

The Impact of Manufacturer Coupon Use in the Statin Market

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ABSTRACT

BACKGROUND: Pharmaceutical manufacturer coupons are a rapidly growing promotional activity intended to encourage initiation and continuing use of brand-name medications, but little is known about impacts on medication adherence and expenditures.

OBJECTIVE: To understand which patients use manufacturer coupons and the impact of coupons on brand-name statin (atorvastatin and rosuvastatin) use and expenditures 1 year after initiation of statin therapy.

METHODS: Using commercially available claims data spanning 3 years and representing 340,350 patients, we compared demographics, statin use, and expenditures of patients initiating generic statins, brand-name statins without manufacturer coupons, and brand-name statins with manufacturer coupons. Differences in user groups were tested using chi-squared statistics and Wilcoxon-Mann-Whitney tests. Main outcome measures included statin fills, adherence, and expenditures, including patient out-of-pocket, payer, and total costs.

RESULTS: With the exception of population density, there were no significant demographic differences between new to therapy brand-name statin users filling prescriptions with and without coupons. New to therapy patients using generics were younger and lived in less populated areas compared with new to therapy brand-name statin noncoupon users. The number of statin fills in the 12 months following initiation was highest for coupon users, slightly lower for patients initiating generic statins, and lowest for noncoupon users (7.1 vs. 6.3 vs. 5.8; $P < 0.001$), with corresponding medication adherence rates (61.1% vs. 60.1% vs. 53.8%; $P < 0.001$). Coupon users had higher total statin prescription costs than generic initiators and noncoupon users (\$798 vs. \$92 vs. \$678; $P < 0.001$), and higher precoupon out-of-pocket costs (\$339 vs. \$53 vs. \$169; $P < 0.001$). Health plan costs for statins excluding rebates were lower for coupon users than noncoupon users (\$460 vs. \$508; $P < 0.001$) but were much higher compared with generic statin initiators (\$460 vs. \$39; $P < 0.001$).

CONCLUSIONS: Brand-name statin initiators using coupons have higher adherence than patients initiating generic statins or brand-name statins without coupons. While the differences in adherence were statistically significant, they may not be clinically significant. Higher adherence among coupon users appears to occur at the expense of higher out-of-pocket and total statin expenditures.

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What is already known about this subject

- Elevated serum cholesterol has long been identified as a major risk factor for the development of cardiovascular disease (CVD). The morbidity costs associated with CVD in the United States are staggering. In 2008, the annual cost of treating CVD in the United States was estimated to be \$297.7 billion.

- Medication adherence and persistence to statins is a significant challenge. A meta-analysis of statin adherence reports that the proportion of patients after 12 months of therapy with a medication possession ratio greater than 80% was only 51%. The percentage of patients remaining on lipid-lowering therapy after 12 months is estimated to be only 65.5%.
- Reduction in patient out-of-pocket costs has been shown to improve medication-taking behavior for statins.
- Manufacturer coupons have become a significant promotional tool for the pharmaceutical industry that is intended to reduce patient out-of-pocket costs.
- Very little is known about the impact of coupons on medication adherence and costs.

What this study adds

- Demographic characteristics of new statin patients who choose to use coupons do not differ in any practically significant way from noncoupon-using statin initiators.
- New to therapy brand-name statin patients using coupons had significantly more refills and significantly better medication adherence during the first year of therapy than noncoupon-using brand-name statin patients.
- There was no practical difference in medication adherence between new to therapy brand-name statin users who redeemed coupons and new to therapy generic statin users.
- Within plans, new to therapy brand-name statin patients using coupons tend to have higher prescription costs (excluding rebates) than noncoupon brand-name-using new statin patients and generic statin-using patients. It is unclear whether these slightly higher plan costs are driven by increased statin adherence or better medication adherence across all medications taken by coupon users.

