

THE IMPACT OF A THREE-TIER FORMULARY ON DEMAND RESPONSE FOR PRESCRIPTION DRUGS

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A large number of health plans and employers have adopted three-tier prescription drug formularies in an effort to control rising prescription drug costs. We assessed the behavioral response to three-tier adoption by estimating econometric models of the probability of selecting drugs assigned to the third tier with the highest co-payment requirement and changes in expected out-of-pocket (OOP) spending. We concluded that implementation of the three-tier formulary resulted in some shifting of costs from the plan to enrollees and some bargaining power gained for the payer, with plan savings from manufacturer rebates a likely result.

1. INTRODUCTION

In recent years, spending on prescription drugs has grown rapidly, causing new policy and management attention to be focused on that part of health care spending (Berndt, 2003). In response to drug cost increases,

We are grateful for funding from the Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization Program, the National Institute for Mental Health (1 K01 MH66109), the Agency for HealthCare Research and Quality (5 P01 HS10803-2), and the Alfred P. Sloan Foundation. The authors are grateful to Patricia Deverka, Arnold Epstein, Robert Epstein, Will Manning, Tom McGuire, Joseph Newhouse, and three anonymous reviewers for many constructive suggestions. Boris Fainstein and Kathryn Trainor provided expert programming.

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Journal of Economics & Management Strategy, Volume 14, Number 3, Fall 2005, 729–753

many employers, health plans, and pharmacy benefit managers (PBMs) (i.e., vendors that specialize in managing pharmacy benefits), have adopted various management techniques, including incentive formularies. A formulary is a list of drugs categorized by the therapeutic uses of specific agents. Under an incentive formulary, a set of economic incentives for consumers of drugs accompanies the drug list. Incentive formularies have particular policy significance because they are likely to be used as a means of controlling benefit costs under the new Medicare Part D drug benefit to be implemented in 2006.

The most common type of incentive formulary is the three-tier formulary. Approximately, two-thirds of privately insured workers and their dependents had prescription drug coverage that used three-tier co-payment structures in 2004 (Kaiser Family Foundation, 2004). Three-tier formularies encourage consumers to choose drugs that are less expensive for the plan. Consumers using generic drugs—the first tier—pay the lowest OOP costs (e.g., \$10) for a prescription; users of preferred brand-name drugs—the second tier—pay a higher OOP price (e.g., \$20) and users of non preferred brand-name drugs—the third tier—pay the highest level of cost-sharing (e.g., \$35). In contrast to a closed formulary (an incentive formulary that provides no coverage for drugs not preferred by the plan), virtually all drugs are covered under a three-tier formulary. However, the OOP prices are such that consumers are encouraged to use the drugs preferred by the health plan. The ability to influence demand through the use of financial incentives to consumers bestows some bargaining power on the PBM to negotiate favorable prices with prescription-drug manufacturers (Frank, 2001).

In the analysis reported below, we make use of a natural experiment in the implementation of a three-tier co-payment structure to study demand response for drugs in three commonly used therapeutic categories. We examine the extent to which patients change to a medication of a lower tier in response to a relative out-of-pocket (OOP) price change for selected drugs in each therapeutic class. We also examine changes in expected OOP spending among users of the medications.

The paper is organized into five additional sections: background on three-tier formularies, a summary of the relevant literature, a description of our empirical approach, a summary of results, and discussion of those results.

2. BACKGROUND

Pharmaceutical manufacturers have long been thought to compete by trying to differentiate their products from those of rival producers (Scherer, 1993; Task Force on Prescription Drugs, 1968).

Prescription-drug products within a therapeutic class are often similar in terms of their active ingredients but can differ in terms of side effects, toxicity, range of therapeutic indications, and mode of administration (e.g., once a day vs. two to three times a day). The industry competes actively to highlight differences between products in the minds of doctors and consumers alike. In 2000, branded drug manufacturers devoted 14% of sales revenues to promotion of their products, of which about 15% was for direct-to-consumer advertising (Rosenthal et al., 2002). Successful product differentiation serves to decrease the price elasticity of demand and reduce price competition in the market. As a result, equilibrium market prices in more highly differentiated markets are typically higher (Tirole, 1988; Viscusi et al., 2000).

Incentive formularies can help offset the differentiation strategies of manufacturers. A three-tier co-payment structure introduces price as a basis for consumer choice instead of allowing competition within a therapeutic drug class to be based primarily on attributes of the products (Ellison et al., 1997). By creating price differentials between products that may have similar mechanisms of action and thus be substitutes in the production of health, PBMs through their formularies may increase consumers' ability to respond to price and thereby enhance the PBM's own bargaining power with manufacturers.

In 2004, when three-tier co-payment structures had become the most common drug benefit design, the average co-payment for first tier (generic) drugs was \$10, the second tier (preferred brand) was \$21, and the average third tier co-payment was \$33 (Kaiser and Hret, 2004). Thus, when a generic product is available a consumer commonly faces a three-fold price differential between the branded drug and generic drug containing the same active ingredient, which is typically close to a perfect substitute in production in most cases. In the empirical work below, we will use the change from a two-tier to a three-tier co-payment structure to estimate consumer demand responses for drugs within a therapeutic class.

3. LITERATURE

There is a fairly extensive body of literature focused on the effect of standard co-payments on use of prescription drugs. A consistent finding is that the aggregate demand curve for prescription drugs slopes downward or that a higher OOP price faced by consumers results in decreased use and spending on prescription drugs (e.g., Brian and Gibbens, 1974; Harris et al., 1990; Hillman et al., 1999; Leibowitz et al., 1985; Manning et al., 1987; Reeder and Nelson, 1985; Smith and Garner, 1974; Soumerai et al., 1987; Tamblyn et al., 2001).

There are several studies that examine the effects of restrictive formularies used by hospitals or state Medicaid programs, which use minimal or no co-payments for prescription drugs (e.g., Dranove, 1989; Dranove et al., 1993; Moore and Newman, 1993; Sloan et al., 1993). These studies found that the formularies were associated with lower drug spending but not lower overall health care spending. In both cases, there were virtually no demand-side incentives for consumers.

A key goal of three-tier formulary adoption is to provide financial incentives that will redirect demand for specific products within a therapeutic class. Several studies examine the impact of implementing a three-tier formulary on utilization and spending patterns (e.g., Goldman et al., 2004; Huskamp et al., 2003; Joyce et al., 2002; Kamal-Bahl and Briesacher, 2004; Motheral and Fairman, 2001; Rector et al., 2003), although most look at three-tier effects on aggregate pharmacy spending or on overall use for a particular drug class (i.e., not by tier). For example, Motheral and Fairman found that one preferred provider organization's (PPO) 1998 switch from a two-tier formulary to a three-tier formulary was associated with a decrease in overall pharmaceutical utilization and spending and a shifting of costs from the plan to the enrollee. Joyce et al. (2002) and Goldman et al. (2004) simulated the impact of pharmacy benefit changes using data on a large cross-section of employers with different pharmacy benefit designs. Joyce et al. predicted that moving from a two-tier to a three-tier formulary would result in a small reduction in total pharmacy spending. Goldman et al. (2004) found that a doubling of co-payments was associated with reductions in use of eight classes, with the largest decreases occurring for non steroidal anti-inflammatory drugs and antihistamines (both often used intermittently to treat symptoms). Kamal-Bahl and Briesacher (2004) used Medstat data on large private employers to examine the impact of tiered formularies on use and spending for medications used to treat hypertension. They found raising co-payments within two-tier plans (particularly those with larger co-pay differentials between generic and brand-name drugs) was associated with a lower likelihood of using the more expensive ACE inhibitors and ARBs (as opposed to less expensive antihypertensives) than raising co-payments within single tier plans.

