

How Does Drug Coverage Vary by Insurance Type? Analysis of Drug Formularies in the United States

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Objectives: To quantify how access to on-patent drugs by tier placement varies by insurance type and therapeutic area.

Study Design: Retrospective analysis of insurance plan drug coverage data.

Methods: Drug coverage information was collected from the Fingertip Formulary database in May 2011 for 3 drug classes (statins, angiotensin II receptor blockers, and protein-tyrosine kinase inhibitors) across 3 therapeutic areas with varying levels of generic drug availability. A generalized linear model was used to estimate the percentage of available on-patent drugs covered in the formulary tiers with lowest copay requirements (tiers 1 and 2) in different types of healthcare insurance plans in the United States.

Results: There were substantial differences between insurance types in the number of on-patent drugs reimbursed in tiers 1 and 2 (ie, with a low copay). Compared with commercial plans, there were more on-patent drugs reimbursed with a low copay in employer plans, union plans, and with pharmacy benefit management companies, and substantially fewer on-patent drugs with a low copay in Medicare plans (Medicare Advantage, special needs, prescription drug plans) and discount prescription programs. These results were expected, as union plans are known for their generosity and Medicare plans rely heavily on cost containment (eg, cost sharing). For commercial Medicaid and municipal plans, the findings were dependent on the therapeutic class, or were inconclusive. The number of competitors a plan faces did not consistently affect the coverage of on-patent drugs.

Conclusions: The degree of coverage of on-patent drugs in the lowest copay tiers varies dramatically between insurance types, especially for expensive protein-tyrosine kinase inhibitors.

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For author information and disclosures, see end of text.

In the United States in 2010, approximately 63% of individuals who had health insurance were insured through private plans, 24% by government health programs, and 13% by both types of programs.¹ The vast majority (approximately 85%) of privately insured Americans had access to health insurance through private employers.¹

The main government programs are Medicaid and Medicare, covering 19% and 17% of the insured population, respectively. Medicaid is available to certain low-income individuals and families. Medicare provides health insurance for individuals older than 65 years, those younger than 65 years with certain disabilities, and people with end-stage renal disease. Additional information regarding source of health insurance can be found in [eAppendix A](#), available at www.ajmc.com.

Health plans usually assign the drugs that they cover to “tiers.” A drug’s tier determines the degree to which the patient will have to contribute a payment for the drug—the lower the tier, the lower the copayment. Tier 1 is typically for generics, tier 2 for preferred brand name drugs, tier 3 for nonpreferred brand name drugs, and tiers 4 (and above) for coinsurance brands. Fixed-sum copayments are required from patients for drugs in tiers 1 through 3 to cover some of the drug costs. Coinsurance copayments are a percentage of a drug’s cost and vary from drug to drug. An individual plan may include patent-protected brand name (“on-patent”) drugs, brand name drugs that are no longer patent protected (“off-patent”), and generic bioequivalents. For individuals receiving healthcare coverage via employment, the average 2012 copayment was \$10 for first-tier drugs, \$29 for second-tier drugs, \$51 for third-tier drugs, and \$79 for fourth-tier drugs.² In 2009, the average Medicare Part D copayment was \$10 for first-tier drugs, \$37 for second-tier drugs, and \$75 otherwise.³ The Medicare Part D coinsurance rate on the specialty tier ranged from 25% to as high as 335, with a median of 30%.³ The drugs assigned to each tier vary with individual healthcare plans, and this is one of the aspects of a plan on which the consumer may base their decision when choosing a plan.

From a patient’s perspective, plans that offer drugs relevant to their condition in the low copay tiers are likely to be more attractive, assuming the monthly premiums are comparable. Another factor that might make a plan

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more favorable is the degree of choice of drugs within a therapeutic class in the low copay tiers. The ability to choose (doctors, hospitals, and drugs) is seen as very important or extremely important by the vast majority of Americans when selecting healthcare plans.⁴ Evidence that the level of copayments for a given medication impacts the choice of health plans or pharmacies is limited, however. Zou and Zhang found that only 5% of Medicare Part D beneficiaries chose the cheapest plan available in their region given their medication needs.⁵ Linton et al found that 22% of Department of Defense beneficiaries older than 65 years used the option with lower copay.⁶ The ability to choose a drug may have implications for patient adherence to prescribed medication regimens. In particular, having access to, and a choice of, on-patent drugs at a reasonable copay level may be an important factor for patients (ie, for patients who have concerns regarding drug switching or generic substitution). There is evidence that increasing a drug's copayment can decrease its utilization level, reduce adherence,⁷ or lead patients to switch drugs.⁸