Pharmaceutical manufacturers have committed significant resources to promotional activities such as drug samples and copay discount coupons that reduce patient out-of-pocket costs associated with the purchase of single-source branded medications. Pharmaceutical industry spending on samples was \$15.9 billion in 2004, representing approximately 27.7% of overall promotional spending.¹ As a result of this investment, 18.3% of patients taking a prescription medication received a drug sample between 1999 and 2005.² Coupons are a smaller, but rapidly growing (260% increase to \$4 billion in past 2 years), promotional activity that is estimated to generate a \$4-\$6 return on every dollar spent.³

However, coupon use has become contentious. Manufacturers argue that patients are familiar with coupons, coupons improve medication adherence by lowering patients' out-of-pocket costs, and coupons are a safer alternative to drug samples because drug dispensing requires a licensed pharmacist.⁴ Managed care organizations (MCOs) counter that coupons provide an incentive for patients to initiate and remain on brand-name medications when a suitable less costly generic medication is available, which interferes with the MCOs ability to ensure appropriate utilization and control medication expenditures.⁵⁻⁷

A recent editorial outlined the hypothetical impacts of coupons on patient and health plan costs for brand-name statins,⁴ but there is no empirical evidence to support or refute these competing claims. Given that manufacturer coupons likely reduce patient out-of-pocket expenses, a large body of literature supports the relationship between reductions in cost sharing and improvements in adherence.⁸⁻¹⁰ Of particular note, work by Pedan et al. (2007) found that adherence to statins was lower for patients with higher copayments. Their findings indicated that adherence decreased by 2.2% for every \$10 increase in copay ($P < 0.001$).¹¹ However, there have been no empirical studies of the impact of coupons on adherence or health care costs.

To provide the first population-based evidence about the impact of coupons, we compared demographics, statin use, and expenditures of new to therapy (incident) users of generic statins, single-source brand-name statins without manufacturer coupon redemption, and single-source brand-name statins with manufacturer coupon redemption. We evaluated the impact of coupons on the statin drug class because of the important role that statins play in managing cardiovascular disease,¹² the number of branded single-source statin manufacturers offering coupons for these agents, and the volume of statins prescribed in the United States each year.¹³ We examined incident statin users to understand the impact of coupons on statin initiation and improve comparability across cohorts in estimating the effect of coupons on adherence.¹⁴

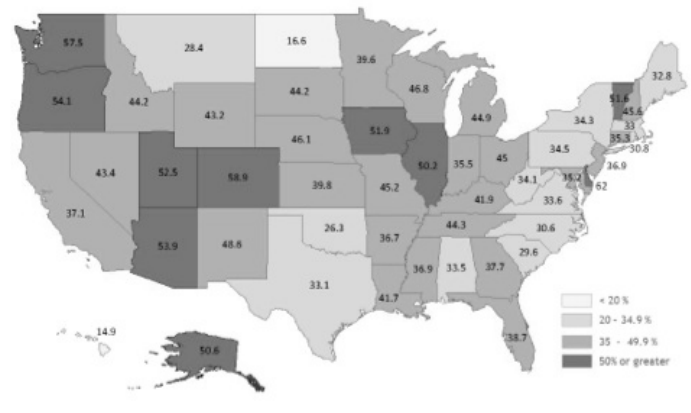
We also examined differences in demographic characteristics, statin fills, adherence, and drug costs across several plans with differing copayment structures for brand-name statins in an effort to inform formulary policy. These results provide the first empirical evidence clarifying manufacturer and MCO claims relative to the adherence and cost impacts of coupons in the statin market. Such information should enable more informed decisions with regard to formulary management of branded statin agents.

Methods

Data

The data used in this study are 2008-2010 retail prescription claims provided by Symphony Healthcare Solutions (SHS), identifying cash claims, primary and secondary insurance

FIGURE 1 Percentage of Total Retail Claims Captured by State (2010)¹⁵



coverage, prescription expenditures, and coupon use. These unique data represent approximately 40% of prescriptions (brand and generic) used in the treatment of dyslipidemias filled by retail pharmacies in the United States and are geographically representative of the U.S. retail pharmacy market in terms of patient demographics and pharmacy ownership. These data are collected from retail pharmacies so they represent all payers, including commercial, Medicaid, Medicare, and cash. Mail-order pharmacy claims are not observable, but they do not bias these results because mail-order pharmacies generally do not accept coupons. The percentages of total retail claims captured by state as estimated by SHS¹⁵ are displayed in Figure 1.

These data are uniquely suited for this analysis because they provide the ability to identify all sources of prescription payment, including primary payers, secondary payers, and cash payments by patients. Furthermore, these data facilitate longitudinal patient tracking upon changes in prescription coverage for patients remaining within the pharmacy cohort. Data related to income, education, and population density from 2010 census data were linked to these prescription claims to facilitate demographic comparisons between the cohorts.