Rector et al. (2003) and Huskamp et al. (2003) are the only studies that looked at medication switching within a drug class in response to three-tier formulary adoption. Rector et al. (2003) estimate regression models of the change in the probability that a claim was for a preferred brand in tier 2 as opposed to a nonpreferred brand in tier 3. They found that tiered formulary adoption was associated with a higher probability of using tier 2 preferred brands relative to tier 3 nonpreferred brands.

They did not look at person level utilization to assess the proportion of previous users who switched medications. In a descriptive analysis, Huskamp et al. (2003) found that pre-period tier 3 users were more likely to switch to a lower-tier medication after three-tier adoption relative to a comparison group of employers that did not adopt a three-tier formulary, but this analysis did not control for characteristics of the population or general trends in prescription drug use over time. These studies did not attempt to estimate changes in expected OOP spending resulting from three-tier adoption.

Other studies have found that parties other than consumers, such as physicians or pharmacists, respond to incentives to select particular medications when such incentives are used (e.g., Domino and Salkever, 2002). In the intervention that we study, no such incentives were involved. In addition, several studies have documented that traditionally, physicians are not responsive to differences in OOP price faced by patients (Schweitzer, 1997).

4. EMPIRICAL APPROACH

To study demand response for drugs within a therapeutic class, we made use of a natural experiment in the implementation of a three-tier formulary by a large employer. This natural experiment involved a pure relative price change. Consumers who were using drugs assigned to tier 3 in the pre-period had an incentive to switch to a lower-tier drug with a lower co-payment.

4.1 NATURAL EXPERIMENT

The employer we study contracts with a large managed care organization (MCO) to provide health insurance to its employees and dependents. The MCO, in turn, contracts with a large pharmacy benefits manager (PBM) to manage the pharmacy benefit for its enrollees.

In April 2000, the employer made a change to its pharmacy benefit design. Previously, the employer used a two-tier formulary that required a \$6 co-payment for all generic drugs and a \$12 co-payment for all brand-name drugs. The employer moved to a three-tier formulary that required a \$6 co-payment for generic drugs, a \$12 co-payment for brand-name drugs preferred by the health plan, and a \$24 co-payment for brand-name drugs not preferred by the plan. The list of drugs available for coverage by the employer did not change, just the co-payments required for specific drugs. The assignment of specific drugs to different tiers of the new three-tier formulary is found in Table I. Thus, although the OOP

TABLE I.
DRUGS AVAILABLE IN EACH TIER

Drug Class	Tier 1	Tier 2	Tier 3
Ace Inhibitors	Captopril enalapril maleate	Accupril Capoten Lotensin Prinivil	Aceon Altace Mavik Monopril Univasc Vasotec Zestril
PPIs	None	Nexium (as of 11/01) Prilosec	Aciphex Nexium (before 11/01) Prevacid Protonix
Statins	lovastatin	Baycol (after 10/00) Lipitor Pravachol Zocor	Baycol (before 10/00) Lescol Mevacor

price to consumers for generic drugs and preferred brand-name drugs did not change, the price for nonpreferred brand drugs doubled relative to competing brands. The OOP price differential gave consumers using a tier 3 drug in the pre-period an incentive to switch to another drug in the class.

Our primary outcome of interest is demand response measured by whether three-tier formulary adoption caused patients using a tier 3 drug in the pre-period to change to a lower-tier drug in the post-period. We assess the tier changes in two ways. First, we used a difference-in-differences approach to estimate any change in the probability of selecting a tier 3 medication so as to control for general trends in prescription drug utilization and spending over time. We compared the probability of tier 3 use changes for the employer's enrollees to a comparison group of enrollees covered by the same MCO who had a two-tier formulary and did not experience a benefit change during the study period. The difference-in-differences approach explicitly recognizes potential non-equivalence of comparison groups. Nevertheless, we tried to select comparison groups who were as similar as possible to the intervention group to ensure that baseline trends for the two groups were similar, the key assumption in a difference-in-differences model. The comparison group was selected from a pool of over 1,000 other employer clients of the MCO and identified using the SAS JMP clustering algorithm. This algorithm is similar to a propensity score matching process in that an

exact match is not required on each variable (D'Agostino, 1998). The comparison group was selected based on similarity to the employer group across several characteristics: medical benefit type, drug co-payment levels for the first two tiers, age, gender, and geographic distribution of the enrollee population.

The second approach recognizes that three-tier adoption may not have an immediate impact and the impact may not be consistent over time. Therefore, a simple difference-in-differences model may not fully capture the effects of three-tier formulary adoption. As a result, we estimate a set of models that allow the intervention to have a different impact at different points in time. Thus, we re-estimate the multinomial logit model allowing for separate time-intervention interactions in each quarter.

As a result of three-tier formulary adoption, the plan has the opportunity to collect rebates from manufacturers, which will lower plan expenditures. However, rebates are not observed in claims data and are considered proprietary information so we observe only part of the net price of each prescription. As a secondary outcome of demand response, we also estimate the impact of three-tier formulary adoption on expected OOP spending to measure changes in consumer risk-bearing.

4.2 DATA

We used eligibility data and prescription-drug claims for a 3-year period beginning January 1, 1999, approximately one year before the changes were implemented, and ending December 31, 2001, approximately 2 years after implementation. We focused our analysis on the 11,653 intervention-group members and 27,051 comparison-group members who were under age 65 and enrolled continuously during this 3-year period. Prescription claims were adjusted for days of medication supplied. For example, in the case of an enrollee who filled a 90-day prescription with a total cost of \$90 on January 1, we considered the individual to have used the drug for 3 months (January, February, and March) with total expenditures of \$30 for each of the 3 months. The 33-month study period for the regression analyses begins on April 1, 1999 instead of January 1, 1999 (the first fill date in our data) to address the censoring associated with mail order use. The unit of observation is the person-month.

We analyzed three classes of commonly used medications: 1) angiotensin-converting enzyme (ACE) inhibitors, used to treat hypertension, diabetic nephropathy and congestive heart failure; 2) proton-pump inhibitors (PPIs), used both acutely and chronically to treat

acid reflux and other gastrointestinal conditions; and 3) HMG Co-A reductase inhibitors, or statins, used to lower serum cholesterol.