The objective of this study was to assess whether the level of on-patent drug coverage varies according to:

- Plan type. Some categories of plans (including some union plans) were expected to offer health insurance packages with generous benefits such as absence of copayments, deductibles, or prior authorizations, even for on-patent drugs for which an alternative generic is available. Those plans can be costly to employers, in which case they would be called "Cadillac plans."^{9,10} In such plans, a range of on-patent drugs might be assigned to lower tiers.
- Therapeutic class. The proportion of on-patent drugs covered by the plan (as a percentage of all on-patent drugs available in the same class) would be expected to be low in therapeutic classes where a large number of drugs are available. For those therapeutic areas, managed care organizations could be effective and aggressive in managing formularies and in influencing physicians' prescribing behavior.¹¹

The implications of the analysis are important for: (1) consumers and employers who, when choosing insurance, want to know whether certain types of plans provide more choice compared with others; (2) lawmakers who want to understand the impact on drug choice of curbing the use of Cadillac plans; (3) public health specialists who want to understand whether the population has affordable access to life-saving medications.

Take-Away Points

- Insurance plans assign the drugs that they cover (ie, reimburse) to "tiers," with the copay varying by tier (the lower the tier, the lower the copay).
- For 3 drug classes in distinct therapeutic areas, access to on-patent drugs in the lowest copay tiers (1 and 2) was higher in employer, union, and pharmacy benefit management plans than in commercial plans. However, in Medicare plans, substantially fewer on-patent drugs were included in these tiers, which could create choice restrictions and thus compliance issues.
- Medicare plans should reconsider access to on-patent drugs by tier for high-cost therapeutic areas without affordable alternatives.

To date, the published literature reporting on drug tiers and formularies in the United States has focused mainly on: the decrease in drug utilization after a copayment increase¹²⁻¹⁵; the association between the formulary position (tier) and value of a drug¹⁶; and the decision-making process in assigning a drug to a tier.¹⁷⁻²⁰ For instance, Linton et al observed that the esomeprazole (Nexium) share of the proton pump inhibitor market dropped from 20.0% to 15.7% in the month after TRICARE moved esomeprazole from tier 2 to tier 3 (copay increased from \$9 to \$22).¹³ Similarly, in the antidepressant market, Hodgkin et al found that drugs that became non-preferred in insurance plans experienced a decrease of 11% in the number of prescriptions filled per enrollee (vs an increase of 5% in the comparison group).¹⁴ No articles have reported on the differences in coverage between insurance type and therapeutic classes. By analyzing such differences, this paper contributes to the more limited literature that advises patients on identifying plans that have limited drug formularies²¹ and whether formularies meet the needs of all patients.^{22,23}

METHODS

Data Description

The data set used was the Fingertip Formulary (Fingertip Formulary LLC, Glen Rock, New Jersey), which is a collection of drug coverage data for 1768 health plans in the United States. Fingertip Formulary estimates that between 95% and 98% of the covered lives in the United States are in the database. The data were collected from health plans' websites or by directly contacting the health plan providers. The information changes regularly; the data used in this paper were downloaded on May 15, 2011. While drug coverage typically changes once a year (before members enroll), it could change during the year if there is a market event (eg, an on-patent drug goes off patent) and/or if the contract with a manufacturer was not renewed. The author accessed the website on May 15, 2011, and

downloaded the information available that day. Since no angiotensin II receptor blockers (ARBs) and no protein-tyrosine kinase inhibitors (P-TKIs) lost patent that year, it is likely that the conclusions would not have changed dramatically in 2011. The conclusions on HMG-CoA reductase inhibitors (HMGs) would have remained valid for most of 2011, since Lipitor lost its patent on November 30, 2011.