Study Design and Sample

This study is a retrospective cohort analysis of incident users of select single-source/single-agent branded statin agents and generic statin therapy. Patients are uniquely identified as coupon users of atorvastatin or rosuvastatin, noncoupon users of the atorvastatin or rosuvastatin, or incident users of a generic statin (lovastatin, pravastatin, or simvastatin). During the observation period, atorvastatin and rosuvastatin had coupons in all geographies.

The initial data extract included more than 20.1 million patients who filled any prescription for a lipid-lowering agent, which was reduced to 2,082,444 patients aged 18-64 who

received atorvastatin or rosuvastatin or a generic statin for the first time between January 1, 2009, and January 1, 2010. Of these 2.08 million incident statin users, patients were excluded if they were not commercially insured (n=423,262) because coupons cannot be used by patients in federally funded programs (Medicaid or Medicare). A commercial population was also selected because use of coupons has been contentious in this population due to the potential impact of coupons on utilization and cost given the large numbers of insured patients.^{3,5,7} A patient is defined to have commercial coverage if more than 50% of their observed prescriptions during the observation period were reimbursed by a commercial payer. We excluded patients with a lapse in prescription activity of 3 or more continuous months during the 24-month period from January 1, 2009, to December 31, 2010 (n=1,261,856), and if they lacked 1 year of prefill data to confirm initiation and 1 year of postfill data to track fills, adherence, and costs.¹⁶ We also excluded 56,976 patients who did not have complete data, resulting in a final analytic cohort of 340,350 patients. These patients were then defined as generic statin initiators, brand-name statin initiators with coupon redemption, or brand-name statin initiators without coupon redemption on the basis of the first observed statin filled in the study period. Patients were defined as a brand-name initiator if their first statin fill was for atorvastatin or rosuvastatin. Within this subgroup of brand-name initiators, patients were identified as coupon users if at least 1 coupon was used in a claim for atorvastatin or rosuvastatin during the 1-year observation period following the initiation of statin therapy. Otherwise, patients were defined as noncoupon users. A consort diagram is presented in Figure 2.

Coupons used in prescription fills were identified using unique payer identifiers corresponding to coupon vendors in the SHS claims data. A total of 12 coupon vendors were identified by the first author (Daugherty) from lists of coupon vendors provided by SHS and a nationally recognized consulting firm that provides syndicated reporting to the health care industries.

The analytic set contains data representing 340,350 patients within 1,327 unique commercial plans. From the original cohort, we identified a subsample of patients from 4 plans with at least 5,000 statin claims to examine whether the association between coupons, medication use, and expenditures varied across statin copayment levels. Of the 4 plans with 5,000 or more statin claims, the average copays ranged from \$25 to \$38 per 30-day fill of atorvastatin or rosuvastatin. Plans were selected subjectively to ensure a distribution in average copayments. The final subgroup of 4 plans contains 10,327 incident statin users.

Outcomes

We selected 2 statin utilization outcomes—count of statin fills and statin refill adherence—1 year after initiation. To evaluate differences in medication adherence, we compared the medication possession ratio (MPR) for statin use among coupon-use