4.3 EMPIRICAL IMPLEMENTATION

For each of the three drug classes, we estimate multinomial logit models of the probability of selecting a tier 3 drug using two model specifications. The first model is a difference-in-differences model where the experimental and control groups share a common quadratic time trend in utilization. The second specification allows the experimental and control group to have different time trends and for the impact of the intervention to have different effects over time. To estimate the effect on expected OOP spending, we used a two-part model. In the first part, we estimated a logit model of the probability of using a drug in the class and in the second part, a robust regression model of the natural logarithm of total OOP spending for the drug class (i.e., all three tiers) conditional on any drug use in the class.

The unit of analysis was the person-month for all models estimated. The key right-hand-side variables were time variables, a dummy variable indicating whether the individual was a member of the intervention group, and the interaction of time variables and the intervention group indicator. In addition, all models included a dummy variable for gender, dummy variables indicating whether the enrollee is the employee or spouse (dependent in the omitted category), and four dummy variables for age categories. The age categories were: less than 40, 41–45, 46–50, 51–55, and 56–60 (the omitted category is 60–64). We discuss below each type of model in detail.

Tier Choice Models

Model 1: Multinomial logit model with overall effect The multinomial logit model specified four choices: (1) no use; (2) tier 1 generic drug use; (3) tier 2 brand-name drug use; and (4) tier 3 nonpreferred brand-name drug use. For this model, the time variables were a counter variable for month and the square of this variable. We also included a dummy variable indicating whether the month in question occurred after the formulary changes were implemented. Because of the quasi-experimental design, the coefficients on the interaction of ordinary least squares (OLS) models were the difference-in-differences estimates. However, as noted by Ai and Norton (2003), in nonlinear models such as the multinomial logit in Approach I, the coefficient on the interaction variable does not necessarily indicate the magnitude of the intervention's effect. To address this issue, we used the multinomial logit estimates to construct estimates of the probabilities of tier 3 use before and after the intervention for the

intervention and comparison groups. We then calculated the difference-in-differences estimates directly using these probabilities.

Model 2: Multinomial logit model with different time effect To understand when an effect of three-tier adoption occurs and whether the impact continues over time, we re-estimate the first model by replacing the month and month-squared variables and the difference-in-differences interactions with 10 time-period dummies, each representing a 3-month interval, and the interaction of the intervention group indicator with the quarter dummies.

Expected OOP Spending Change Models We estimated the changes in total drug class OOP spending (not just tier 3 spending) due to the formulary changes. The detailed models are:

$$M = E(OOPSpending) = E(\hat{p} * \exp(X_{class}\hat{\beta}_2) * \hat{\kappa})$$

where

$\hat{p} = \Phi_2(X\hat{\beta}_1)$ = estimated probability of using any drug in the drug class (Part 1 in Model 2),

$\exp(X_{class}\hat{\beta}_2) * \hat{\kappa}$ = estimated OOP drug class spending conditional on any drug use in the class, where smearing factor $\hat{\kappa} = \frac{1}{n} * \sum_{i=1}^n \exp(\varepsilon_i^\wedge)$, was heteroskedastically applied for subsamples indicated by POST and INTVN (Part 2 in Model 2),

$\hat{\beta}_1$ and $\hat{\beta}_2$ are the parameter vectors estimated in each part of the model,

X = a vector of explanatory variables.

ΔM is the expected difference-in-differences effect on OOP spending. To calculate each component of ΔM , we need to compute probability of use, expected conditional spending, and a smearing factor with heteroskedastic re-transformation for each of four subsamples: post-period intervention group, preperiod intervention group, postperiod comparison group, and preperiod comparison group.

Part 1 of the two-part model is a logit model estimating the probability of drug- class use as compared with no use. The predicted difference-in-differences probability was computed using the same method as in Model 1. The second part of the model is an OLS regression of OOP spending for each class conditional on drug-class use. To obtain the difference-in-differences estimates of overall OOP spending changes due to the changes in formulary structure, we computed the conditional spending and smear factors in this direct derivation. Thus, for example, $M_{11} = E(\hat{p}_{11} * \exp(X_{class}\hat{\beta}_{2_{11}}) * \hat{\kappa}_{11})$, where the subscript 11 represents the post-period intervention group category, $\exp(X_{class}\hat{\beta}_{2_{11}})$ is expected conditional spending predicted for the postintervention group, and $\hat{\kappa}_{11}$ is

the smearing factor with heteroskedastic retransformation for the same group.

In the OLS models of spending conditional on use, we first used a log transformation of expenditures to alleviate the highly skewed dependent variable. Following the algorithm specified by Manning and Mullahy (2001), we first estimated an OLS model for $\ln(y) = x\beta + \varepsilon$ and calculated the log-scale residuals (Manning and Mullahy, 2001). The log-scale OLS residuals indicate heteroskedasticity for predicted log spending, the pre-post intervention dummy variable, the intervention group indicator, and all other covariates except age between 40–45 and 50–55. Due to heteroskedasticity, the OLS method without retransformation will cause biased estimation. The normality test for log-scale OLS residual notes leptokurtotic residuals (kurtosis = 4.8 and skewness = 0.64), which indicates the distribution of the log-scale residual is not highly skewed but heavily tailed. Because the leptokurtotic residuals will result in a substantial inefficiency loss from using GLM methods, we selected a robust OLS model with cluster correction and heteroskedastic retransformation.

We discovered the log-scale OLS residual is heteroskedastic to the predicted dependent variable, so instead of retransforming for each explanatory variable, we chose to run a nonparametric smearing estimate. First, we computed the exponential of the log-scale residual (call it “smr”) after estimating OLS for $\ln(y) = x\beta + \varepsilon$, and then we ran a robust OLS regression with cluster correction of smr on all the right-hand variables as in the original models. Then we computed the predicted smr values for each subsample: precomparison, postcomparison, preintervention, and postintervention, which are considered as smearing factors for each subsample. (Duan et al., 1983; Manning, 1998).

Because smearing with heteroskedastic retransformation corrects potential bias caused by the OLS method for the heavy-tailed log-scale residual but does not address the imprecision problem, we bootstrapped (1,000 repetitions) to assess the magnitude of the problem. We assessed the biases and revised confidence intervals for 1,000 repetitions. Because the biases of coefficients were very small in comparison to the observed values and were too small to affect the confidence interval, we used robust OLS estimation for log-transformed expenditures.

5. RESULTS

Descriptive statistics on the study population are found in Table II. There are small differences in the demographic characteristics studied between the intervention and comparison groups.

