

Sofosbuvir Initial Therapy Abandonment and Manufacturer Coupons in a Commercially Insured Population

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Chronic hepatitis C virus (HCV) infection can lead to cirrhosis, liver failure, hepatocellular carcinoma, and liver transplantation.^{1,2} In 2013, there were more than 29,000 reported cases of acute HCV in the United States and more than 2.7 million individuals estimated to be chronically infected with the virus.³ As the population continues to age, the burden of disease is expected to increase along with the economic burden on patients and the healthcare system.²

In 2013, the FDA approved simeprevir (Olysio) and sofosbuvir (Sovaldi) for the treatment of HCV. In contrast to earlier treatments, these products yield substantially higher cure rates—as high as 84% to 96%⁴—lower risks of side effects, and a shorter treatment course. Since then, additional interferon-free therapies, such as ledipasvir/sofosbuvir (Harvoni) and dasabuvir/ombitasvir/paritaprevir/ritonavir (Viekira Pak), have also been approved.

The new products are costly for patients and third-party payers alike. CMS has defined drugs that cost more than \$600 per month as specialty drugs.⁵ HCV drugs are an example of extremely high-cost specialty drugs. Ledipasvir/sofosbuvir costs \$94,500 for a 12-week course, or about \$1125 per day. A 12-week course of sofosbuvir, when used in combination with ribavirin, costs about \$84,000, or about \$1000 per day. The potential costs of treating all Americans infected with the virus⁶ has thus generated a great deal of controversy. In addition to the issue of societal affordability, is the question of how much a member should contribute, as their cost share (ie, out-of-pocket cost), when they have insurance. There are many different pharmacy benefit designs, ranging from a fixed cost share per prescription—\$50 per month, for example—to a fixed percentage coinsurance—20%, for example, which, for sofosbuvir, would result in thousands of dollars in insurer-required member cost share.

Previous research has identified a negative association between a member's cost share and starting or re-initiating

ABSTRACT

Objectives: To describe rates of sofosbuvir initial medication adherence as a function of the insurer-required member cost (ie, out-of-pocket cost) and to determine how manufacturer coupons affect insurer-required member cost.

Study Design: Observational cross-sectional analysis.

Methods: Administrative pharmacy claims data from 13 million commercially insured members were used to identify sofosbuvir new starts between January and September 2014. Members were categorized as either sofosbuvir initial adherence or as abandoning therapy. A multivariate logistic regression model adjusting for sociodemographic characteristics, severity of illness, and total drug costs (health insurer plus member amount) for non-sofosbuvir pharmacy claims in 2014 was used to evaluate the association between insurer-required member cost and initial medication adherence. In a sub-analysis, sofosbuvir index claims with coupon data available were analyzed to determine how coupon use impacted insurer-required member cost.

Results: A total of 67.3% of members had a pre-coupon member cost of <\$250 for their index sofosbuvir claim. Just 201 (5.0%) members were exposed to a member cost of more than \$10,000. The logistic regression model demonstrated an association between member cost and abandonment starting at \$2500 to <\$5000 (odds ratio: 1.9; 95% CI, 1.01-3.43; *P* = .0393). The average member sofosbuvir index claim cost was \$1349 before a coupon was applied, and \$28 after. Overall, coupons offset the member amounts paid by 98%: \$771,593 of the \$787,860 member cost requested by the insurer.

Conclusions: These findings indicate that a 30-day supply of sofosbuvir (member cost of >\$2500) was associated with increased initial therapy abandonment and that manufacturer coupons substantially reduced sofosbuvir insurer-required member cost. Insurers and policy makers should consider the impact of member cost on medication adherence and the impact coupons have on the actual member cost.

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therapy—also called initial medication adherence.⁷ For multiple sclerosis (MS), oral oncology, and biologic anti-inflammatory drug therapies, member cost shares above \$250 per month supply were associated with significantly lower initial medication adherence rates.⁸⁻¹¹ As member cost sharing rose to more than \$2000 a month, initial medication adherence was less than 50%, meaning that more than half of members abandoned their newly prescribed therapy for MS or an autoimmune disease when they were asked to pay more than \$2000 monthly.