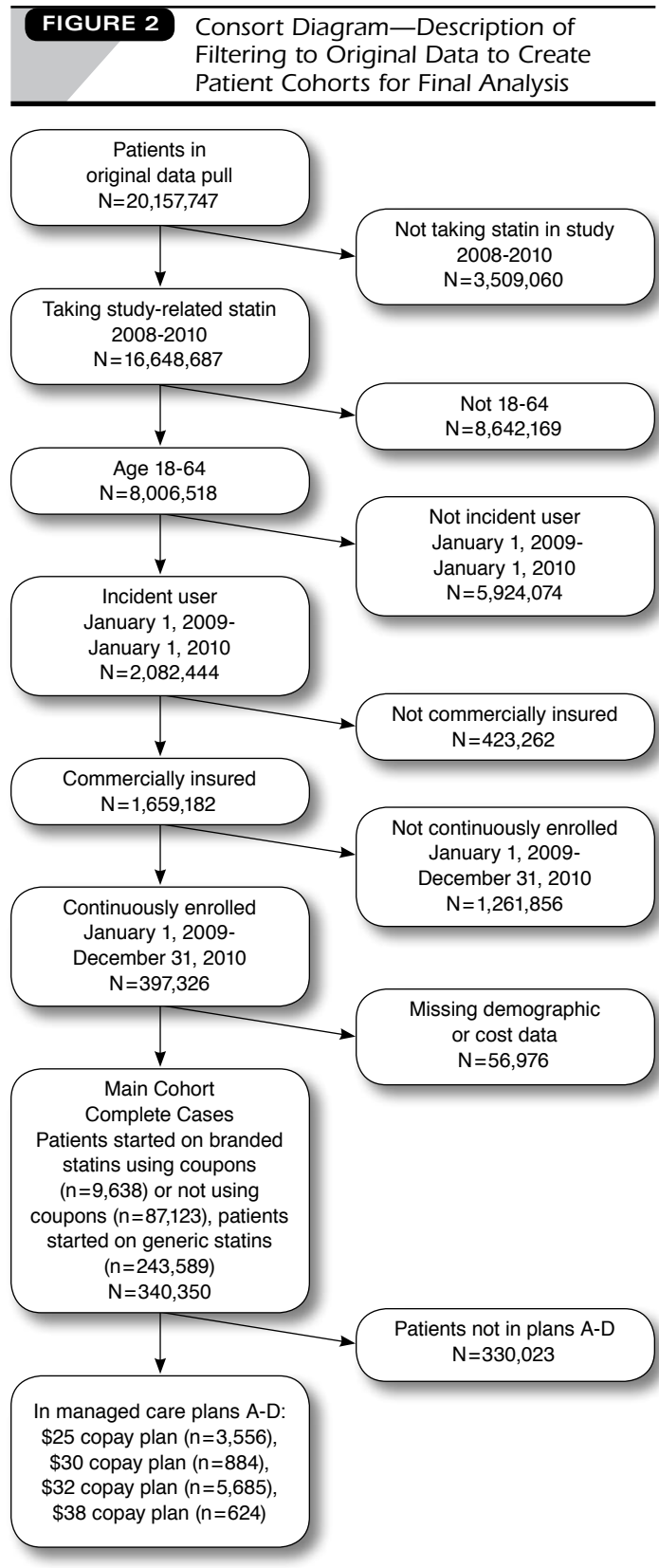


TABLE 1 Demographics of Brand and Generics Statin Users by Coupon Use Group (2008-2010)

	Brand Non-Coupon Users (n = 87,123) Mean (SE)	Brand Coupon Users (n = 9,638) Mean (SE)	Generic Users (n = 243,589) Mean (SE)
Demographic Characteristics			
Male (%)	47.7	47.4 ^b	43.4 ^d
Age	54.4 (0.03)	54.2 (0.08) ^c	54.0 (0.01) ^c
Expected Rx-risk score	\$1,980 (6)	\$1,798 (15) ^d	\$1,846 (3) ^d
Bachelor's degree in ZIP code (%) ^a	25.5 (0.03)	24.5 (0.09) ^d	24.4 (0.02) ^d
Median income in ZIP code ^a	\$47,328 (45)	\$46,129 (119) ^d	\$45,596 (23) ^d
Population per square mile in ZIP code ^a	2,987 (33)	1,491 (52) ^d	1,692 (12) ^d
Medication Utilization in 12 Months Following Statin Initiation			
Count of fills for all prescriptions	40.3 (0.10)	39.0 (0.25)	40.3 (0.06) ^c
Total expenditures for all prescriptions	\$3,302 (18)	\$3,022 (35)	\$2,168 (12) ^d
Total nonstatin Rx expenditures	\$2,625 (17)	\$2,224 (35) ^d	\$2,075 (12) ^d
Statin use			
Number of fills	5.8 (0.01)	7.1 (0.04) ^d	6.3 (0.01) ^d
Statin adherence (%)	53.8 (0.11)	61.1 (0.30) ^d	60.1 (0.07) ^d
Percent of patients MPR > 80%	30.4	36.7	38.4

^aUsing 2009 data; ZIP code is aggregated to the first 3 digits.

^bP < 0.05.

^cP < 0.01.

^dP < 0.001.