TABLE II.
DESCRIPTIVE STATISTICS FOR THE STUDY POPULATION

Characteristic	Three-tier Group	Comparison Group	P-value
Age as of 12/31/01	37.51 (17.59)	34.82 (17.14)	<0.05
% Male	0.47	0.47	NS
Employee Status			
% Employee	52.1%	47.5%	<0.05
% Spouse	20.2%	22.2%	<0.05
% Dependent	28.0%	31.0%	<0.05
Mean Total Spending Across Users			
Ace Inhibitors	30.00 (16.64)	29.20 (18.17)	<0.05
PPIs	119.06 (48.68)	116.87 (43.99)	<0.05
Statins	76.52 (34.44)	76.29 (35.67)	0.52
Monthly Probability of Use			
ACE inhibitors	2.3%	2.2%	NS
PPIs	2.0%	2.0%	NS
Statins	3.0%	2.9%	NS
Total N	11,653	27,051	—

Note: Standard deviations appear in parentheses.

Tables III and IV present results from the Model 1 multinomial logit model estimating the probability of tier 3 use. The reference category is no drug use in each class. For the class of PPIs, there are no results for the probability of selecting tier 1 because there were no generic options in this class during the study period. Because only three enrollees used a generic statin drug, we do not present results for the probability of selecting a tier 1 statin. For all three classes, we estimate a statistically significant decrease in the likelihood of using a tier 3 drug after formulary implementation for the intervention group relative to the comparison group.

As noted above, the expected difference-in-differences effect for the probability of tier 3 use was constructed using fitted probabilities resulting from the multinomial logit model. The unit of observation was the person-month. To assess the magnitude of the response we present results on the ACE inhibitor class as an example. Before the formulary changes, the sample average of the predicted probability of using a tier 3 ACE inhibitor for the intervention group was 0.87%. After the changes, only 0.68% used tier 3 ACE drugs on average. In the comparison group,

TABLE III.
MULTINOMIAL LOGIT MODEL ESTIMATING THE
PROBABILITY OF USING A TIER 3 DRUG (MODEL I WITH
OVERALL EFFECT)

	ACE			PPI		STATIN	
	TIER 1	TIER 2	TIER 3	TIER 2	TIER 3	TIER 2	TIER 3
POST	0.037 (0.28)	-0.012 (0.35)	-0.061 (1.34)	0.010 (0.29)	0.003 (0.05)	-0.061 (2.45)*	0.355 (2.77)**
INTVN	0.409 (1.33)	0.083 (0.83)	0.284 (2.84)**	-0.035 (0.39)	0.042 (0.31)	0.205 (3.21)**	0.744 (3.28)**
POST*INTVN	-0.179 (0.67)	0.219 (3.28)**	-0.184 (1.99)*	0.059 (1.00)	-0.273 (2.43)*	0.066 (1.60)	-0.885 (4.14)**
AGE<=40	-2.994 (8.02)**	-2.295 (14.44)**	-2.843 (13.82)**	-1.416 (10.56)**	-1.229 (7.33)**	-3.378 (26.06)**	-3.659 (6.60)**
AGE 41-45	-1.319 (4.82)**	-1.470 (9.39)**	-1.666 (9.68)**	-0.961 (6.92)**	-0.712 (4.10)**	-2.071 (20.33)**	-3.017 (5.50)**
AGE 46-50	-1.451 (5.49)**	-0.771 (5.87)**	-1.353 (8.52)**	-0.523 (3.94)**	-0.489 (2.95)**	-1.330 (15.96)**	-1.687 (4.99)**
AGE 51-55	-0.642 (2.77)**	-0.419 (3.33)**	-0.723 (5.15)**	-0.061 (0.48)	-0.142 (0.86)	-0.714 (9.23)**	-1.487 (4.73)**
AGE 56-60	0.051 (0.23)	-0.054 (0.44)	-0.422 (3.08)**	0.032 (0.24)	0.001 (0.01)	-0.260 (3.41)**	-0.799 (2.75)**
MALE	0.501 (3.35)**	0.335 (4.42)**	0.489 (5.32)**	-0.165 (2.41)*	-0.203 (2.31)*	0.584 (11.36)**	0.231 (1.04)
EMPLOYEE	3.323 (4.09)**	3.685 (8.07)**	4.095 (5.84)**	2.311 (11.01)**	2.091 (8.57)**	3.616 (9.01)**	3.831 (3.42)**
SPOUSE	3.211 (3.92)**	3.572 (7.74)**	4.035 (5.71)**	2.113 (9.68)**	1.944 (7.61)**	3.440 (8.53)**	3.804 (3.26)**
MONTH	0.125 (4.73)**	0.036 (6.73)**	-0.003 (0.44)	0.028 (5.07)**	0.039 (4.30)**	0.039 (10.16)**	0.004 (0.25)
MONTHSQ	-0.001 (2.81)**	-0.000 (3.52)**	-0.000 (2.79)**	-0.000 (1.95)	0.000 (0.38)	-0.000 (4.00)**	-0.001 (1.72)
Constant	-10.421 (11.49)**	-7.527 (15.93)**	-7.488 (10.42)**	-6.035 (25.03)**	-6.945 (23.18)**	-6.490 (15.84)**	-8.681 (7.44)**
Observations	12,77,232	12,77,232	12,77,232	12,77,232	12,77,232	12,77,232	12,77,232

Notes: Robust z statistics in parentheses.

*Significant at 5%; **significant at 1%.

In multinomial logit models for each class, base reference group is no drug class use. There are no generic drugs in the PPI class, so only Tier 2 and Tier 3 are listed in the table. Because there are only three cases of Tier 1 Statin use, we do not present these results.

the predicted probability of using a tier 3 ACE drops slightly from 0.66% to 0.63%, so the predicted difference-in-differences effect is -0.15%, or a 22.7% decline in tier 3 use. The probability of tier 2 ACE use increases significantly, but there was no statistically significant change in the use of tier 1 drugs within the drug class.

The share of use attributable to tier 3 drugs over time is depicted in Figure 1. Figures 1A-C show an immediate downward shift of tier 3

TABLE IV.
**PREDICTED PROBABILITY OF USING A TIER 3 DRUG
 USING MULTINOMIAL LOGIT MODEL ESTIMATION
 REPORTED IN TABLE III**

	ACE		PPI		STATIN	
	Intervention	Control	Intervention	Control	Intervention	Control
Before	0.870%	0.660%	0.720%	0.690%	0.179%	0.087%
After	0.680%	0.630%	0.550%	0.694%	0.106%	0.124%
Diff-in-Diff	-0.160%	-	-0.174%	-	-0.111%	-

drug use among drug class users by the intervention group relative to the comparison group, which diminishes over time.

The results for Model 2 are shown in Table V. For all three classes, we see a negative coefficient on the interaction of time and intervention group dummies beginning with the April–June 2000 dummy (approximately 3 to 6 months after three-tier adoption). Figure 2 is a graphic illustration of the multinomial logit results for the predicted probability of tier 3 use for each 3-month interval by intervention and comparison group. Compared to no use, the share of tier 3 use of ACE and STATIN is higher in the intervention group than in the comparison group at baseline. After the formulary change, the share of tier 3 use drops much more in the intervention group than in the comparison group for these two classes (Table IV). For the PPIs, we see an overall increase in tier 3 use, but the increase for the intervention group is smaller than for the comparison group. Figure 3 shows the actual probability of tier 3 use across drug classes by the comparison group. Comparing Figures 2 and 3, we observe that the multinomial logit model appears to fit the data well.

