugs to cover in a given therapeutic class in light of the EHB rule. I interpret these results as indicating that plans that were forced to cover an additional drug by the EHB rule cover 4.1 percentage points more drugs with utilization management than plans that voluntarily covered the same number of drugs. Drawing on the theoretical model, one could hypothesize that plans that cover more drugs voluntarily are lower-cost (α in the model) plans that would also be less likely to use utilization management. As a result, the 4.1 percentage point increase is a combination of a selection effect (higher α plans being pushed to cover more drugs) and a response to the EHB rules. To a certain extent, the non-compliant plans (locating <0 drugs from the threshold) capture some of the selection effect, which would suggest that the selection effect, while real, does not explain the entire increase in the percentage of drugs subject to utilization management exactly at the EHB threshold.

Plans that cover more drugs are also more likely to use utilization management (Table 4, panel C), but when plans are exogenously forced to cover more drugs, as in the instrumental variable (IV) estimates in panel C, I find a significantly stronger relationship between the share of drugs in a class that are covered and the share of drugs that are subject to utilization management, principally prior authorization. The 'implied effect on the mean' and the 'implied inframarginal effect', which rescale the IV estimates to reflect how much of the average effect of the EHB rule is explained by marginal or inframarginal drugs, indicate that, while marginal drugs are important, the majority of the effect on the average rate of utilization management arises from changes affecting inframarginal drugs. The implication is that firms are covering more drugs; on the margin, these newly covered drugs are being covered less generously than inframarginal drugs, but they are also making inframarginal coverage less generous.

In the supporting information, I present class-specific and drug-specific versions of Eq. 5. The class-specific results (Tables S2 and S3) present the estimated elasticity of formulary size with respect to the EHB requirement, 6 which scales the reduced-form coefficients. The results indicate that across 10 different drug classes, the marginally covered drug is significantly more likely to be subject to utilization management, typically prior authorization, than the average drug in that class. I find relatively little evidence, however, that the marginal drug in most classes is assigned to the

highest tier used in that drug class. Table S4 presents reduced-form results for individual drugs, which indicates that some drugs are more likely to be covered and to be subject to utilization management when the EHB requirement increases.

4.3 Tier assignment

The EHB requirement also affects tier assignment, with a more stringent requirement associated with an increased likelihood that a drug is covered in a relatively high formulary tier for the majority of plans (Table 5). Unlike the results for coverage and utilization management in panels A and C of Table 4, it is not possible to provide a causal interpretation to the tier assignment results because plans choose the number of tiers to employ in a formulary. Using class and plan fixed effects, 7 I find that the EHB rule is associated with increases in drug coverage for two-tier, four-tier, and five-tier plans, which is consistent with the estimates in Table 4. With the exception of one-tier and three-tier plans, my results also demonstrate that more stringent EHB rules are associated with more drugs being assigned to relatively high formulary tiers, which is consistent with a reduction in unregulated quality due to the EHB requirement.

Table 5. Effect of EHB on tier assignment

	(1)	(2)	(3)	(4)	(5)	(6)
	Not covered	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5 or 6
One-tier plans (N=15 plans)						
% drugs required	0.037*	−0.037*				
	(0.017)	(0.017)				
	{0.396}	{0.604}				
Two-tier plans (N=16 plans)						
% drugs required	−0.090**	−0.076**	0.166***			
	(0.034)	(0.027)	(0.037)			
	{0.400}	{0.287}	{0.313}			
Three-tier plans (N=48 plans)						
% drugs required	−0.034	0.040	−0.019	0.013		
	(0.028)	(0.021)	(0.040)	(0.054)		
	{0.150}	{0.262}	{0.217}	{0.371}		
Four-tier plans (N=153 plans)						
% drugs required	−0.080***	0.023	−0.004	0.075***	−0.013	
	(0.011)	(0.012)	(0.021)	(0.016)	(0.013)	
	{0.166}	{0.251}	{0.136}	{0.243}	{0.205}	
Five-tier and six-tier plans (N=75 plans)						
% drugs required	−0.051*	0.004	0.002	−0.082***	0.028	0.100***
	(0.024)	(0.017)	(0.025)	(0.022)	(0.018)	(0.016)
	{0.121}	{0.144}	{0.119}	{0.160}	{0.236}	{0.220}