MPR = medication possession ratio; Rx = prescription; SE = standard error.

groups. The MPR calculation used in this study was the total days of therapy available during the observation period divided by 365 (the length of the observation period). We dropped any days supply remaining after the 1-year observation period. If the total of days supply dispensed exceeded 365, we truncated the MPR to 1.0.¹⁷

We also selected 3 statin expenditure outcomes—out-of-pocket costs, plan costs, and total costs—1 year after initiation. As the incentive to use a coupon may be related to the initial out-of-pocket prescription costs, we standardized the out-of-pocket costs to the cost prior to coupon use by adding the coupon discount to the final patient out-of-pocket cost noted on the claim. This facilitates comparison of copays among groups in an effort to identify patterns of coupon use that may be dependent upon the copay required by the primary insurer. To determine the gross cost of the medication to the plan, we subtracted the patient out-of-pocket costs from the total cost of the claim. Plan costs in this analysis do not take into consideration any rebates available from the manufacturers. All cost data are inflation adjusted to 2009 dollars.

Explanatory Variables

To examine demographic differences between the 3 cohorts, we examined gender, age, and comorbidity as measured by the Rx-Risk score.¹⁸ This score is a measure of comorbidity generated from the presence of prescription claims across 45 distinct pharmacologic classes shown to be predictive of prescription expenditures. Higher Rx-Risk scores generally represent higher levels of comorbidities. The Rx-Risk score has been shown to explain more variation in total medical expenditures than the Charlson Comorbidity Index.^{19,20} The Rx-Risk values represent the expected value of pharmacy costs. Population-weighted averages of median income, education (proportion earning a college degree), and population density (population per square mile) were estimated using 2009 census data at the 3-digit ZIP code level. This information is included to better understand the potential role of socioeconomic status on coupon use and is not meant to infer causal relationships.

Statistical Analysis

Continuous variables (age, Rx-Risk score, statin cost, and adherence) were compared among groups using the Wilcoxon-Mann-Whitney test, while gender differences were examined using chi-squared tests. Due to the large sample size of the overall cohort, differences in the total sample are considered significant if $P < 0.01$. Since the plan-level analysis is conducted on smaller samples, differences at the plan level are considered significant if $P < 0.05$. All analyses were performed using SAS Enterprise Guide v4.2 (SAS Institute, Inc., Cary, North Carolina).

Results

Characteristics, Medication Utilization, and Expenditures in the Overall Cohort

The vast majority (n = 243,589 or 71.6%) of the overall cohort initiated generic statins during the study period, 25.6% (n = 87,123) of the sample initiated statin therapy with atorvastatin or rosuvastatin and had no coupon use, and 2.8% (n = 9,638) initiated atorvastatin or rosuvastatin and used a coupon during the study period. Compared with noncoupon users who initiated statin therapy (Table 1), coupon users were slightly less often male (47.4% vs. 47.7%; $P < 0.01$), slightly younger (54.2 vs. 54.4; $P < 0.01$), had lower expected comorbidity scores (\$1,798 vs. \$1,980; $P < 0.001$), and lived in areas with modestly lower proportions of college graduates (24.5% vs. 25.5%; $P < 0.001$) and lower population density (1,491 population/square mile vs. 2,987 population/square mile, $P < 0.001$). Compared with generic statin initiators, coupon users who initiated atorvastatin or rosuvastatin therapy were more often male (47.4% vs. 43.4%; $P < 0.01$), modestly older (54.2 vs. 54.0; $P < 0.01$), had slightly lower comorbidity scores (\$1,798 vs. \$1,846; $P < 0.001$), and lived in areas with modestly higher

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TABLE 2 Average 12-Month Prescription Count, Adherence, Rx Risk, Coupon Redemption, and Coupon Value by Coupon Use by Managed Care Plan