Results of the two-part model of OOP spending are reported in Tables VI and VII. There is no statistically significant change in the probability of using drugs in any therapeutic class but we estimated a positive and statistically significant change in OOP spending on ACE inhibitors conditional on ACE class use. As reported in Table VIII, expected OOP spending per enrollee increased by 5% for ACE inhibitors, 2% for PPIs and 1% for statins. Table IX reports expected OOP spending per user, which increased 17% for ACE, 17% for PPI and approximately 1% for statins. Figure 4 shows how the probabilities of drug class use change over time. Coupled with Figure 1, Figure 4 confirms that three-tier formulary implementation does not change the overall demand for drugs in a particular drug class; instead, the effect of three-tier adoption occurs within a drug class, with enrollees switching from tier 3 drug use to tier 2 drug use.

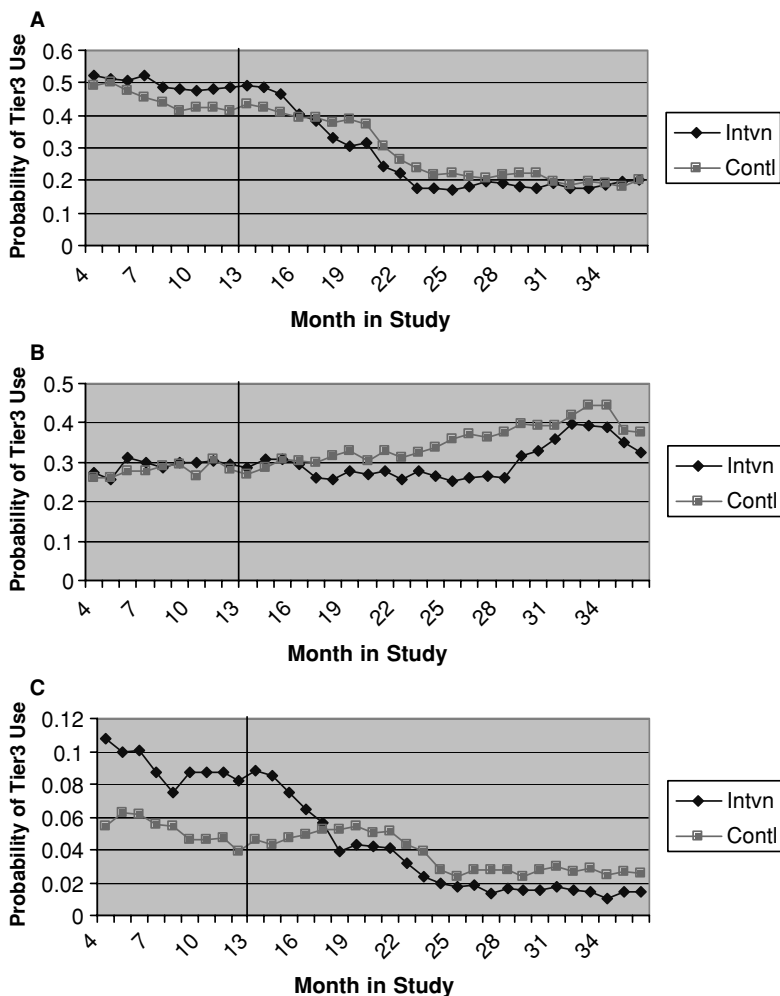


FIGURE 1. (A) SHARE OF TOTAL ACE INHIBITOR USE ATTRIBUTED TO TIER 3 DRUGS (B). SHARE OF TOTAL PPI USE TIER 3 DRUGS (C). SHARE OF TOTAL STATIN USE ATTRIBUTED TO TIER 3 DRUGS

6. DISCUSSION

For all three drug classes studied, the difference-in-differences models of the probability of tier 3 use showed significant reductions in the use of tier 3 medications after three-tier formulary adoption. For two of the three classes, ACE inhibitors and statins, there was a negative, statistically significant effect of the intervention beginning in the second

TABLE V.
MULTINOMIAL LOGIT MODEL ESTIMATING THE
PROBABILITY OF USING A TIER 3 DRUG WITH TIME
DUMMIES (MODEL II WITH TIME EFFECT)

	ACE			PPI		STATIN	
	TIER 1	TIER 2	TIER 3	TIER 2	TIER 3	TIER 2	TIER 3
INTVN	0.266 (1.44)	0.229 (2.59)**	0.250 (2.59)**	0.023 (0.28)	-0.026 (0.23)	0.262 (4.54)**	0.611 (2.75)**
JUL-SEP99	-0.726 (5.08)**	-0.003 (0.11)	0.065 (1.99)*	-0.095 (2.82)**	-0.210 (3.72)**	-0.108 (4.58)**	0.009 (0.09)
OCT-DEC99	-0.743 (4.88)**	0.065 (1.90)	0.072 (1.90)	-0.025 (0.69)	-0.156 (2.50)*	-0.013 (0.48)	-0.063 (0.51)
JAN-MAR00	-0.724 (4.66)**	0.073 (2.04)*	0.077 (1.82)	-0.023 (0.63)	-0.133 (2.12)*	0.066 (2.42)*	0.045 (0.33)
APR-JUN00	-0.723 (4.46)**	0.175 (4.58)**	0.038 (0.80)	0.085 (2.16)*	0.056 (0.89)	0.090 (3.18)**	0.194 (1.40)
JUL-SEP00	-0.359 (3.18)**	0.210 (5.43)**	-0.044 (0.86)	0.117 (2.94)**	0.163 (2.61)**	0.164 (5.74)**	0.280 (1.90)
OCT-DEC00	0.708 (7.55)**	0.258 (6.47)**	-0.422 (6.13)**	0.216 (5.48)**	0.271 (4.43)**	0.255 (8.74)**	0.008 (0.06)
JAN-MAR01	0.916 (10.07)**	0.333 (8.12)**	-0.457 (6.06)**	0.281 (7.09)**	0.516 (9.02)**	0.347 (12.01)**	-0.231 (1.43)
APR-JUN01	0.839 (8.99)**	0.361 (9.09)**	-0.420 (5.52)**	0.292 (7.16)**	0.628 (10.90)**	0.426 (14.30)**	-0.176 (1.14)
JUL-SEP01	0.880 (9.91)**	0.440 (10.65)**	-0.510 (6.48)**	0.314 (7.89)**	0.781 (14.23)**	0.459 (15.56)**	-0.069 (0.45)
OCT-DEC01	0.868 (10.17)**	0.462 (11.34)**	-0.540 (6.65)**	0.364 (9.07)**	0.792 (15.15)**	0.475 (15.93)**	-0.141 (0.83)
JUL-SEP99*INT	0.083 (0.41)	-0.197 (3.74)**	0.019 (0.38)	-0.118 (2.08)*	-0.016 (0.17)	-0.055 (1.56)	0.026 (0.20)
OCT-DEC99*INT	0.250 (1.20)	-0.188 (3.20)**	0.037 (0.63)	-0.116 (1.88)	0.023 (0.22)	-0.100 (2.61)**	0.179 (1.15)
JAN-MAR00*INT	0.195 (0.88)	-0.125 (2.05)*	0.089 (1.35)	0.029 (0.46)	0.155 (1.48)	-0.041 (1.00)	0.174 (0.98)
APR-JUN00*INT	0.175 (0.73)	0.025 (0.41)	-0.092 (1.16)	-0.003 (0.05)	-0.116 (1.02)	0.007 (0.17)	-0.378 (1.77)
JUL-SEP00*INT	0.206 (1.18)	0.149 (2.42)*	-0.205 (2.21)*	0.045 (0.68)	-0.112 (0.95)	0.021 (0.49)	-0.627 (2.57)*
OCT-DEC00*INT	-0.041 (0.29)	0.135 (2.12)*	-0.231 (1.88)	0.013 (0.19)	-0.204 (1.71)	0.019 (0.43)	-0.787 (2.84)**
JAN-MAR01*INT	-0.187 (1.32)	0.094 (1.47)	-0.213 (1.64)	0.007 (0.11)	-0.424 (3.68)**	-0.013 (0.29)	-0.921 (2.83)**
APR-JUN01*INT	-0.013 (0.09)	0.069 (1.10)	-0.218 (1.69)	-0.007 (0.11)	-0.326 (3.03)**	-0.003 (0.07)	-0.927 (2.68)**
JUL-SEP01*INT	-0.043 (0.31)	-0.000 (0.01)	-0.128 (0.98)	-0.053 (0.78)	-0.146 (1.45)	0.000 (0.00)	-1.030 (3.16)**