Fingertip Formulary data include a number of fields that are identical for all drugs: (1) health plan identifier; (2) provider (ie, company providing the health plan) identifier; (3) state(s) where the health plan operated; (4) lives covered (ie, number of enrollees in the plan); (5) plan/insurance type (commercial, pharmacy benefit manager [PBM], employer, Medicare Advantage [MA], Medicare Part D plan [PDP], special needs plan [SNP], state Medicaid, commercial Medicaid plan [if the Medicaid plan was contracted to private health companies], union, municipal, discount prescription programs). In Fingertip Formulary, employer plans are those offered by organizations that arrange pharmaceutical benefits for workers as part of their total benefit plan and whose data Fingertip Formulary can source in an ongoing basis. Commercial plans are set by non-Medicare and non-Medicaid organizations that offer pharmaceutical benefits to individuals and/or groups such as businesses and local governments. The database allows for information to be included on the tier status (whether a drug is in tiers 1-6, not reimbursed, or not available) for each drug within each plan. [eAppendix B](#) provides the number of plans and the number of insured individuals for each insurance type.

Three different therapeutic classes with different levels of generic competition and disease burden were analyzed in this paper: (1) statins (3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors; HMGs), used to lower serum cholesterol levels; (2) ARBs, used to reduce hypertension; and (3) P-TKIs, treatments for chronic myeloid leukemia (CML) and gastrointestinal stromal tumor. At the time of the data download, the HMG class comprised 4 off-patent products that had generic equivalents and 8 on-patent products. Six ARBs had patent protection and 1 ARB was available off patent and as a generic equivalent. Azilsartan medoxomil (Edarbi) had only recently been launched and was not included in the analysis, as a number of plans had no information on the drug. All available P-TKIs were still within patent, and no generic versions were available. Coinsurance copays were much higher for P-TKIs than for HMGs and ARBs. For instance, if the coinsurance rate was 30%, the average 2011 copay for a 30-day supply was \$1820 for imatinib mesylate

(Gleevec), \$56 for atorvastatin 80 mg (Lipitor) and \$48 for valsartan/hydrochlorothiazide 320 mg/25 mg (Diovan HCT).²⁴

The Model

The objective of the model was to explain how the number of on-patent drugs in a low tier varies by insurance type (eg, commercial, municipal, Medicare) and therapeutic area. The level of drug coverage could be defined in several ways: number of reimbursed drugs, number of reimbursed on-patent drugs, number of drugs with a low-tier copay, number of on-patent drugs with a low-tier copay, etc. Because generics are typically reimbursed and/or are affordable, the focus was on on-patent products. Therefore, coverage was defined as the number of drugs with patent protection that were in a low copay tier (ie, tiers 1 or 2), and is referred to as “on-patent drug coverage” hereafter. Medicare PDPs, MA, and SN plans were grouped into a Medicare variable.

A logit regression was used to explain drug coverage. Tobit and count models were also considered to ensure that the findings did not depend on the methodology. More details on the models can be found in [eAppendix C](#). Plans without coverage information for all products in a therapeutic area were excluded for such analyses. On-patent drugs used in the analysis are shown in [eAppendix D](#).

Generalized Linear Model With Logit Link

A generalized linear model (GLM) with a logit link function was used to examine the relationship between the percentage of available on-patent drugs in a therapeutic area that are covered in tiers 1 or 2 and the variables of interest: insurance type and therapeutic areas. Hosmer-Lemeshow and Pregibon link tests were used to ensure that the model adequately fit the data.

Count Model

Use of Poisson or negative binomial regressions was also considered, as the number of on-patent drugs with favorable tier coverage was a count variable. However, the Poisson distribution was not deemed relevant because the distributions were overdispersed ([eAppendix E](#)). Therefore, only a negative binomial model was analyzed.

Censored Model

Drug coverage data can be considered right-censored, as the number of covered drugs was, by definition, bound by the number of approved brands. Therefore, applying a censored model (Tobit regression) would be appropriate. Intuitively, a censored model should be more relevant

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Table 1. Average Number of Drugs Covered by Healthcare Insurance Plans, According to Formulary Position