To help members avoid cost shares, most manufacturers of brand-name drugs for any condition offer coupons that reduce the insurer-required member's cost share to less than \$50 per month. For the HCV drugs, pharmaceutical manufacturer coupons are available to lower a member's cost to "\$5 per prescription fill, up to a maximum of 25% of the catalog price of a 12-week regimen. The offer is valid for 6 months from the time of first redemption."^{12,13} However, we know little about the extent to which HCV drug coupons are used or about their potential impact on initial medication adherence.

The primary objectives of this study were to describe member cost sharing for sofosbuvir, to quantify sofosbuvir initial medication adherence rates as a function of the insurer-required member cost, and, in a subset of members, to determine how member cost for sofosbuvir is lowered by manufacturer coupons.

METHODS

The methods applied in this analysis are identical to those found in previous research.^{7,8} We used administrative pharmacy claims data from a pharmacy benefit manager with more than 13 million commercially insured members from 14 different plans. We identified members for our analytic sample as those newly initiating HCV therapy with sofosbuvir between January and September 2014; members with a sofosbuvir claim in December 2013 were excluded. Only sofosbuvir was chosen because it was recently approved and it was the primary HCV specialty drug treatment during the treatment initiation analysis period of January through September 2014. Members were eligible for the analysis if they were continuously enrolled for 90 days after the first sofosbuvir transaction. The first sofosbuvir transaction was the index claim for a member. For a sensitivity analysis, we required 180 days of continuous enrollment after the first transaction.

Take-Away Points

The member cost share, coupon use, and impact of member cost share (ie, out-of-pocket cost) on adherence are unknown among members with hepatitis C virus that have been prescribed sofosbuvir. This study of more than 13 million commercially insured members in 2014 found:

- Increasing member cost share is significantly associated with lower initial sofosbuvir adherence. A sofosbuvir member cost share between \$2500 and <\$5000 was associated with 1.9 higher odds of new sofosbuvir therapy abandonment compared with the abandonment when member cost share was <\$50.
- The average member cost share on the initial sofosbuvir 30-day supply claim was \$1349 and coupons covered \$1321 (98%), meaning a member actually paid \$28 on average.

Members with a sofosbuvir pharmacy benefit insurance transaction—where the pharmacy receives the prescription and is adjudicated with the insurer—were categorized as either initial medication adherence or as abandoning therapy if sofosbuvir was never picked up by the member and returned to pharmacy stock. Members were placed into cost-share groups based on the amount of insurer-required cost share from their index sofosbuvir claim: <\$50; \$50 to <\$100; \$100 to <\$250; \$250 to <\$1000; \$1000 to <\$2500; \$2500 to <\$5000; \$5000 to <\$10,000; and \$10,000 or more. Sofosbuvir initial therapy abandonment was categorized by member cost group. The member cost shares are unadjusted for coupons because that information was unavailable for all members in the analysis.

To evaluate the impact of a coupon on insurer-required member cost, we conducted a subgroup analysis limited to the members filling their index sofosbuvir at a particular specialty pharmacy for which we had coupon data available. Claims data from the pharmacy benefit manager were merged at a member level with coupon records from the specialty pharmacy to examine the impact of the coupon on the member's cost. By linking data from the specialty pharmacy to the pharmacy benefit manager's claim records, we were able to identify sofosbuvir index claims that had been filled with the use of a coupon. We compared the member's cost as defined by the insurer with the true member cost after the coupon was applied.

Statistical Analyses

After stratifying by initial sofosbuvir member cost group, we used descriptive statistics to examine differences in member characteristics, including age and gender; education, income, and race at a zip-code level, derived from Census Bureau information; Optum pharmacy risk group score,¹⁴ which measures disease burden; index sofosbuvir claim filled at the specialty pharmacy; and total drug costs (health insurer plus member amount) for non-sofosbuvir pharmacy claims in 2014. A Cochran-Armitage trend test

was performed to evaluate the trend in abandonment rates as the member cost increased. The member group in which the initial cost of sofosbuvir without coupon adjustment was <\$50 was used as the reference group for univariate abandonment rate comparisons.