Continued

TABLE V.
CONTINUED

	ACE			PPI		STATIN	
	TIER 1	TIER 2	TIER 3	TIER 2	TIER 3	TIER 2	TIER 3
OCT-DEC01*INT	-0.033 (0.24)	0.023 (0.37)	0.009 (0.06)	-0.009 (0.14)	-0.117 (1.17)	0.025 (0.56)	-1.135 (3.09)**
AGE<=40	-2.993 (8.02)**	-2.295 (14.44)**	-2.843 (13.82)**	-1.415 (10.55)**	-1.228 (7.33)**	-3.376 (26.05)**	-3.660 (6.60)**
AGE 41-45	-1.318 (4.82)**	-1.469 (9.39)**	-1.666 (9.68)**	-0.960 (6.92)**	-0.712 (4.09)**	-2.070 (20.32)**	-3.018 (5.50)**
AGE 46-50	-1.451 (5.49)**	-0.771 (5.87)**	-1.354 (8.52)**	-0.523 (3.94)**	-0.489 (2.95)**	-1.329 (15.96)**	-1.688 (5.00)**
AGE 51-55	-0.642 (2.77)**	-0.419 (3.33)**	-0.724 (5.15)**	-0.061 (0.48)	-0.142 (0.86)	-0.714 (9.23)**	-1.488 (4.73)**
AGE 56-60	0.051 (0.23)	-0.054 (0.44)	-0.422 (3.08)**	0.032 (0.24)	0.001 (0.01)	-0.259 (3.41)**	-0.799 (2.75)**
MALE	0.501 (3.35)**	0.335 (4.42)**	0.489 (5.33)**	-0.165 (2.41)*	-0.203 (2.31)*	0.584 (11.36)**	0.232 (1.05)
EMPLOYEE	3.323 (4.08)**	3.685 (8.07)**	4.095 (5.84)**	2.311 (11.01)**	2.091 (8.57)**	3.616 (9.01)**	3.831 (3.42)**
SPOUSE	3.211 (3.92)**	3.572 (7.74)**	4.035 (5.71)**	2.113 (9.68)**	1.944 (7.61)**	3.440 (8.54)**	3.804 (3.26)**
Constant	-8.591 (10.17)**	-7.214 (15.33)**	-7.644 (10.69)**	-5.705 (23.96)**	-6.329 (22.17)**	-6.085 (14.89)**	-8.727 (7.52)**
Observations	1277232	1277232	1277232	1277232	1277232	1277229	1277229

Robust z statistics in parentheses.

*significant at 5%; ** significant at 1%

quarter after its implementation. For PPIs, a decrease in probability of tier 3 use was evident beginning in the third quarter after three-tier adoption. The duration of the impact varied across the classes. For statins, the effect on the probability of tier 3 use persisted over time. For ACE inhibitors and PPIs, the predicted probability of use began increasing again for the intervention group relative to the comparison group by the end of the study period. Together, these results show that the behavioral response associated with three-tier formulary adoption was not immediate, but was statistically significant nevertheless.

The analysis of OOP spending showed no impact of three-tier adoption on overall use of each drug class, as might be expected given that the three-tier formulary involved a relative price change but not an absolute price change for all drugs in each class. The implementation of a three-tier formulary did result in a statistically significant increase in OOP spending for all three classes, although small for statins.

The relatively modest demand response observed suggests that three-tier formulary adoption resulted in some cost shifting from the

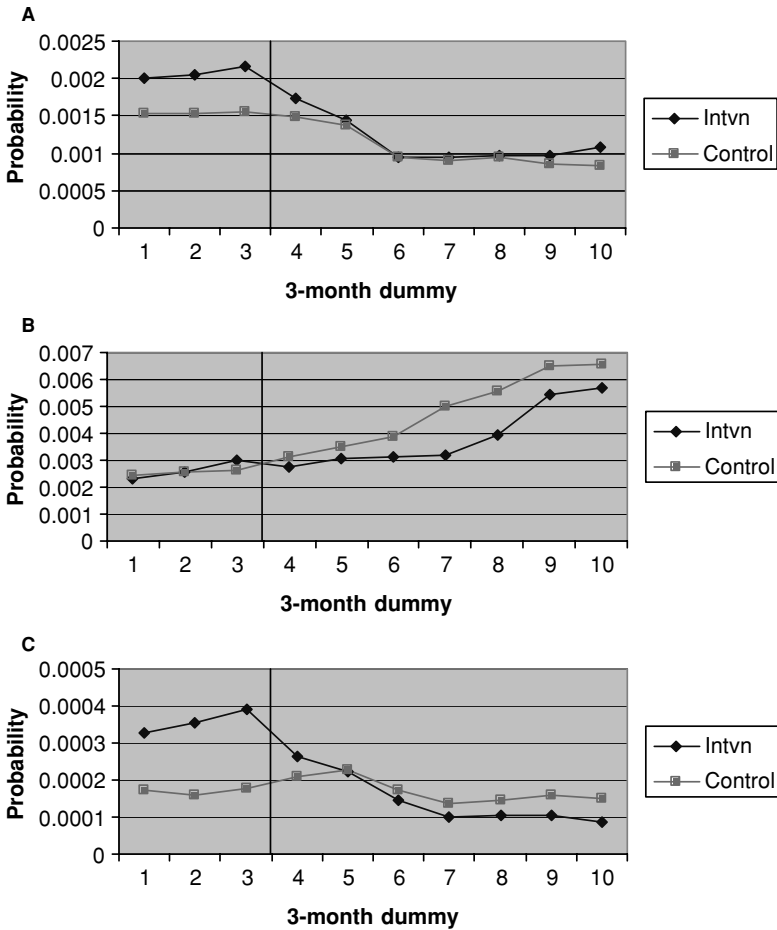


FIGURE 2. (A) MULTINOMIAL LOGIT RESULTS FOR THE PREDICTED PROBABILITY OF TIER 3 USE FOR ACE INHIBITORS (B). MULTINOMIAL LOGIT RESULTS FOR THE PREDICTED PROBABILITY OF TIER 3 USE FOR PPIS (C). MULTINOMIAL LOGIT RESULTS FOR THE PREDICTED PROBABILITY OF TIER 3 USE FOR STATINS

