

# Lowering Copayments: Impact of Simvastatin Patent Expiration on Patient Adherence

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In an effort to keep pace with rising prescription drug costs, health plans have implemented various cost-sharing strategies including prescription medication copayments, tiering, and coinsurance. Goldman and colleagues reported in their literature review of 65 studies that a 10% increase in patient cost sharing (eg, copayment increase) would result in a 2% to 6% decline in prescription medication use or expenditures.<sup>1</sup> The resulting decline in medication utilization is cause for concern, given the reported relationship between patient adherence and health outcomes.<sup>2,3</sup> Understandably, 1 method to improve prescription medication adherence that has received considerable attention among health plan decision makers is to lower patient copayments. Unfortunately, the benefit of this approach for medication adherence has not been evaluated fully.

The 3-hydroxy-3-methyl-glutaryl-CoA reductase inhibitors (statins) have been shown to be efficacious in reducing morbidity and mortality associated with coronary heart disease.<sup>6,7</sup> Several studies have reported a relationship between increasing statin copayments and decreasing adherence.<sup>2,5-7</sup> Evidence from these studies has been used to speculate that a similar marginal increase in adherence will result from lowering copayments.<sup>8</sup> However, only 1 study to date has provided data to support this hypothesis by examining the relationship between decreasing copayments and statin adherence.<sup>9</sup> In this quasi-experimental study of patients enrolled in a disease management program, copayment amounts were decreased from \$5 to \$0, \$25 to \$12.50, and \$45 to \$22.50 for generics, brands, and nonpreferred drugs, respectively, resulting in a 3.4% increase in statin medication adherence.

On June 23, 2006, the patent for the statin Zocor (simvastatin) expired. This patent expiration and ensuing introduction of generic simvastatin resulted in lower copayments for patients who had at least a 2-tiered (brand/generic) prescription medication benefit and whose refills were automatically converted to the generic. This occurrence provided a naturalistic setting to contrast adherence changes among patients without a copayment decrease (ie, those who were receiving a non-simvastatin brand statin before the patent expiration) and patients with a copayment decrease (ie, those who were receiving the branded simvastatin before the patent expiration). Thus, the purpose of this study was to examine the effect on medication adherence of a decrease in patient copayments and demand for statins after the simvastatin patent expiration.

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**Objective:** To assess the impact of a decrease in statin copayments on medication adherence and demand for statins.

**Study Design:** Quasi-experimental, pre/post design.

**Methods:** Patients in more than 700 health plans from June 2005 to May 2007 were evaluated. The intervention group (n = 13,319) and matched control group (n = 26,569) included patients who had at least 1 branded simvastatin or non-simvastatin statin purchase, respectively, before the simvastatin patent expired in June 2006. Intervention and control patients had to have purchased at least 1 generic simvastatin and non-simvastatin statin, respectively, after patent expiration. Intervention patients were matched to control patients up to 1:2 on incident statin use (yes/no) and pre-patent expiration copay ( $\pm$  \$2). Adherence was calculated with the medication possession ratio (MPR). Adjusted and unadjusted changes in MPR were compared between groups. Elasticity of demand for statins was estimated.

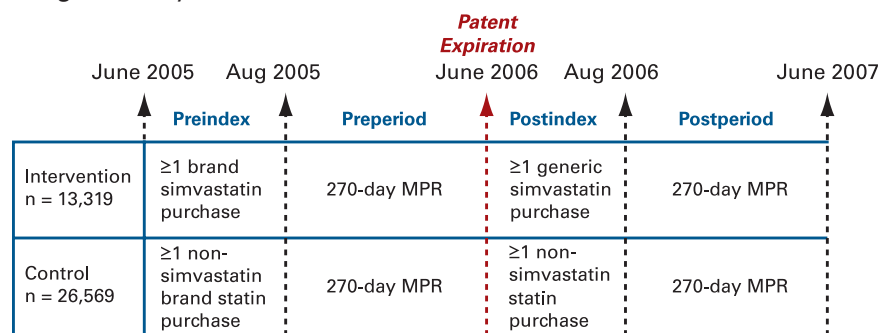
**Results:** A small but statistically significant difference was observed between groups in the change in MPR (intervention = 0.52% adjusted mean increase, control = 2.02% adjusted mean decrease; adjusted  $P < .01$ ). A marginally higher percentage of intervention patients (10.5%) compared with control patients (10.0%) increased their MPR from  $<80\%$  in the preperiod to  $\geq 80\%$  in the postperiod (adjusted  $P < .01$ ). Elasticity of demand for statins was estimated at 0.02 and  $-0.02$  for the copayment reduction categories of \$0 to \$5 and  $> \$15$ , respectively.