	Percentage of Available Drugs (average number of drugs) Covered by Plans					
	All Drugs (on-patent and off-patent brand name drugs and generics)			On-patent Drugs Only		
	HMGs	ARBs	P-TKIs	HMGs	ARBs	P-TKIs
Total available	100 (16)	100 (8)	100 (4)	100 (8)	100 (6)	100 (4)
Tier 1^a	20 (3.1)	13 (1.0)	3 (0.1)	3 (0.3)	3 (0.2)	3 (0.1)
Tier 2	23 (3.7)	23 (2.3)	39 (1.6)	35 (2.8 ^b)	34 (2.0)	39 (1.6)
Tier 3	23 (3.6)	27 (2.1)	9 (0.4)	26 (2.0)	30 (1.8)	9 (0.4)
Tier 4 and above	3 (0.5)	3 (0.3)	31 (1.2)	4 (0.3)	4 (0.2)	31 (1.2)
Not reimbursed	29 (4.7)	27 (2.1)	12 (0.5)	29 (2.3)	27 (1.6)	12 (0.5)
No information	3 (0.5)	2 (0.1)	6 (0.3)	3 (0.2)	2 (0.1)	6 (0.3)

ARB indicates angiotensin II receptor blocker; HMG, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor; P-TKI, protein-tyrosine kinase inhibitor.

^aTier 1 is the insurance plan drug-formulary tier with the lowest copay requirement and generally includes generic drugs. Tiers 2 and 3 have higher copay requirements and typically comprise preferred and non-preferred brand name drugs, respectively. Tiers 4 and above include coinsurance tiers in which plans ask for coinsurance instead of copayments.

^bExample calculation: on average, across all the plans, there are 2.8 on-patent HMGs in tier 2. This was calculated by: (1) identifying for each plan the number of on-patent HMGs that were in tier 2 (1768 data points); and (2) calculating the average of those 1768 data points. The percentage indicates the percentage of the total available on-patent HMGs (ie, 2.8 divided by 8).

for therapeutic classes with few or no interchangeable options. In this case, one could assume that insurance companies would be willing to cover more drugs if more were available. The high number of plans covering all 4 P-TKIs was consistent with this hypothesis. As the number of approved drugs was specific to each therapeutic area, a Tobit model was run separately for HMGs, ARBs, and P-TKIs. As the assumption of normality of the residuals was rejected (ie, the maximum-likelihood estimator was inconsistent), a bootstrap approach was used (with 1000 replications at 95% CI).

Statistical Analysis

All analyses were performed using the statistical analysis program Stata, version 12.1 (StataCorp LP, College Station, Texas).

RESULTS

Table 1 shows the average, across all plans, of the number of drugs in each tier. The numbers were calculated by first extracting, from the database, the number of drugs by tier for each plan. Then, for each tier, the average of the number of drugs was calculated across all 1768 plans. The results can be interpreted in terms of how the drugs are split across tiers. On average, 4.7 HMGs and 2.1 ARBs were not reimbursed. Most P-TKIs were reimbursed—an average of only 0.5 drugs out of 4 available drugs (12%) was not reimbursed. HMGs and ARBs were rarely assigned to tiers 4 and above (average

3% of available ARBs and HMGs were in such tiers), but P-TKIs were more frequently found in those tiers (average 31% of available P-TKIs). As expected, on-patent drugs were rarely in tier 1 because it is typically reserved for generics. On average, approximately 30% of on-patent ARBs and HMGs were not reimbursed by health insurance plans. The proportion of on-patent drugs in tier 2 was similar across therapeutic classes (34%-39%), but tier 3 was used much less for on-patent P-TKIs than for on-patent HMGs or ARBs (9% vs 26% and 30%, respectively).

On-patent drug coverage varied greatly by plan type (**Table 2**). Across therapeutic areas, discount prescription programs and Medicare plans offered the lowest number of on-patent drugs in tiers 1 and 2, especially for P-TKIs. P-TKIs were often in tier 4 or higher in Medicare plans, meaning that a coinsurance was required, likely due to their relatively high cost (eg, in 2011, the average wholesale price of the P-TKI imatinib mesylate [Gleevec] was \$202 per day for patients with chronic-phase Philadelphia chromosome-positive CML^{24,25}). Union and municipal plans had many on-patent HMGs in tier 1 or 2 (ie, the lowest copay tiers), which seems to corroborate the assumption that those plans offer generous drug benefits. Commercial Medicaid plans placed a high proportion of the on-patent drugs in the lowest copay tiers. The results for state Medicaid will be further discussed in the Summary and Discussion section.