Descriptive statistics were used to examine the proportion of members who used drug coupons and how much these coupons reduced member cost. We could not assess the relationship between abandonment and coupons because no member who abandoned therapy had presence of a coupon on their index claim.

Finally, we used multivariate logistic regression to examine the impact of a member's cost on abandonment using the same <\$50 group as the reference group, and controlling for the same member characteristics above. The overall fit of the logistic regression model was evaluated using the C statistic. All statistical tests were performed using SAS version 9.1.3 (SAS Institute Inc, Cary, North Carolina) and significance was set a priori at $P < .05$.

RESULTS

Between January 1 and September 30, 2014, we identified 3991 members who met study criteria for attempting a sofosbuvir pharmacy claim transaction and were continuously enrolled for 90 days after the index claim. The majority of members had an insurer-required cost share of less than \$250 for their index sofosbuvir claim. Specifically, 1132 (28.4%), 743 (18.6%), and 809 (20.3%) were in the \$0 to <\$50, \$50 to <\$100, and \$100 to <\$250 member cost groups, respectively. Five percent of members (201) were exposed to a cost of more than \$10,000. **Table 1** summarizes member characteristics by insurer-required member cost group.

Overall, the index sofosbuvir abandonment rate was 7.4%. The **Figure** shows that the unadjusted proportion of members abandoning sofosbuvir therapy starts out at 3.8% in the \$0 to <\$50 member cost group and stays below 8% up to the \$5000 to <\$10,000 cost group. At member cost of \$10,000 or more, 52.7% of members abandoned sofosbuvir therapy. The unadjusted abandonment rate was statistically significant at \$2500 compared with <\$50 member cost ($P < .05$).

The logistic regression model results in **Table 2** demonstrate the association between member cost and abandonment, starting at \$2500 to <\$5000 (odds ratio [OR], 1.9; 95% CI, 1.01-3.43; $P = .0393$). There is a trend toward abandonment at lower member cost; however, results were not significant in the adjusted model. The \$5000 to <\$10,000 and \$10,000 or more member cost groups were statistically sig-

nificantly associated with increased sofosbuvir abandonment (OR, 1.7; 95% CI, 1.03-2.79; and OR, 21.2; 95% CI, 13.6-33.5, respectively). Members with higher total drug costs (health insurer plus member amount) for non-sofosbuvir pharmacy claims in 2014 had a lower odds of sofosbuvir abandonment (OR, 0.24; 95% CI, 0.16-0.36 for total drug cost [health insurer plus member amount] for non-sofosbuvir pharmacy claims of \$4500 to <\$12,000; OR, 0.25; 95% CI, 0.18-0.36 for \$12,000 to <\$68,000; and OR, 0.13; 95% CI, 0.08-0.22 for more than \$68,000). Similarly, compared with members with low pharmacy risk group scores, those with higher scores had lower odds of abandoning sofosbuvir therapy (OR, 0.41; 95% CI, 0.27-0.6 for pharmacy risk group score 6 or higher). The logistic regression model had a C statistic of 0.816, suggesting good concordance with sofosbuvir abandonment and member cost. The sensitivity analysis using abandonment rates at 180 days yielded similar results (data not shown).

There were 1123 (28.1%) of 3991 members using the specialty pharmacy for their index sofosbuvir prescription and 585 (52.1%) of 1123 members had evidence of a coupon applied to their index claim. The average member sofosbuvir index claim cost share was \$1349 before a coupon was applied and only \$28 after. Median member cost share decreased from \$150 before the coupon to \$4 after the coupon. Overall, coupons offset the member amount paid by 98%. Coupons amounted to \$771,593 of the \$787,860 total member cost. **Table 3** reviews index sofosbuvir amounts before and after a coupon was applied. None of the 585 members with a coupon abandoned their index sofosbuvir claim.