	Brand Initiating Patient Sample		Plan A (\$25 Average Copay)		Plan B (\$30 Average Copay)		Plan C (\$32 Average Copay)		Plan D (\$38 Average Copay)		Generic First Patient Sample	
	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)
12-Month Statin Count												
No coupon use	87,123	5.8 (0.01)	3,301	6.3 (0.1)	843	6.6 (0.1)	5,082	6.8 (0.1)	555	6.8 (0.2)	243,589	6.3 (0.01)
Coupon users	9,638	7.1 (0.04) ^c	255	7.0 (0.2) ^b	41	8.1 (0.5) ^a	603	8.0 (0.2) ^c	69	8.6 (0.5) ^c		N/A
Statin Adherence												
No coupon use (%)		53.8 (0.1)		52.1 (0.6)		55.2 (1.1)		55.3 (0.5)		57.5 (1.4)		60.1 (0.1)
Coupon users (%)		61.1 (0.3) ^c		57.8 (2.0) ^a		66.6 (4.2) ^a		64.6 (1.2) ^c		70.3 (3.3) ^b		N/A
Rx Risk Score												
No coupon use		\$1,980 (6.2)		\$1,960 (28.6)		\$1,931 (71.2)		\$1,868 (23.4)		\$1,785 (66.5)		\$1,846 (3.2)
Coupon users		\$1,798 (15.5) ^c		\$1,809 (102.1)		\$1,702 (187.4)		\$1,639 (54.6) ^b		\$1,666 (137.5)		N/A
Average coupon redemptions per patient	9,638	3.8 (0.03)	255	3.7 (0.20)	41	4.1 (0.47)	603	4.1 (0.14)	69	4.2 (0.41)		N/A
Average coupon value	26,344	\$16.17 (0.09)	868	\$14.55 (0.46)	148	\$15.19 (0.67)	2,188	\$17.01 (0.29)	264	\$21.44 (0.89)		N/A

^a $P < 0.05$.

^b $P < 0.01$.

^c $P < 0.001$.

N/A = not applicable; Rx = prescription; SE = standard error.

proportions of college graduates (24.5% vs. 24.4%; $P < 0.001$) and lower population density (1,491 population/square mile vs. 1,692 population/square mile; $P < 0.001$). Those initiating generic statins had the lowest total and nonstatin-related prescription costs, followed by coupon users and noncoupon users (Table 1).

The number of statin fills in the 12 months following initiation was highest for coupon users, slightly lower for patients initiating generic statins, and lowest for noncoupon users (7.1 vs. 6.3 vs. 5.8; $P < 0.001$), with corresponding medication adherence rates (MPR 61.1% vs. 60.1% vs. 53.8%; $P < 0.001$). However, the proportion of patients with 80% or greater adherence in the 12 months following initiation was highest for patients initiating generic statins, followed by coupon users and noncoupon users (38.4% vs. 36.7% vs. 30.4%; $P < 0.001$) (Table 1). Coupon users redeemed an average of 3.8 coupons in the 12 months following initiation, with an average value of \$16.17 (Table 2).

Coupon users had total statin expenditures that were much higher than generic statin initiators (\$798 vs. \$92; $P < 0.0001$), much higher out-of-pocket costs (\$339 vs. \$53; $P < 0.0001$), and much higher statin costs to the health plan (\$460 vs. \$39; $P < 0.001$) (Figure 3). When comparing brand-name statin initiators, coupon users had somewhat higher total statin costs than noncoupon users (\$798 vs. \$678; $P < 0.0001$), much higher out-of-pocket costs (\$339 vs. \$169; $P < 0.001$), but lower health plan costs (\$460 vs. \$508; $P < 0.001$).

Characteristics, Medication Utilization, and Expenditures in the Managed Care Cohorts

In an effort to identify impacts of coupon use within plans, we compared 4 commercial plans from 1 national MCO and 3 different pharmacy benefit managers with a range of average copays on a 30-day supply of the atorvastatin or rosuvastatin. Plans with the largest claim counts for 30-day supplies of atorvastatin or rosuvastatin with minimum average copay differences of \$2 were selected. The average copay for atorvastatin or rosuvastatin was \$25 in Plan A, \$30 in Plan B, \$32 in Plan C, and \$38 in Plan D (Table 2). As in the overall patient sample, coupon users in all 4 plans filled more prescriptions for statins than noncoupon users in the year following initiation: Plan A (7.0 vs. 6.3; $P < 0.01$), Plan B (8.1 vs. 6.6; $P < 0.05$), Plan C (8.0 vs. 6.8; $P < 0.001$), and Plan D (8.6 vs. 6.8; $P < 0.001$). Medication adherence to statins in the first year of initiation was significantly higher for coupon users across all plans: Plan A (54.5% vs. 48.8%; $P < 0.05$), Plan B (66.4% vs. 50.0%; $P < 0.01$), Plan C (60.7% vs. 50.7%; $P < 0.001$), and Plan D (67.1% vs. 50.1%; $P < 0.001$) (Table 2). Coupon redemptions ranged across plans from 3.7 to 4.2, with the highest average coupon redemption rate (4.2 per patient) in the plan with the highest average copay (Plan D).