Table 3 shows summary statistics for the independent variables used in the model specifications. Commercial

■ **Table 2.** Percentage of On-Patent Drugs in Tier 1 or Tier 2 by Plan Type and Drug Class

Plan Type	HMGs	ARBs, %	P-TKIs, %
Commercial	38	33	47
Commercial Medicaid	41	42	70
Discount prescription programs	0	2	0
Employer	48	41	68
MA	23	22	4
Medicare PDP	29	26	8
Medicare SNP	26	25	24
Municipal	51	57	52
PBM	46	45	59
State Medicaid	95	95	98
Union	60	52	55
Average across all plans	39	37	42

ARB indicates angiotensin II receptor blocker; HMG, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor; MA, Medicare Advantage; PBM, pharmacy benefit management; PDP, prescription drug plan; P-TKI, protein-tyrosine kinase inhibitor; SN, special needs plan. The average across all plans is lower than in Table 1 because not all on-patent drugs are in tier 1 or tier 2.

■ **Table 3.** Descriptive Statistics of Independent Variables

Plan Type	Number of Plans	Average Number of Competitors		Lives Covered (thousands)	
		Mean	SD	Mean	SD
Commercial	996	26.4	13.9	313	876
Commercial Medicaid	614	14.3	9.3	95	126
Discount prescription programs	39	6.5	0.9	1700	0
Employer	476	0	0	72	170
MA	913	30.8	14.2	27	118
Medicare PDP	368	46.2	6.6	149	480
Medicare SNP	441	13.1	7.4	8	17
Municipal	684	13.0	5.2	258	1018
PBM	180	52.1	1.1	3039	5086
State Medicaid	146	—	—	683	842
Union	26	4.0	2.0	201	150
Across sample		21.4	16.9	218	997
Observations	4883	4883		3932	
Missing	421	421		1372	

ARB indicates angiotensin II receptor blocker; HMG, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor; MA, Medicare Advantage; PBM, pharmacy benefit management; PDP, prescription drug plan; P-TKI, protein-tyrosine kinase inhibitor; SD, standard deviation; SN, special needs plan. The numbers differ from those in Table 1 since each plan could potentially have 3 observations (1 per therapeutic area). In addition, out of the potential 5304 observations (1768 × 3), only 4883 were included; 95 records were excluded because they did not have coverage information for all ARBs, 137 were excluded for lack of information on P-TKIs, and 189 were excluded for lack of information on HMGs.

plans were the most prevalent plans in the database. PBMs were the plans with the most enrollees, on average. The variable capturing the number of competitors is also called “plan competition” in the remainder of the article. Its calculation can be found in online [eAppendix F](#). The categories of plans with the highest number of competitors were PBMs and Medicare PDP.

Generalized Linear Model

The results of the GLM regression are presented in [Table 4](#). The reference categories for plan and therapeutic dummies were commercial plans and HMGs, respectively. A positive coefficient sign indicates an increased probability of on-patent drug coverage in a low tier. On average, 40.1% of on-patent drugs were in a low tier. All

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■ **Table 4.** Logit Regression Results for the Proportion of On-Patent Brands in a Low Tier

Plan Type	Regression Coefficient	Average Marginal Effect (dc/dx), Market Share Point	Base model + Interaction + Competition	Base Model + Interaction + Competition + Lives
Constant ^a	-0.39 ^b	NA	-0.41 ^b	-0.49 ^b
Commercial Medicaid	0.41 ^b	+8.3	0.12	-0.31 ^b
Discount prescription programs	-15.89 ^b	Out-of-range	-15.97 ^b	Not available ^c
Employer	0.69 ^b	+14.1	0.28 ^d	0.29 ^d
State Medicaid	3.62 ^b	+73.9	3.55 ^b	3.54 ^b
Medicare	-1.12 ^b	-22.8	-0.69 ^b	-0.55 ^b
Municipal	0.48 ^b	+9.9	0.44 ^b	Not available ^c
PBM	0.43 ^c	+8.9	0.52 ^b	0.71 ^b
Union	0.99 ^d	+20.2	0.92 ^d	0.90 ^c
ARB	-0.12 ^c	-2.4	-0.06	-0.16 ^b
P-TKI	0.28 ^c	+5.6	0.57 ^b	1.18 ^b
Number of competitors			-0.00	-0.00
ARB × number of competitors			-0.00	0.00
P-TKI × number of competitors			-0.01 ^e	-0.02 ^b
P-TKI × commercial Medicaid			0.79 ^b	0.55 ^d
P-TKI × employer			1.49 ^b	0.99 ^b
P-TKI × Medicare			-1.44 ^b	-1.71 ^b
Lives (millions)				0.04 ^d
Observations	4883		4883	3700
Akaike's information criterion	0.99		0.96	0.89
Predicted mean	40.1%			
Predicted mean (HMG)	39.0%			
Predicted mean (ARB)	36.7%			
Predicted mean (P-TKI)	44.8%			