**Conclusions:** Decreasing statin copayments was associated with adherence increases. However, the overall increase in medication adherence was modest and its clinical significance uncertain.

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Figure. Study Timeline<sup>a</sup>



MPR indicates medication possession ratio.

<sup>a</sup>The preperiod extended from the date of the first statin purchase in the preindex period through the following 270 days. The postperiod extended from the date of the first statin purchase in the postindex period through the following 270 days.

## METHODS

### Study Population

Prescription claims data from a nationwide population of more than 700 plan sponsors (managed care organizations, insurance carriers, employer groups, third-party administrators, and public sector–sponsored and union-sponsored pharmacy benefit plans) that were enrolled with the pharmacy benefit manager Express Scripts Inc from June 2005 through May 2007 were eligible for this study. Only those plan sponsors that offered integrated prescription coverage that included both a home-delivery and retail benefit within an employer-based market (ie, no Medicare or Medicaid) and did not change their preferred brand copayment during the preindex period and postindex period by more than \$3 were eligible for inclusion. In addition, eligibility was limited to patients ≥18 years of age who were statin purchasers and were continuously eligible during the study period. This study was not submitted to an institutional review board; however, all regulations related to the Health Insurance Portability and Accountability Act were followed.

### Research Design

A quasi-experimental, pre/post, controlled design was used. From eligible plans, 13,319 patients who purchased at least 1 brand simvastatin prescription between June 1, 2005, and August 31, 2005 (preindex period) and at least 1 generic simvastatin prescription between June 1, 2006 and August 31, 2006 (postindex period) were identified as intervention group patients (Figure). A control group of 26,569 patients who purchased at least 1 non-simvastatin brand statin prescription in the preindex period and at least 1 non-simvastatin statin prescription in the postindex period were identified as control group patients. Adherence, as measured by the medication possession ratio (MPR),<sup>10</sup> was assessed from the date of the first purchase in the

preindex period through the following 270 days (preperiod) and date of the first purchase in the postindex period through the following 270 days (postperiod) (Figure). This schema restricts a patient's MPR calculation to the dates most proximal to the simvastatin patent expiration.

The control group was matched to the intervention group at a ratio of 2:1 based on incident statin purchaser (yes/no) and preperiod copayment amount ( $\pm$  \$2) using the method of Bergstralh and Kosanke.<sup>11</sup> To avoid overmatching, only these variables were selected

because they have been associated previously with statin adherence.<sup>2</sup> Incident statin purchaser was defined as a patient with no statin purchase in the 130 days before his or her first preindex period purchase. Two controls and 1 control were matched to 13,250 and 69 intervention patients, respectively.

### Outcomes

The primary outcome measure for this study was the change in adherence. The change in MPR was calculated by subtracting the preperiod MPR from the postperiod MPR. Secondary outcomes include assessment of the percentages of patients who increased their MPR to  $\geq 80\%$  in the postperiod from  $< 80\%$  in the preperiod and decreased their MPR to  $< 80\%$  in the postperiod from  $\geq 80\%$  in the preperiod. Elasticity of demand for statins was estimated between the highest and lowest copayment reduction categories. Comparisons of changes in MPR between various subgroups were made.

### Analysis

Medication possession ratios were calculated for each patient as the sum of the days' supply for statin purchases in each observation period divided by 270 and then multiplied by 100 to obtain a percentage.<sup>10</sup> The days' supply of the last statin purchase in the observation period was truncated if it went beyond the 270-day follow-up period; thus, MPR values could not exceed 100%. Although the initial statin purchase was brand simvastatin for the intervention group and any other brand statin for the control group, adherence was based on any filled statin prescription in the pre- or postperiod to allow for switching within the statin class.

The MPR in both the pre- and postperiods was categorized as  $< 80\%$  and  $\geq 80\%$ . A chronic disease score (CDS) was calculated using prescription medication purchases from the first 6 months of 2006.<sup>12</sup> The CDS provides a numerical accounting of each patient's baseline health status. The CDS

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was log transformed because of its nonnormal distribution. Mean copayments during the pre- and postperiods were determined for intervention patients. A change in copayment was determined for the intervention patients by subtracting the postperiod copayment from the preperiod copayment. These values were categorized as  $\geq \$0$ , declines of \$0.01 to \$5.00, declines of \$5.01 to \$10.00, declines of \$10.01 to \$15.00, and declines of  $> \$15.00$ . This change was not assessed in the control patients as the percentage of patients with a copayment decrease was negligible.