DISCUSSION

These findings have 3 main implications. First, our results show a wide array of members' insurer-required cost-share amounts for a sofosbuvir initial prescription. These member cost shares range from less than \$250 for two-thirds of members to \$10,000 or more for 5% of members. Second, among the subset of members with a known manufacturer coupon applied, the coupon paid down the member cost share by an average of \$1321, meaning that coupons paid 98% of insurer-required member costs, leaving an actual member mean cost share of \$28. These sofosbuvir coupon data demonstrate that when a coupon was applied, the member paid a nominal amount for their initial sofosbuvir prescription. Lastly, using the insurer-required member cost share and sofosbuvir prescription abandonment rates, the data revealed 3 levels of associated abandonment: <\$250 at 4.1%, \$250 to <\$10,000 at 7.2%,

Table 1. Sofosbuvir Initiators' Characteristics by Insurer-Required Member Cost Share

	\$0 to <\$50, % (n = 1132)	\$50 to <\$100, % (n = 743)	\$100 to <\$250, % (n = 809)	\$250 to <\$1000, % (n = 201)	\$1000 to <\$2500, % (n = 269)	\$2500 to <\$5000, % (n = 227)	\$5000 to <\$10,000, % (n = 409)	≥\$10,000, % (n = 201)
Age, years								
<50	23.9	24.2	24.4	22.8	26.3	24.6	26.4	25.3
50 to 54	25.8	24.7	27.0	26.8	23.4	24.2	25.4	25.3
55 to 59	25.7	25.4	25.9	28.3	23.0	23.7	24.2	21.8
≥60	24.5	25.5	22.5	21.8	27.1	27.3	23.9	27.3
Female								
Female	35.2	32.5	34.2	39.8	34.9	33.0	29.3	35.8
Male								
Male	64.7	67.4	65.7	60.2	65.0	66.9	70.6	64.1
Zip code-level proportion of Caucasians								
<68% ^a	25.9	22.6	23.7	18.4	27.1	24.2	29.8	16.9
68% to <82%	23.2	27.7	29.1	25.8	24.1	26.8	27.3	29.8
82% to <90%	22.0	20.7	22.3	22.8	17.4	29.5	19.8	24.8
≥90%	28.8	28.9	24.7	32.8	31.2	19.3	22.9	28.3
Zip code-level median income								
<\$41,000	25.3	21.6	26.4	20.4	20.4	21.1	23.2	22.8
\$41,000 to <\$51,000	24.2	24.7	25.2	27.8	22.6	25.5	24.2	19.4
\$51,000 to <\$66,000	23.3	25.8	24.8	27.8	28.2	22.9	22.4	27.8
≥\$66,000	27.0	27.7	23.4	23.8	28.6	30.4	30.0	29.8
Zip code-level proportion with bachelor's degree								
<16%	27.8	23.2	25.9	22.3	21.5	17.6	29.8	20.4
16% to <24%	24.2	25.8	24.9	26.3	22.6	24.2	22.9	23.8
24% to <38%	22.8	26.2	24.4	26.3	25.6	26.8	20.5	26.3
≥38%	25.0	24.6	24.6	24.8	30.1	31.2	26.6	29.3
Index claim filled at a specialty pharmacy ^{a,b}								
Specialty pharmacy	68.3	64.1	59.0	70.7	81.0	85.5	84.8	86.6
All other pharmacies								
All other pharmacies	31.7	35.9	41.0	29.4	19.0	14.5	15.2	13.4
Total drug cost ^c for non-sofosbuvir pharmacy claims in 2014								
<\$4500 ^a	21.2	23.9	26.4	34.8	23.4	25.1	29.1	49.7
\$4500 to <\$12,000	20.4	26.9	26.9	25.8	23.4	27.7	23.7	13.9
\$12,000 to <\$68,000	29.6	31.2	30.0	23.3	29.7	29.0	27.8	26.8
≥\$68,000	28.6	17.9	16.5	15.9	23.4	18.0	19.3	9.5
Optum Pharmacy Risk Group Score								
<3 ^a	30.4	30.2	32.8	33.8	40.1	36.1	37.6	45.7
3 to <4	19.1	21.6	18.4	21.8	19.3	25.5	24.6	15.4
4 to <6	19.4	20.0	20.6	21.8	18.5	16.7	19.8	19.9
≥6	30.9	27.9	28.0	22.3	21.9	21.5	17.8	18.9