ARB indicates angiotensin II receptor blocker; HMG, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor; NA, not applicable; PBM, pharmacy benefit management, P-TKI, protein-tyrosine kinase inhibitor.
Standard errors were calculated assuming that the data were clustered at the plan level; dc/dx for factor levels is the discrete change from the reference point level (HMG and commercial) to the variable of interest.
^aThe constant is the predicted log odds ratio of the percentage of on-patent HMGs in a low tier in commercial plans without competition.
^bP <.001.
^cDiscount prescription programs were not included since only 1 of 14 discount prescription programs and 79 of 235 municipal plans had information on lives covered.
^dP <.01.
^eP <.05.

variables were highly significant and therefore had an impact on the probability that an on-patent drug had a low copay requirement. The average marginal effect of P-TKIs represents the incremental probability, relative to HMGs, of on-patent PTKIs to be covered in a low tier. The value was +5.6 points and the branded P-TKIs were predicted to be in a low tier in 44.8% of cases versus 39.0% for HMGs. The marginal effect was -2.4 points for on-patent ARBs, which were predicted to be in a low tier in 36.7% of cases. On average, the percentage

of on-patent drugs in tiers 1 or 2 was 20 points higher for union plans and 74 points higher for state Medicaid than for commercial plans. All else being equal, PBMs, commercial Medicaid, employer, and municipal plans also covered more on-patent drugs with a low copay than did commercial plans. However, Medicare on-patent drug coverage in tiers 1 or 2 was substantially lower than that of commercial plans (-23 points). If we do not control for the differences between plans, the conclusion remains that P-TKIs (relative to ARBs) have

higher (respective to lower) probability of on-patent drug coverage in a low tier than HMGs ($P < .001$).

Model Specification

Additional covariates. Medicare plans had relatively few on-patent drugs in tiers 1 and 2 for P-TKIs (Table 2). Conversely, commercial Medicaid and employer plans had a high number of P-TKIs with a low copay. Interaction variables were therefore introduced between P-TKIs and Medicare, commercial Medicaid, and employer plans. The number of competitors a plan faces was introduced, since high levels of competition could impact drug coverage in 2 opposing ways: by triggering a drug “arms race” to attract enrollees, or by leading to cost and drug control. Interaction variables between plans’ competition and therapeutic areas were introduced to investigate whether the competition impact varied by therapeutic area.

Table 4 shows the impact of introducing additional variables (see online Appendix 3 for additional details). As expected, the sums of the coefficients for P-TKIs and for the interaction between the Medicare/commercial Medicaid plans and P-TKIs were negative and positive respectively ($P < .001$), which means that Medicare (respective to commercial Medicaid) plans covered fewer (respective to more) P-TKIs than HMGs in a low tier. In other words, Medicare plans had a substantially lower proportion of P-TKIs than on-patent HMGs in tier 1 or 2. Commercial Medicaid plans were less restrictive for P-TKIs than for HMGs. The average number of competitor plans had a significant negative effect for P-TKIs ($P = .05$). The more competition faced by plans, the less likely they were to cover P-TKIs in the low copay tiers. However, the number of competitor plans did not impact coverage of on-patent ARBs differently from coverage of HMGs. Overall, the number of competitors was not significant across therapeutic areas (F test $P = .15$). The other variables remained significant, with similar coefficient values. The interaction variables added some information to the core model (Akaike’s information criterion of 0.99 vs 0.96, respectively).