Source: Authors' analysis of Managed Markets Insight and Technology Data for November 2014.Each row reports the marginal effect of an increase in the percentage of drugs in a class a plan must cover from a multinomial logit model. The dependent variable is tier assignment (including not covered as a tier). All models include the percentage of drugs a plan must cover; additional fixed effects are indicated by the row label. Standard errors in parentheses are clustered on drug class; means are reported in curly brackets.
*p<0.05, **p<0.01, ***p<0.001.

Unfortunately, I am unable to estimate specifications that test if plans that locate at the EHB requirement are more likely to assign drugs to a higher tier than plans that locate far from the EHB requirement. Models in which I attempt to estimate these parameters consistently fail to converge.

4.4 Robustness and specification checks

Table S1 presents several robustness checks. Panel A restricts the sample to drug classes where I observe at least as many drugs as the most stringent EHB requirement (that is, I omit the drug–class pairs in the antihepatitis agents and sympathomimetic respiratory agent classes based on Table 1). My results are essentially unchanged between panel A and my main results in Table 4. Panel B checks if states with more plans, which also tend to be larger, and classes with more drugs are driving my results by reweighting the data so that each drug class and state receive equal weight (mechanically, I first weight each drug class by the inverse of the number of drugs in a class and then weight states by the inverse of the number of plans in the state). Again, my results are consistent with my main results, indicating that neither larger states nor larger drug classes are driving my results. Panel C allows for states to differ in the share of drugs covered in a category (I cannot estimate a model with state-by-class fixed effects because the EHB rule is defined at the state-by-class level), but my results are unaffected. Panels E and F demonstrate that my results are robust to using either the log number or the number of drugs required to measure the EHB requirement.

Panel D considers a different model where insurers design formularies that span multiple states; as a result, the formulary must satisfy several different EHB rules. Therefore, I estimated a series of model where I used the most stringent requirement for a given drug class among the states in which a given formulary was offered. These results differ from my main results in that I find weaker evidence of a coverage effect and my estimates of effects on utility management are marginally significant and substantially smaller for the probability of having any form of utility management and one of prior authorization or step therapy; none of the estimates for the remaining forms of utilization management were statistically significant, even at the 10% level. Unlike my main results, the EHB rule in these estimates is endogenous because it reflects an insurer's decision about which states to cover with a single formulary.

4.5 Falsification tests

There are two main threats to the validity of my results. First, the EHB rule may reflect consumer preferences, in which case the correlation between the EHB requirement and coverage would reflect consumer preferences rather than the effect of the rule on firm behavior. If consumer preferences for drugs are similar for people over and under 65 years of age, then one would expect formularies in Medicare Advantage programs, which are not subject to the EHB rule, to be similar to the formularies for marketplace plans, with a similar effect of the EHB rule on Medicare Advantage formularies. I am able to reject this hypothesis based on two sets of facts. First, columns 5 and 6 of Table 3 indicate that the EHB rule did not affect the number of drugs covered in a class for Medicare Advantage plans, which is inconsistent with the hypothesis that the EHB rule reflects consumer preferences. Second, panel A of Table 6 reports results from estimates of Eq. 3 using data from Medicare Advantage plans and indicate that the EHB rule had no affect on coverage or utilization management decisions of Medicare Advantage plans.