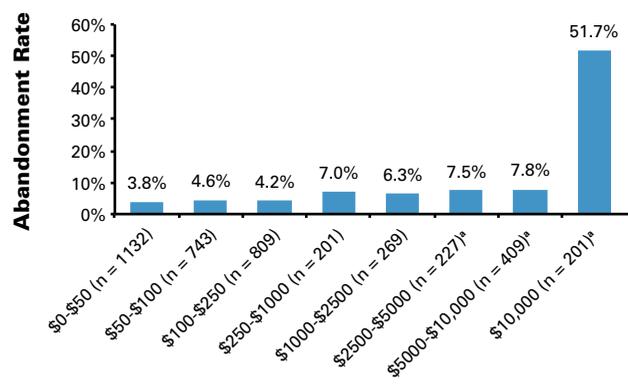
^aChi-square test across categories statistically significant at *P* < .05.
^bSpecialty pharmacy for which we had coupon data available.
^cTotal drug costs = health insurer plus member amount.

and \$10,000 or more at 51.7%. A statistically significant increase in sofosbuvir abandonment occurred when the cost was \$2500 or more. Among the 14.7% of members with a known coupon applied, no member abandoned their initial sofosbuvir prescription. To explicitly link cou-

pons, member cost sharing, and initial medication non-adherence (ie, abandonment), further research is needed.

Our results are consistent with other research demonstrating an association between increased member cost share and specialty drug prescription abandonment. How-

Figure. Unadjusted Abandonment Rates of Sofosbuvir by the Insurer-Required Member Cost Share Among 3991 Commercially Insured Members



*Chi-square $P < .05$ compared with \$0 to <\$50 group. Cochran-Armitage test for trend $P < .001$.

ever, in comparison to the statistically higher abandonment found at a member cost share greater than \$250 seen in MS, oral oncology, and autoimmune drug categories,^{8,11} we did not see significant sofosbuvir abandonment until the \$2500 or more level. There are several possible explanations for this difference. We did not have coupon informa-

tion for members who filled their sofosbuvir prescriptions at locations other than a single specialty pharmacy. It is possible that members had and were able to apply sofosbuvir coupons at other locations. Other studies have examined adherence to medications for chronic conditions, while HCV treatment lasts 6 months or less and is curative. It is possible that the shorter treatment duration and curative capabilities of this drug motivated adherence. Members with higher cumulative drug cost (health insurer plus member amount) for non-sofosbuvir pharmacy claims in 2014 were less likely to abandon their sofosbuvir therapy, indicating that they may be less sensitive to high sofosbuvir member cost sharing due to the curative value. In addition, sofosbuvir abandonment could have been affected by what a member anticipates they will pay for drugs in the future as a result of reaching their pharmacy benefit-defined maximum annual cumulative out-of-pocket cost.

Although these abandonment findings are severely limited by the lack of coupon-adjusted member cost share, they are directionally informative and the insurer-required member cost share is an amount told to the member by the pharmacist at the time the prescription is filled. In addition, a member's knowledge of a coupon is dependent on his or her own research or on the pharmacy informing them.

Table 2. Adjusted Association Between Sofosbuvir Insurer-Required Member Cost Share and Abandonment Rate at 90 Days Post Index (n = 3991)^{a,b}

Description	Category	Odds Ratio (95% CI)	P
Insurer-required member cost share	<\$50	Reference	
	\$50-<\$100	1.16 (0.72-1.85)	.5489
	\$100-<\$250	0.93 (0.58-1.50)	.781
	\$250-<\$1000	1.43 (0.73-2.68)	.2755
	\$1000-<\$2500	1.43 (0.76-2.56)	.2457
	\$2500-<\$5000	1.9 (1.01-3.43)	.0393
	\$5000-<\$10,000	1.71 (1.03-2.79)	.0347
	≥\$10,000	21.17 (13.61-33.45)	<.0001
Total drug cost ^c for non-sofosbuvir pharmacy claims in 2014	<\$4500	Reference	
	\$4500-<\$12,000	0.24 (0.16-0.36)	<.0001
	\$12,000-<\$68,000	0.25 (0.18-0.36)	<.0001
	≥\$68,000	0.13 (0.08-0.22)	<.0001
Optum Pharmacy Risk Group Score ¹⁴	<3	Reference	
	3-<4	0.35 (0.24-0.52)	<.0001
	4-<6	0.34 (0.23-0.51)	<.0001
	≥6	0.41 (0.27-0.60)	<.0001

^aOnly statistically significant covariates displayed in the table. Model also adjusted for age; gender; zip code-derived race, education, and income levels; and index claim filled at specialty pharmacy.