Finally, a variable measuring the number of insured lives by plan was introduced to assess whether the size of a plan had an impact on on-patent drug coverage. The hypothesis was that larger plans had lower general marketing expenses (as percentage of sales) due to economies of scale, and could afford to cover more on-patent drugs in tiers 1 and 2. The variable measuring insured lives was significant and positive, meaning that plans with more enrollees covered, on average, more on-patent drugs in tiers

1 and 2. All variables remained significant after adding this variable and analyzing a subset of the original data set. One variable (commercial Medicaid) experienced a significant switch in sign. The regression did not include municipal plans or discount prescription programs since only 1 of 14 discount prescription programs and 79 of 235 municipal plans had information on lives covered. Since the data set with lives data is only a subset of the universe, care must be taken when comparing the results, in particular Akaike’s information criterion, of previous regressions.

Logit Model Specification Tests

The logistic model with interaction terms passed the Pregibon link test but not the Hosmer–Lemeshow test (F test $P = .46$ and $P = .01$, respectively). The model with interaction terms and lives covered variable passed both tests (F -test $P = .85$ and $P = .23$, respectively) and its goodness of fit was not rejected.

Finally, a bootstrap estimation (using 1000 bootstrap replications at 95% CI) was performed for the GLM, with interaction variables. The coefficients from the bootstrap estimates were found to be similar to those of the GLM. The only difference was that the commercial Medicaid variable became significant. Based on these results, the coefficients’ estimates and significance levels from the GLMs were not driven by outliers.

Tobit and Negative Binomial Models

The sign and significance of coefficients were similar for the Tobit and negative binomial models (Table 5). The sign and significance of coefficients were also similar to those of the logit model (Table 5).

DISCUSSION

To the author’s knowledge, this article is the first report of an attempt to analyze drug tier data in this way. Across all models and therapeutic areas, Medicare plans and discount prescription programs had consistently fewer on-patent drugs in the lowest copay tiers than did commercial plans. These results were expected. The revenue per enrollee of Medicare PDP and MA plans is capped, since these plan providers have to offer standard plan designs (or designs at least actuarially equivalent to the standard plan designs). Therefore, these plans may try to contain costs to increase profits. Discount prescription programs are basic drug insurance programs that mainly cover generics. Conversely, PBMs, employer, and union plans had higher on-patent drug coverage than com-

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■ **Table 5.** Tobit and Negative Binomial Results for Low-Tier On-Patent Drugs (with robust standard errors)

Plan type	Tobit (bootstrap)			Negative Binomial		
	HMGs	ARBs	P-TKIs	HMGs	ARBs	P-TKIs
Constant	3.20 ^a	2.07 ^a	2.67 ^a	1.15 ^a	0.70 ^a	0.74 ^a
Commercial Medicaid	0.31	0.60 ^b	1.39 ^a	0.06	0.21 ^b	0.32 ^a
Discount prescription programs	-3.20 ^a	-2.07 ^a	-2.67 ^a	-22.66	-20.2	-21.29
Employer	0.98 ^a	0.39 ^b	2.85 ^a	0.27 ^a	0.18 ^b	0.49 ^a
State Medicaid	7.19 ^a	5.94 ^a	5.19	0.89 ^a	1.04 ^a	0.63 ^a
Medicare	-1.23 ^a	-0.67 ^a	-2.20 ^a	-0.47 ^a	-0.37 ^a	-1.66 ^a
Municipal	0.96 ^a	1.73 ^a	0.21	0.27 ^a	0.52 ^a	0.01
PBM	0.49 ^c	0.61 ^c	1.20 ^c	0.16	0.27 ^c	0.25 ^c
Union	2.61 ^b	1.40 ^c	1.51	0.56 ^c	0.49 ^c	0.36
Observations	1579	1673	1631	1579	1673	1631

ARB indicates angiotensin II receptor blocker; HMG, 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor; PBM, pharmacy benefit management; P-TKI, protein-tyrosine kinase inhibitor.
^a*P* < .001.
^b*P* < .01.
^c*P* < .05.

mercial plans. Therefore, employees had access to more on-patent drugs in the low copay tiers when companies outsourced pharmacy benefits to a PBM and when companies created their own formulary. State Medicaid covered more on-patent drugs in a low-copay tier than any other types of plans. This result reflects the fact that 46 out of 49 Medicaid plans only had 2 tiers. In addition, only 1 Medicaid plan (Mi Salud, Puerto Rico Medicaid) did not reimburse all on-patent drugs. One explanation could be that 2 tiers may be enough to convince patients to use drugs in tier 1 since a marginal copay difference may dissuade patients on low incomes from using a drug. Alternatively, Medicaid plans may have high bargaining power, and/or pharmaceutical companies may be willing to offer substantial rebates to grant access to this segment of the population. Medicaid administrators may also limit cost-sharing for on-patent drugs so that cost is not a barrier to compliance with treatment regimens.