Baseline differences between the intervention and control groups with respect to age, sex, incident statin purchaser, CDS, preperiod adherence, and preperiod copayment were assessed with adjustment of the standard errors for the intracorrelations of matched patients using multiple linear regression models for continuous variables and logistic regression for categorical variables. The unadjusted relationship of the group on the change in MPR was assessed using multivariate linear regression with adjustment for the intracorrelations of matched patients. The adjusted relationship of the group on the change in MPR was assessed with multivariate linear regression with adjustment for the intracorrelations of matched patients and age, sex, incident statin purchaser, CDS, preperiod MPR, and pre-period copayment. Using this fitted regression model, adjusted mean MPR changes were calculated for the intervention and control groups by setting all covariates to the population mean values.

To further explore the relationship between adherence and copayment amount, another multivariate linear regression model was fit using data from the intervention group only. The 5 levels of change in copayment amount were regressed on change in MPR while adjusting for the covariates listed previously. Adjusted mean MPR changes were calculated for the categories of copayment change by setting all covariates

to their mean values. Elasticity of demand was calculated as the percent change in MPR divided by the percent change in copayment. Sensitivity analyses were performed by removing subpopulations of patients including (1) all patients with coinsurance (ie, they may not have experienced as dramatic a decrease in copayment because of market exclusivity of the generic for the first 6 months after patent expiration, when typically the price of the generic is only marginally lower than the multisource brand) and (2) intervention patients who switched from generic simvastatin to a non-simvastatin statin in the postperiod (ie, they may have experienced a copayment increase). All statistical analyses were performed with STATA/SE, version 8.0 (StataCorp LP, College Station, TX) using 2-sided statistical tests with an alpha level of .05.

## RESULTS

The intervention group was an older population with more women, a higher CDS, and a higher likelihood of having a statin preperiod MPR  $\geq 80\%$  compared with the control group (all  $P < .01$ ) (Table 1). Despite matching, the mean preperiod copayment was higher in the intervention group ( $P < .01$ ); however, the mean difference (\$0.03) was minor.

Although the overall unadjusted MPR decreased in both the intervention and matched control groups, the intervention group experienced a smaller decrease (mean change of  $-0.17\%$  and  $-1.67\%$  in the intervention and control groups, respectively;  $P < .01$ ) (Table 2). The intervention patients consistently had greater mean MPR increases across a variety of subpopulations (all adjusted  $P < .01$ ). A marginally higher percentage of intervention patients (10.5%) compared with control patients (10.0%) increased their MPR from  $< 80\%$  in the preperiod to  $\geq 80\%$  in the postperiod (adjusted  $P < .01$ ). Correspondingly, a higher percentage of control patients

■ **Table 1.** Preperiod Demographics and Prescription Use Patterns by Matched Study Groups<sup>a</sup>

Characteristic	Intervention Group (Branded Simvastatin) (n = 13,319)	Control Group (Non-Simvastatin Brand) (n = 26,569)	P
Mean age, y (SD)	63.33 (12.02)	57.74 (10.53)	<.01
Female, %	44.51	40.35	<.01
Incidence statin purchasers, %	13.23	13.23	.67
Median chronic disease score (IQR)	7770.08 (5086.44-11608.45)	6713.39 (4529.29-9893.51)	<.01 <sup>b</sup>
Preperiod adherence $\geq 80\%$	79.08	72.09	<.01
Mean preperiod MPR (SD)	88.93 (15.86)	85.30 (0.19)	<.01
Mean preperiod copayment (SD)	\$14.60 (\$9.11)	\$14.57 (\$9.10)	<.01

IQR indicates interquartile range (25%-75%); MPR, medication possession ratio.

<sup>a</sup>The preperiod extended from the date of the first statin purchase in the preindex period through the following 270 days. The study groups were matched on incident statin purchaser (yes/no) and preperiod copayment ( $\pm \$2$ ).

<sup>b</sup>P value based on the log-transformed values of the chronic disease score.

■ **Table 2.** Mean Percentage Change in Adherence (MPR) Pre- to Postperiod by Covariates Among Matched Study Groups<sup>a</sup>