Table 6. Falsification Tests

	Utilization Management					
	(1)	(2)	(3)	(4)	(5)	(6)
	Covered	Any	Prior Auth.	Step Therapy	Prior Auth./Step Therapy	Quantity Limits
A: Medicare Advantage Plans						
% Drugs Required	0.000627	-0.00290	-0.00625	-0.00564	-0.00700	-0.00141
	(0.00178)	(0.00476)	(0.00506)	(0.00668)	(0.00588)	(0.00450)
# Plan-Drug-Class Tuples	573180	573180	573180	511668	573180	570384
Mean	0.810	0.378	0.253	0.107	0.273	0.217
B: New vs. Old Drugs						
% Drugs Required	0.0381	0.0707	0.0601	0.0317	0.0578	-0.0229
	(0.0558)	(0.0628)	(0.0564)	(0.0193)	(0.0586)	(0.0343)
X Existing Drug	0.0948	0.0513	0.0211	0.0174	0.0261	0.0513
	(0.0642)	(0.0792)	(0.0696)	(0.0234)	(0.0741)	(0.0402)
# Plan-Drug-Class Tuples	63549	63549	63549	63135	63549	62928
Mean	0.778	0.373	0.273	0.048	0.306	0.176

Source—Author's analysis of MMIT Data for November 2014.

Notes—Dependent variable is an indicator that a given drug is covered or has the indicated utilization management technique. Sample in Panel A excludes "Protected urn:x-wiley:hec:media:hec3491:hec3491-math-0010 drug classes in the Medicare Part D program, while sample in panel B is restricted to branded drugs in drug classes that contain at least one new product. All models include state and drug class fixed effects. Point estimates are marginal effects from probit regressions; standard errors, calculated via the delta method, in parentheses clustered on drug class (panel A) or drug (panel B).

$*p<0.1, **p<0.05, ***p<0.01$

The second threat is if the EHB rule affected plan entry—specifically if less generous plans were less likely to enter states with more stringent EHB requirement. Assuming that less generous plans are also less likely to cover new drugs, I test this hypothesis by studying coverage of drugs that were approved after November 2012, which would not count for purposes of meeting the EHB requirement. Because there were only 28 new drugs in my sample (33 unique drug-by-class pairs), which were in 17 classes, I restricted the sample to drugs in classes with any new drugs and clustered standard errors at the drug, rather than drug class, level. Panel B of Table 6 indicates that the EHB rule did not affect coverage of new drugs, nor were these drugs more likely to be subject to utilization management.

5 Conclusion

In this paper, I studied the effect of the ACA's EHB rule governing the design of prescription drug formularies. Using variation within states and drug classes and comparing marketplace to Medicare Advantage plans that offer prescription drug coverage, I demonstrated that the EHB rule increases the number of drugs a plan covers but also increases the share of drugs that are covered with some form of utilization management and is correlated with higher-tier assignments, both of which reduce access to prescription drugs. The increase in drug coverage and utilization management was concentrated at the EHB requirement, and the size of the change in utilization management is too large to have been explained by changes to the marginal covered drugs, indicating that the EHB rule also affected inframarginal drugs.

These results complement previous work on the generosity of prescription drug coverage in health insurance marketplace plans (Buttorff et al. 2015), which found evidence of significant heterogeneity in the generosity of drug coverage across metal tiers. My results demonstrate that

there is also significant heterogeneity in formulary placement. There are some early indications that marketplace enrollees who enrolled early are filling more prescriptions than those on employer coverage, indicating they may be sicker (Donohue et al. 2015). However, the study found that on the whole, marketplace enrollees were spending less than those on employer coverage. It is not yet known to what extent this is due to differences in health status or the formulary management techniques discussed in this paper.

My results have ambiguous implications for social welfare. On the one hand, increasing the number of drugs covered on a formulary increases social welfare, all else being equal. However, there are two offsetting effects that I cannot easily account for. First, the broader breadth of coverage goes hand-in-hand with higher insurance premiums, and consumers may not value this additional coverage at the incremental premium cost. Second, the increase in formulary breadth was also associated with declines in the generosity with which drugs were covered. As a result, the increase in welfare from access to a greater number of drugs may be offset by consumers undervaluing the incremental coverage and effects on coverage of inframarginal drugs.

My results also imply that regulators should consider how regulated entities will respond to rules such as the EHB requirement. In this case, it is not clear that a higher, or lower, EHB requirement would increase social welfare because of how firms responded to the policy.

Future work should assess the consequences of these EHB rules using data on plan choices and utilization of both prescription drug and other health insurance benefits and should assess how insurers implement utilization management policies. These results would provide insight into the social welfare implications of the EHB requirement.

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