plan to the patient as well as some likely savings from rebates, as indicated by the decreased probability of tier 3 use and the magnitude of the changes in OOP spending. The General Accounting Office (GAO) recently estimated that plans that contracted with PBMs for the management of their prescription drug benefits received manufacturer rebates that resulted in plan spending decreases for prescription drugs of

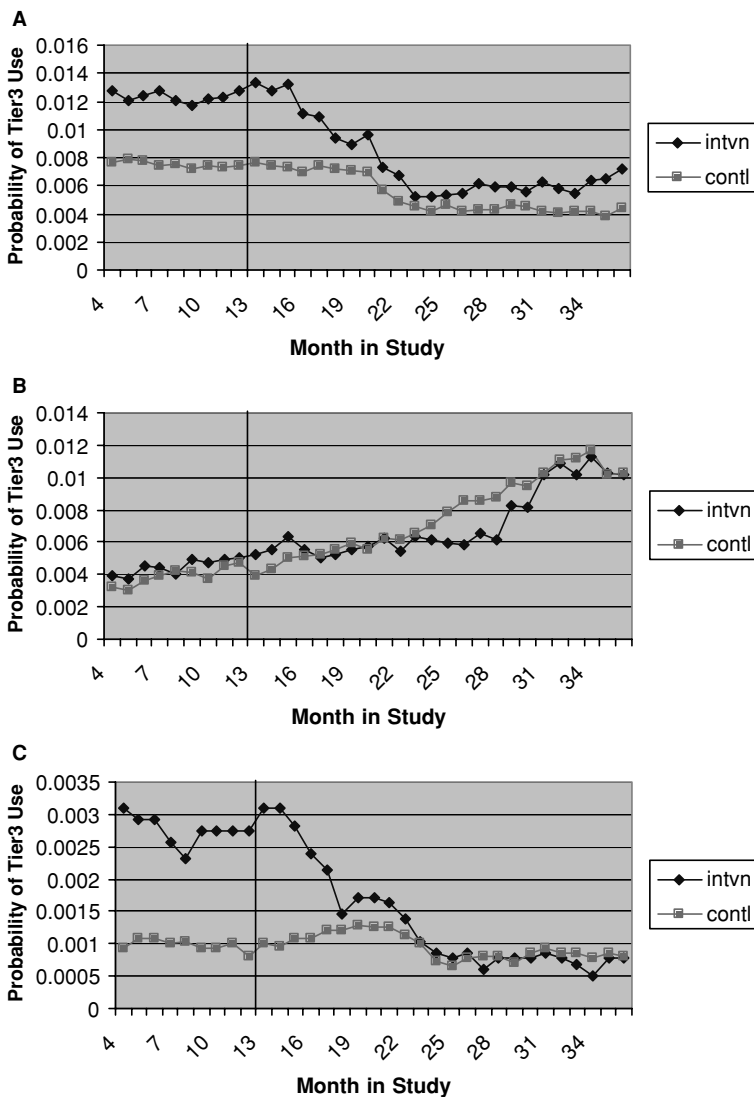


FIGURE 3. (A) ACTUAL PROBABILITY OF ACE TIER 3 USES (B). ACTUAL PROBABILITY OF PPI TIER 3 USES (C). ACTUAL PROBABILITY OF STATIN TIER 3 USE

between 3 and 9% (US GAO, 2003). This estimate represents an average across all drug classes (both those with generic alternatives and those without) and all formulary arrangements. Implementation of a three-tier formulary for these three classes is likely to have resulted in larger

TABLE VI.
LOGIT MODEL ESTIMATING THE PROBABILITY OF USING A
DRUG IN THE CLASS (PART 1 OF TWO-PART MODEL OF
OUT-OF-POCKET SPENDING)

	ACE	PPI	STATIN
POST	-0.027 (1.10)	0.011 (0.38)	-0.040 (1.67)
INTVN	0.195 (2.76)**	-0.012 (0.16)	0.243 (3.92)**
POST*INTVN	0.047 (1.13)	-0.050 (1.00)	0.016 (0.40)
AGE<=40	-2.536 (19.85)**	-1.352 (12.43)**	-3.393 (26.56)**
AGE 41-45	-1.520 (13.01)**	-0.874 (7.75)**	-2.109 (20.98)**
AGE 46-50	-1.020 (9.95)**	-0.513 (4.76)**	-1.349 (16.43)**
AGE 51-55	-0.548 (5.69)**	-0.087 (0.83)	-0.748 (9.80)**
AGE 56-60	-0.164 (1.74)	0.022 (0.20)	-0.286 (3.81)**
MALE	0.400 (6.71)**	-0.177 (3.17)**	0.570 (11.23)**
EMPLOYEE	3.750 (10.07)**	2.226 (13.66)**	3.625 (9.26)**
SPOUSE	3.655 (9.73)**	2.046 (12.03)**	3.454 (8.79)**
MONTH	0.015 (4.61)**	0.030 (6.52)**	0.035 (9.78)**
MONTHSQ	-0.000 (1.42)	-0.000 (0.87)	-0.000 (3.74)**
Constant	-6.676 (17.40)**	-5.669 (29.62)**	-6.388 (15.99)**
Observations	1,277,232	1,277,232	1,277,232

Notes: Robust *t* statistics in parentheses.

*significant at 5%; ** significant at 1%.

rebates, given the limited generic competition in the classes studied during this time period. If so, plan and total savings resulting from three-tier formulary adoption may have been of sizeable magnitude.