Covariate	Percent Change		Unadjusted P Value	Adjusted P Value <sup>b</sup>
	Intervention (n = 13,319)	Control (n = 26,569)		
<b>Overall</b>	-0.17	-1.67	<.01	<.01
<b>Prepost MPR</b>				
<80%/≥80% <sup>c</sup>	28.71	28.57	.09	<.01
≥80%/<80% <sup>d</sup>	-29.75	-32.58	.03	<.01
<b>Age, y</b>				
<50	0.87	-2.59	<.01	<.01
50-60	0.07	-1.48	<.01	<.01
60-70	-0.27	-1.45	<.01	<.01
70+	-0.67	-1.30	.10	<.01
<b>Sex</b>				
Male	-0.17	-1.58	<.01	<.01
Female	-0.16	-1.80	<.01	<.01
<b>Incident statin purchaser</b>				
Yes	-0.26	-1.76	.02	<.01
No	0.47	-1.10	<.01	<.01
<b>Chronic disease score</b>				
Quartile 1	0.22	-1.28	<.01	<.01
Quartile 2	0.63	-1.64	<.01	<.01
Quartile 3	0.06	-1.86	<.01	<.01
Quartile 4	-1.20	-1.97	.04	<.01
<b>Copay (preperiod)</b>				
≤\$5.00	-0.80	-1.44	.06	<.01
\$5.01-\$15.00	-0.36	-1.90	<.01	<.01
\$15.01-\$20.00	-0.54	-1.28	.08	<.01
\$20.00+	1.23	-2.00	<.01	<.01

MPR indicates medication possession ratio.

<sup>a</sup>The preperiod extended from the date of the first statin purchase in the preindex period through the following 270 days. The postperiod extended from the date of the first statin purchase in the postindex period through the following 270 days. The study groups were matched on incident statin purchaser (yes/no) and preperiod copayment (±\$2).

<sup>b</sup>Adjusted for preperiod MPR and all other variables in the table.

<sup>c</sup>Based on intervention group n = 1398 and control group n = 2644.

<sup>d</sup>Based on intervention group n = 1507 and control group n = 3202.

(12.1%) compared with intervention patients (11.3%) decreased their MPR from ≥80% in the preperiod to <80% in the postperiod (adjusted *P* <.01).

After adjusting for age, sex, incident statin purchase, CDS, preperiod MPR, and preperiod copayment, the increase in MPR experienced by the intervention patients was modest ( $\beta = 0.0253$ , *P* <.001; **Table 3**). Utilizing group mean values for the covariates in the model, a 0.52% adjusted mean increase in MPR was identified among the intervention patients compared with a 2.02% adjusted mean decrease among the

control patients (adjusted mean difference = 2.54%). When copayment was entered as a continuous variable into a model of change in MPR with only the intervention patients, an adjusted linear trend was observed in the MPR change (*P* <.001). The adjusted mean MPR increased by 3.51% and 1.81% for copayment declines of more than \$15 and \$10.01 to \$15.00, respectively, for these patients. However, adjusted mean MPR decreased by 0.21%, 1.71%, and 3.22% for declines in copayments of \$5.01 to \$10.00, \$0.01 to \$5.00, and \$0, respectively. Elasticity of demand for statins was estimated at 0.02 and -0.02 for the copayment reduction categories of \$0 to \$5 and more than \$15, respectively.

Additional sensitivity analyses were performed by excluding subpopulations from the analysis to assess the robustness of the data. When patients with coinsurance (n = 2979, 7.5%) were excluded, the results changed minimally (+0.44% vs -2.01% change in the adjusted mean MPR among the intervention and control patients, respectively; *P* <.01). Furthermore, when 549 (4.1%) intervention patients who switched from generic simvastatin to another statin in the postperiod

were excluded, similar change values were obtained (+0.53% vs -2.01% change in the adjusted mean MPR among the intervention and control patients, respectively; *P* <.01).

## DISCUSSION

This matched cohort analysis provides evidence that declines in patient copayments only modestly increase patient adherence with prescribed statin pharmacotherapy. Although we found a linear relationship with decreasing copayments

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and increasing MPR, the maximum level of decrease in copayment (mean of \$20) was associated with an MPR increase (3.5%). Little evidence exists regarding the health effects of incremental increases in statin MPR.<sup>13</sup> Reaching and maintaining statin adherence at MPR levels  $\geq 80\%$  for primary and secondary prevention are correlated with beneficial health outcomes.<sup>14,15</sup> We found that only about 1 in 10 intervention patients with an MPR  $< 80\%$  in the preperiod increased their MPR to  $\geq 80\%$  in the postperiod—a proportion similar to that observed in the control group.

We identified a range of elasticity of demand across the various copayment reduction categories. Elasticities ranged from 0.02 and  $-0.02$  for copayment reductions of \$0 to \$5 and more than \$15, respectively. Based on patients whose copayments were reduced the most ( $> \$15$ ), a 10% decrease in copayment led to an absolute 0.2% increase in utilization. Other researchers who reported on the effect on statin demand of copayment decreases reported a price elasticity estimate of  $-0.18$ .<sup>9</sup> Chernew and colleagues reported that a 30% decrease in copayments was associated with an absolute increase in utilization of 3.4% (or a 10% decrease that led to a 1.1% increase in utilization).<sup>9</sup> Differences observed between these results and our findings may be due in part to study populations. Chernew and colleagues' study population included patients who were targeted for participation in a disease management program with relatively low baseline adherence.<sup>9</sup> Our study included an expansive cross-section of usual care patients receiving a branded statin without benefit of a disease management cointervention with higher preperiod adherence.