Consistent with higher numbers of statin fills and higher adherence, total first-year statin treatment costs and out-of-pocket costs for coupon users were higher than nonusers (Table 3). Health plan expenditures for statins were significantly higher for coupon users in the higher copay plans: Plan C (\$581 vs. \$507; $P < 0.001$) and Plan D (\$579 vs. \$473; $P < 0.01$).

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TABLE 3 Statin Out-of-Pocket, Health Plan, and Total Costs by Coupon Use Overall and by Plan

	Brand First Patient Sample		Plan A (\$25 Average Copay)		Plan B (\$30 Average Copay)		Plan C (\$32 Average Copay)		Plan D (\$38 Average Copay)		Generic First Patient Sample	
	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)	n	Mean (SE)
12-Month Rx Costs												
Total Statin Costs												
No coupon use	87,123	\$678 (1.7)	3,301	\$706 (8.4)	843	\$705 (16.0)	5,082	\$716 (6.7)	555	\$723 (21.0)	243,589	\$92 (0.3)
Coupon users	9,638	\$798 (4.8) ^c	255	\$798 (30.6) ^b	41	\$883 (59.1) ^a	603	\$875 (18.1) ^c	69	\$975 (57.4) ^c		N/A
Out-of-Pocket Costs												
No coupon use		\$169 (0.6)		\$152 (2.4)		\$189 (5.8)		\$209 (2.5)		\$250 (10.1)		\$53 (0.1)
Coupon users (precoupon)		\$339 (3.1) ^c		\$239 (13.4) ^c		\$333 (30.5) ^c		\$294 (7.7) ^c		\$395 (27.0) ^c		N/A
Coupon users (postcoupon)		\$194 (1.7) ^c		\$169 (6.6)		\$266 (26.3) ^b		\$209 (5.7)		\$293 (22.9) ^b		N/A
Net plan cost (before rebates)												
No coupon use		\$508 (1.4)		\$554 (7.1)		\$516 (13.0)		\$507 (5.3)		\$473 (16.3)		\$39 (0.2)
Coupon users		\$460 (3.8) ^c		\$559 (23.4)		\$550 (48.6)		\$581 (14.4) ^c		\$579 (40.6) ^b		N/A

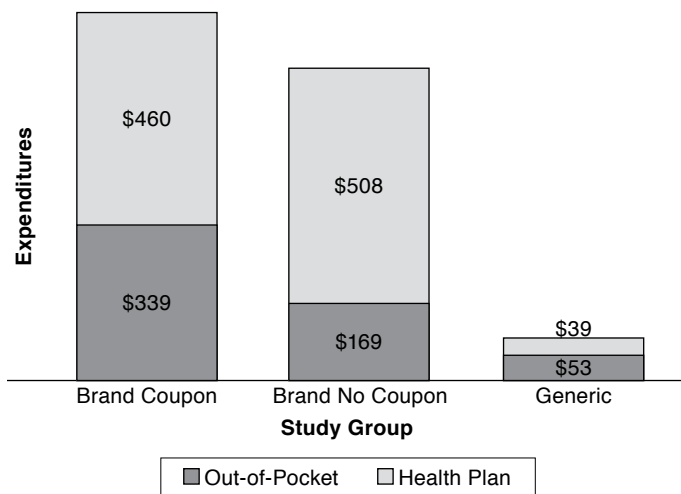
^aP < 0.05.

^bP < 0.01.

^cP < 0.001.

N/A = not applicable; Rx = prescription; SE = standard error.

FIGURE 3 Out-of-Pocket, Health Plan, and Total Statin Expenditures in 12 Months Following Statin Initiation



The finding that noncoupon-using patients initiating brand-name statins had lower adherence is not surprising as it is well established that high patient cost sharing is a significant barrier to medication adherence^{10,21,22} and that adherence to chronic medications improves when cost sharing is reduced.^{23,24}

It is apparent from our study that coupon users experienced reduced out-of-pocket costs for branded statins. We find that reduced out-of-pocket costs were associated with improved adherence as demonstrated by coupon users filling 1.3 more prescriptions than noncoupon users in the year after initiation. These findings are consistent with literature examining the relationship between lower out-of-pocket cost and adherence.^{8-11,23,24} In the plan subsample, coupon users in the plans with the highest statin copayment had 1.8 more fills than nonusers, while coupon users in the plans with the lowest statin copayment had 0.7 more fills than nonusers. This finding suggests that coupons are used more often by patients in plans with higher copayments.