If demand response for particular drugs within a therapeutic class were zero, there would be no welfare effects in consumption associated with three-tier adoption and the savings to the plan represents a pure cost-shift onto enrollees. As a result, a three-tier formulary would serve to remove some risk protection and consumers would lose welfare from

TABLE VII.
POOLED ORDINARY LEAST SQUARES REGRESSION MODEL
OF THE LOGARITHM OF OUT-OF-POCKET SPENDING
CONDITIONAL ON DRUG CLASS USE (PART 2 OF
TWO-PART MODEL OF OUT-OF-POCKET SPENDING)

	ACE	PPI	STATIN
POST	0.042 (2.16)*	0.026 (1.18)	-0.001 (0.04)
INTVN	-0.018 (0.48)	0.143 (3.60)**	-0.055 (1.71)
POST*INTVN	0.074 (2.23)*	0.048 (1.34)	-0.006 (0.22)
AGE<=40	0.096 (1.44)	0.265 (4.28)**	0.229 (3.95)**
AGE 41-45	0.079 (1.37)	0.273 (4.29)**	0.134 (2.77)**
AGE 46-50	0.116 (2.18)*	0.201 (3.30)**	0.097 (2.33)*
AGE 51-55	0.027 (0.55)	0.052 (0.86)	0.052 (1.37)
AGE 56-60	0.071 (1.45)	0.083 (1.36)	0.055 (1.56)
MALE	-0.029 (0.92)	0.016 (0.53)	-0.083 (3.28)**
EMPLOYEE	-0.056 (0.42)	-0.175 (2.13)*	0.013 (0.09)
SPOUSE	-0.008 (0.06)	-0.135 (1.58)	0.064 (0.44)
MONTH	-0.010 (3.32)**	0.002 (0.69)	-0.006 (2.17)*
MONTHSQ	0.000 (3.83)**	0.000 (0.66)	0.000 (4.01)**
Constant	1.902 (13.37)**	1.950 (18.36)**	1.903 (12.71)**
Observations	27,998	25,423	37,788
R-squared	0.01	0.05	0.02

Notes: Robust *t* statistics in parentheses.
 *significant at 5%; ** significant at 1%.

the diminished insurance protection. With zero demand response, the changes would not increase a payer's bargaining power with manufacturers, because they would not be able to move market share, resulting in no rebates in the long run and thus, no change in total price. On the other hand, if demand response were complete, all tier 3 drug users would change to a lower-tier medication in the class and avoid a price increase.

TABLE VIII.
ESTIMATED CHANGES IN EXPECTED OUT-OF-POCKET
SPENDING ACROSS ALL ENROLLEES

	ACE	PPI	STATIN
Base Out-of-Pocket Spending	1.833	1.825	1.870
Expected Out-of-Pocket	0.097	0.030	0.012
Spending Change	(0.048)	(0.014)	(0.007)
Percentage Change of Spending	5.29%	1.63%	0.63%

TABLE IX.
ESTIMATED CHANGE IN EXPECTED OUT-OF-POCKET
SPENDING AMONG USERS

	ACE	PPI	STATIN
Base Out-of-Pocket Spending	6.615	8.108	7.00
Expected Out-of-Pocket	1.117	1.362	0.0411
Spending Change	(0.046)	(0.156)	(0.004)
Percentage Change of Spending	16.89%	16.80%	0.59%

As a result, there would be no change in OOP spending and all gains would come from savings extracted from pharmaceutical manufacturers in the form of rebates.

Our results fall in between the two polar cases.¹ The empirical estimates of demand response showed notable changes in the demand for products in response to changes in the OOP price. These ranged from 22% to 65% reductions in the probability of using tier 3 drugs in response to the 100% increase in OOP price. This suggests some significant behavior change but also cost shifting. The analysis of OOP spending confirms this implication for two of the three classes. The magnitude of the cost shift was relatively small (17% at most). We anticipate that the savings obtained by the plans from the ability to redirect demand would likely substantially exceed the cost shift. Thus, the gains to premium payers may well exceed the losses to users of the drug classes. It is important to recognize that the results represent a single employer's experience and thus may not reflect the general experience.

1. We do not have adequate power to disaggregate impacts of three-tier adoption on new versus ongoing users of medications for the three classes we studied. Consequently, our results may represent underestimates of demand response if demand of new users is more sensitive to OOP price than demand of ongoing users.

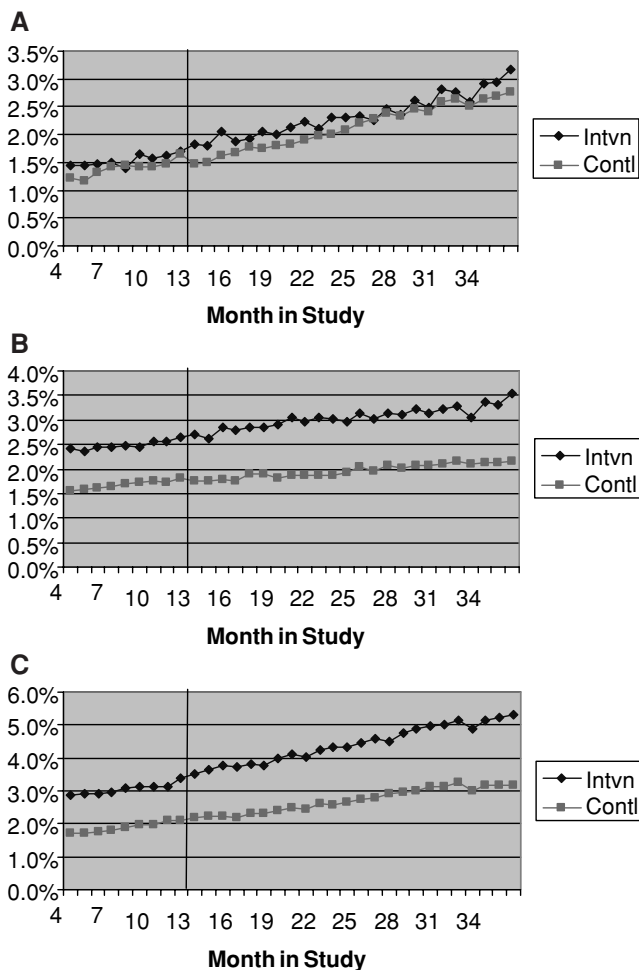


FIGURE 4. (A) PROBABILITY OF ACE INHIBITOR USE OVER TIME (B). PROBABILITY OF PPI USE OVER TIME (C). PROBABILITY OF STATIN USE OVER TIME

7. CONCLUDING REMARKS

In this research we find evidence of moderate demand response to a “pure relative price change” implemented in the context of a three-tier formulary. In our judgment, the savings from increased bargaining power for plans may well be substantial (since it includes the most frequently used drugs in the class). However, we do not have direct data that captures the outcomes of new price negotiations that follow

the formulary change. A substantial portion of three-tier users does not switch to therapeutic alternatives resulting in a reduction in risk protection that is modest. This is particularly surprising for the PPI class where the clinical literature suggests a very high degree of substitutability in production (Wolfe, 2003). This suggests that some consumers may be incurring increased OOP costs without meaningful clinical benefits relative to lower-priced alternatives. Such a finding raises issues of the normative interpretation of observed demand behavior, in the context of the agency relations that underlie such clinical choices. More studies of such natural experiments are, therefore, necessary to develop a general understanding of both the positive and normative impacts of what is becoming a dominant economic institution in drug purchasing.

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