The significance of coefficients for commercial Medicaid and municipal plans varied by therapeutic area and/or methods. Commercial Medicaid plans covered, on average, more P-TKIs (all within patent) than did commercial plans as a whole. This was not the case for HMGs (Table 5). One explanation may be that state Medicaid agencies, when negotiating with commercial Medicaid companies, include clauses regarding maximum allowable cost sharing for classes with generics.

Across all plans, the percentage of on-patent drugs covered in a low tier was substantially higher for P-TKIs than for HMGs and ARBs, despite P-TKIs being more expensive. One explanation might be that the high unmet medical need associated with CML justifies an affordable choice (ie, the clinical data outweigh the economics). On-patent ARBs were slightly less well covered than on-patent HMGs, despite a lower degree of generic competition. Plan providers might consider that other classes of antihypertensives (eg, calcium channel blockers or beta-blockers) are acceptable alternatives to ARBs, and thus do not feel compelled to place numerous drugs in tiers 1 or 2.

Plan competition had a negative impact on P-TKI coverage, but no significant impact on on-patent ARB or HMG coverage. In other words, when on-patent drugs were more scarce and expensive (such as P-TKIs), plans in competitive states limited the number of on-patent drugs with a low copay, possibly to reduce costs.

The key findings were robust: the coefficients' signs and significance levels remained similar for the core variables when: (1) additional covariates were added; (2) alternative models were applied; and (3) subsets of data were analyzed. Additionally, the most comprehensive logit model passed the goodness-of-fit tests.

The analysis presented in this paper could have some public health implications. Newhouse argued that the optimal cost sharing indicated by the RAND health

insurance experiment (HIE) (25% coinsurance) may be suboptimal for medications for chronic diseases, especially medications whose benefits only become apparent in the long term.^{26,27} For instance, Goldman et al found that compliance with cholesterol-lowering therapy was associated with a reduction in the annual rate of hospitalization. However, the study authors also found that higher levels of cost sharing were associated with a reduction in compliance.²⁸ As such, Medicare plan designs may be suboptimal because they rely heavily on cost-sharing (ie, tier 4) for expensive chronic therapies such as P-TKIs.

Limitations

There were some limitations in the data. First, coverage information was not complete for all plans. For example, of 1768 plans in the database, 1579 plans had coverage information for all on-patent HMGs; 1673 for all ARBs; and 1631 for all P-TKIs. Only plans that had coverage information for all on-patent drugs within a therapeutic area were included in the analysis, which could, therefore, suffer from censoring issues. Of the plans that did not have information for all HMGs, 39% were commercial plans and 29% were employer plans. In the whole Fingertip Formulary database, commercial and employer plans represented 22% and 11% of the plans, respectively. There was a high overlap across therapeutic areas between plans without coverage information for all products. For instance, 92% of the plans that did not have coverage information for all ARBs did not have information for all HMGs.

Second, clear conclusions for municipal plans could not be derived because they are heterogeneous, as described in the Background and Objectives sections.

Third, only 11 union plans were included, which made it difficult to draw robust conclusions. If prescription data were available, a Herfindahl index based on the market share of plans may be a better measure of competition than a plan count.

Finally, the analysis was a snapshot of the situation in 2011. As more generics launch in each therapeutic area and as more new drugs become available, the results of this study may not be applicable.

CONCLUSIONS

Compared with commercial plans, the level of on-patient drug coverage was consistently higher in employer, union, and PBM plans, and consistently lower in Medicare plans. One implication would be to reconsider cov-

erage by Medicare plans for chronic therapeutic diseases with high costs. Patients enrolled with Medicaid (ie, the economically poorest segment of the population) had excellent on-patient drug coverage and good access to new technologies. Increased competition between plans does not reduce on-patient drug coverage for all therapeutic areas.

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