We found evidence that greater adherence among coupon users came at the expense of higher out-of-pocket, health plan, and total statin expenditures. While coupon use appears to positively impact adherence to brand-name statins, overall pharmacy plan costs associated with coupon use are significant because the average annual plan costs for generic statin therapy was \$39 compared with \$460 for coupon users. This 12-fold difference in statin cost provides a significant incentive for health plans to switch patients to a therapeutically equivalent generic when clinically appropriate. Therapeutic interchange programs for statins have been shown to be cost effective for payers.^{25,26} The impact of coupon use on total costs and outcomes remains an issue for further research.

Discussion

There is an ongoing debate about the value of coupon programs among prescription manufacturers, MCOs, and patients.³⁻⁷ This study presents the most rigorous evidence to date regarding the impacts of coupons on medication adherence and costs based on a large cohort of incident users of rosuvastatin or atorvastatin. We find that brand-name statin initiators who used coupons had slightly higher adherence than patients initiating generic statins or brand-name statins without coupons.

Research into the use of coupons for consumer package goods has shown that women²⁷ and people with more education or higher incomes are more likely to use coupons.²⁸ Prior research has shown that patients receiving prescription drug samples also tend to have higher income²⁹ and are younger.³⁰ We found that patients using coupons for brand-name statins were demographically distinct (less often male, slightly younger, and somewhat healthier) from patients receiving samples, which suggests that coupons may be reaching a different cohort of patients than samples. However, our expenditure results are consistent with prior work showing that patients receiving drug samples have higher prescription expenditures than their counterparts.³⁰ Given the paucity of evidence about the characteristics of prescription coupon users, impacts on medication adherence and drug expenditures, and the rapid growth in coupon programs, future research should examine whether the results reported here remain consistent or vary by therapeutic class.

As evidenced from higher adherence among coupon users, coupon use may support adherence upon initiation of a statin in cases where the branded product is clinically appropriate. It is important to realize that coupon use is a self-selected activity requiring patients to remember to provide the coupon to the pharmacist when provided by the physician or to actively seek a coupon via the Internet and then provide the coupon to the pharmacy. In both cases, the patient displays a potentially higher level of engagement with their drug therapy. Patients with higher levels of engagement in their medical care, so-called healthy users, have been shown to have better medication adherence^{31,32} and better medical outcomes.³²⁻³⁴ It is unclear from these data if patients using coupons were those with higher levels of engagement or displayed higher levels of medication adherence in general. The relationship between coupon use, patient engagement, and prior medication adherence patterns should be a topic of further research.

Limitations

This study is subject to several limitations. As previously mentioned, we approximated patient characteristics of education, income, and population density by linking prescription claims to Census data because these data were not available in the prescription claims. These covariates aggregated to the 3-digit ZIP code level introduce significant potential for ecological fallacy and limit the statistical power compared with patient-level covariates. The plan cost data should be interpreted with caution because manufacturer rebates have been omitted from plan costs. No attempts were made to model the impact of covariates on outcome measures. Lastly, the adherence measures used represent the average medication-taking behavior for all statins received by the patient. We did not identify switching behavior or changes in adherence that might have been associated with switches from brand to generic products.

This is significant because coupon-using patients who switch to a generic statin and maintain or improve their medication adherence with similar lipid-lowering effects represent a clearly cost-effective scenario for plans. It is unclear from this research if this is the case. Additional research is needed to resolve this question in an effort to further inform payer policy.

Conclusions

Brand-name statin initiators using coupons have slightly higher adherence than patients initiating generic statins or brand-name statins without coupons at the expense of higher out-of-pocket and total statin expenditures, which suggests that generics remain the most cost-effective pharmacotherapy for both patients and plans. Whether the impact of improved adherence associated with coupon use is associated with lower overall medical costs and improved outcomes remains an open question.

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DISCLOSURES

Daugherty is currently employed in Global Health Outcomes at GlaxoSmithKline and holds stock and stock options at GlaxoSmithKline. Maciejewski and Farley have received consultation funds from Takeda Pharmaceuticals, Novartis, and the Surgical Review Corporation. Maciejewski is supported by a VA HSR&D Research Career Scientist Award (RCS-10-391); he owns stock in Amgen due to his spouse's employment. None of the authors have any affiliation with companies, products, or services mentioned in this article.

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