To our knowledge, few other studies have investigated the effects of decreased patient contributions on adherence.<sup>16,17</sup> A study to assess the effect of legislation in New England mandating insurance companies to cover glucose monitors and test strips without copayment resulted in improvement in self-monitoring among patients with diabetes.<sup>16</sup> Conversely, another investigation of the effect of similar legislation in California reported no change in adherence among ongoing users of these products.<sup>17</sup> In subanalysis, adherence rates did not increase even among those patients paying the most for their test strips before the mandate.<sup>17</sup> These studies are difficult to compare with ours as they were conducted in regard to self-monitoring of blood glucose and without control groups.

■ **Table 3.** Multivariate Linear Regression Modeling of Change in Adherence (MPR)

Predictor	$\beta$ Coefficient	P
Study group (intervention–patent expiration)	0.0253	$< .001$
Age <sup>a</sup>	0.001	$< .001$
Female	$-0.009$	$< .001$
Incident statin purchaser	$-0.029$	$< .001$
Chronic disease score <sup>b</sup>	$-0.002$	.279
Preperiod MPR <sup>c</sup>	$-0.473$	$< .001$
Preperiod copay <sup>c</sup>	$-0.001$	$< .001$
Constant	0.351	$< .001$

MPR indicates medication possession ratio.  
<sup>a</sup>Age as of June 1, 2005.  
<sup>b</sup>Log transformed.  
<sup>c</sup>The preperiod extended from the date of the first statin purchase in the preindex period through the following 270 days.

Other investigations that have reported elasticity of demand ranges relied on data from populations with copayment increases. Landsman and colleagues estimated that the elasticity of demand was  $-0.11$  for statins<sup>7</sup>; the elasticity of demand ranged from  $-0.2$  to  $-0.6$  for all prescription drugs.<sup>1</sup> Our identified higher elasticity estimate (ie, lower price sensitivity) range may be because of differences in measurement and, importantly, copayment change (ie, contribution *increases* rather than decreases). Greater response to copayment increases than to decreases has been predicted by behavioral economic theory.<sup>18</sup> Under this theory, patients have a more pronounced demand response when required to increase their contribution as opposed to when they pay less than their usual cost.

This study is not without limitations. Although prescription claims data are a reliable source of information regarding prescription drug purchases,<sup>19</sup> prescription purchases do not guarantee consumption. The MPR calculation assumes that patients are ingesting correctly the medications they purchased. Nevertheless, we have no evidence to suggest that patients in one group would take their medication differently than the other. Additionally, our analysis included only patients with a statin purchase in both the pre- and postperiods. Thus, an adherent population may have been examined, leading to a more conservative elasticity estimate. It also should be noted that the conversion from the brand to generic may impact adherence differently than continuation on brand medication with a reduction in cost sharing. Our findings are limited by the lack of adjustment for household income. This information has been shown to influence healthcare utilization, with increasing income related to decreasing contribution sensitivity.<sup>20</sup> Finally, reductions in copayments occurred in our study not in the context of a disease management pro-



### Take-away Points

Decreasing statin copayments because of the patent expiration of simvastatin has led to increases in therapy adherence, especially among those patients with a decline of \$10 or more.

- The overall extent of this increase is moderate and its clinical significance uncertain.
- Given the small identified relationship between decreases in copayments and medication adherence, plan sponsors who wish to lower copayment for their patients should consider the use of cost-effective therapies such as lower cost brands and generics.

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gram or with additional patient outreach. Other health plans may find that coimplementation of copayment reduction and care coordination/outreach results in a greater increase in adherence than copayment reduction alone.

Our findings suggest that only minimal increases in adherence to statin therapy are likely if copayments decrease from branded to generic copayment levels. Although increases in MPR, especially among those patients with a copayment reduction of \$10 or more, were identified, the clinical value of the modest MPR increases detected is unresolved. Nevertheless, given the relationship we identified between decreased copayment and increased adherence, health plans may want to consider options to reduce patient cost sharing. Structuring copayments to encourage the use of cost-effective therapies (eg, generics) in a manner that is beneficial for both patients and plans can assist in containing healthcare costs while maintaining high-quality health outcomes.

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