^bC statistic = 0.81615.

^cTotal drug costs = health insurer plus member amount.

Limitations

Our study has several limitations. First, we did not analyze member characteristics such as health literacy, treatment preferences, or prior treatment failures. We also assumed the members who abandoned therapy did so because of their insurer-required sofosbuvir member cost share, while other unmeasured factors—such as side effects of therapy, stigma of the disease, or a provider's decision to change a course of therapy—may all influence initial sofosbuvir abandonment. This, along with data availability and study design, limits our ability to conclude causality between the insurer-required member cost share and sofosbuvir therapy abandonment. Second, our study was conducted within a commercially insured population, limiting generalizability nationally and to publicly insured populations. The impact of sofosbuvir coupons on member cost share was limited to members who filled their initial sofosbuvir claim at a specialty pharmacy. This further limits the generalizability to populations filling their prescriptions elsewhere.

■ **Table 3.** Insurer-Required Member Cost Share and Coupon Amount From Index Sofosbuvir Claim (n = 585)^a

	Insurer-Required Member Cost Share Before Coupon	Insurer-Required Member Cost Share After Coupon	Coupon Amount
Average (SD) amount on index sofosbuvir	\$1349 (\$3297)	\$28 (\$437)	\$1321 (\$3180)
Median (25th and 75th percentiles) amount on index sofosbuvir	\$150 (\$75, \$439)	\$4 (\$4, \$4)	\$146 (\$71, \$434)
Total amount index sofosbuvir	\$787,860	\$16,267	\$771,593

^aThese members used a specialty pharmacy for their index sofosbuvir and had a coupon associated with that sofosbuvir claim.

Additionally, we only examined a single product within the HCV class, although more than 90% of new HCV treatment regimens included sofosbuvir during the analysis period.¹³ The coupon analysis is also subject to bias, as we did not have information on the utilization of manufacturer coupons unless the claim was filled at the specialty pharmacy. For 71.9% of members, we do not know if a coupon was applied to their sofosbuvir claim. Finally, we did not evaluate the impact of sofosbuvir abandonment on health outcomes. Further research is necessary in this area to understand the long-term impact of HCV treatment on the clinical, healthcare cost, and societal cost outcomes associated with adherence to HCV therapy.

Manufacturer coupons have increased dramatically in the past 5 years. The pharmaceutical industry will have spent about \$7 billion on coupons and discount cards in 2015—a significant increase from the \$1 billion spent in 2010.¹⁵ Although we found evidence that sofosbuvir coupons significantly reduced member cost, understanding the long-term impact of coupons on how insured members purchase and utilize prescription drugs is important. The cost-saving benefits that manufacturer coupons provide to members may only be experienced in the short term.¹⁶ Manufacturer coupons offset the difference in member cost share between generic and brand-name drugs available to them by their insurer.¹⁷ By doing so, manufacturer coupons could alter incentives of both patients and providers away from utilizing low-cost alternatives that are equally safe and effective. This altering of incentives and the subsequent impact on costs is why the HHS issued a ruling banning coupons in Medicare.¹⁸ The negative impact of manufacturer coupons can be 2-fold: increased direct healthcare costs,¹⁶ when a manufacturer ends a coupon program and the costs fall back onto the member, and increased indirect costs, such as rising insurance premiums.^{16,19}

\$1321, lowering the member's true amount paid for their initial sofosbuvir prescription to an average of \$28. The manufacturer coupon for HCV therapy can potentially assist in preventing new therapy abandonment, as our findings suggest that an insurer-required member cost share of greater than \$2500 was associated with higher sofosbuvir abandonment rates. However, coupons for nonpreferred drugs may result in higher premiums, due to loss of formulary management capabilities that are essential to keep premiums low.

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CONCLUSIONS

When a sofosbuvir manufacturer coupon was used, it dramatically lowered a member's cost share by an average of

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