

Coverage for Hepatitis C Drugs in Medicare Part D

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Prescription drug spending in the United States increased by 13.1% in 2014—the highest rate for the decade thus far—driven by a 30.9% hike in specialty drug spending.¹ Among specialty drugs, Sovaldi (sofosbuvir) is considered a major contributor to the 2014 increase in drug spending,¹ and since its arrival, this new drug for hepatitis C virus (HCV) has drawn intense attention from the media, policy makers, and researchers. Despite Sovaldi's novel aspects, its high price tag has been at the center of the discussion, igniting debates over how much our society is willing to pay for innovative prescription drugs. Two additional HCV drugs—Harvoni (a combination of ledipasvir and sofosbuvir) and Viekira Pak (ombitasvir/paritaprevir/ritonavir co-packaged with dasabuvir)—entered the market with similarly high prices in late 2014.

These HCV drugs are not an isolated case: highly effective, yet extremely expensive, drugs for other diseases are increasingly being introduced to market. Nevertheless, HCV drugs present a clear example of the fiscal pressures that new drugs are imposing on the healthcare system. The financial impact of the new HCV drugs has been particularly salient in Medicare Part D, where spending on these drugs jumped from \$283 million in 2013 to \$4.5 billion in 2014.² Spending on Sovaldi alone—the drug with the highest spending in Part D—exceeded \$3 billion.³ HCV drug spending in Part D is expected to reach \$9.2 billion in 2015.⁴

With this alarming trend, strategies and benefit designs to effectively manage HCV drug spending are being sought.^{5,6} Coverage decisions on these drugs are challenging because they require a balance between ensuring patients' access to needed drugs and controlling healthcare expenditures. Examination of benefit designs currently used for HCV drugs can be informative in exploring tools to manage HCV drug spending and refining benefit designs to improve patients' access. We analyzed the current Part D coverage for HCV drugs and calculated expected out-of-pocket (OOP) spending for beneficiaries to complete a course of treatment.

ABSTRACT

Objectives: The recent arrival of new hepatitis C virus (HCV) drugs has brought fiscal pressures onto Medicare Part D; spending on HCV drugs in Part D jumped from \$283 million in 2013 to \$4.5 billion in 2014. We examined the current benefit designs for HCV drugs in Part D plans and analyzed patients' financial burden for those drugs.

Study Design: A cross-sectional analysis of CMS' July 2015 Part D Plan Formulary File and the Wolters Kluwer Health Medi-Span Electronic Drug File v.2.

Methods: We analyzed the type and amount of cost sharing for HCV drugs and the extent to which plans apply utilization management tools. We then estimated total out-of-pocket spending for beneficiaries to complete a course of treatment.

Results: All Part D plans covered at least 1 recently introduced HCV drug, as of July 2015. Nearly all plans charged relatively high coinsurance and required prior authorization for new HCV drugs. For enrollees with no subsidy, the mean out-of-pocket spending needed to complete a course of treatment is substantial, ranging from \$6297 to \$10,889. For enrollees with a low-income subsidy, out-of-pocket spending varies between \$10.80 and \$1191.

Conclusions: Under the current Part D benefits, HCV drug users with no subsidy face sizable financial burdens, even with catastrophic coverage and the recent in-gap discount for brand name drugs. As baby boomers—the group most likely to have HCV—join Medicare, efforts should be made to ensure patient access to these needed drugs.

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HCV and Its Treatments

More than 3 million Americans are infected with HCV, with its prevalence concentrated among baby boomers, who were born between 1945 and 1965.⁷ HCV causes more deaths in the United States than HIV/AIDS.⁸ Chronic HCV is a cause of serious and costly liver diseases, such as cirrhosis and liver cancer, and related hospitalizations and costs have increased during the past decade.⁹ Although the burden of HCV can be reduced through screening and treatments, the implementation of recommended screening is limited, and half of the infected population goes undiagnosed.⁹

The conventional HCV treatment for the most common type of HCV (genotype 1) consisted of peginterferon and ribavirin (known as PR therapy), which required a 48-week treatment course. Both peginterferon and ribavirin have several products (brand names). The “cure” rate, measured by sustained virologic response (SVR) and defined as having no HCV ribonucleic acid in the blood 24 weeks after a treatment, was about 50% for PR therapy.¹⁰ Due to the side effects of interferon, some patients could not tolerate this therapy. One study reported about 40% of patients completed the interferon therapy.¹¹

The first direct-acting antivirals (DAAs)—Incivek (telaprevir) and Victrelis (boceprevir)—were approved in 2011. With these drugs, SVR reached 75% to 80%¹⁰; however, patients had to simultaneously be on the PR regimen and were required to dose every 7 to 9 hours.

Sovaldi (sofosbuvir), introduced in December 2013, brought several innovative aspects, including convenient administration (once-a-day pill), a short treatment period (12 weeks), and a high cure rate (90%).¹⁰ However, Sovaldi also came with a price tag of \$1000 per pill, which immediately caught the attention of the media and payers. Two competing drugs entered the market in late 2014: Harvoni (ledipasvir/sofosbuvir) and Viekira Pak (ombitasvir/paritaprevir/ritonavir co-packaged with dasabuvir). An additional drug, Olysio (simeprevir), was introduced in 2013 to be used in combination with PR therapy; however, its utilization increased after it was approved for combined usage with Sovaldi in November 2014.¹² The first DAAs were discontinued after these new drugs arrived.¹²

Medicare Part D Benefits

Medicare Part D provides outpatient prescription drug coverage to the elderly and disabled. It is delivered through private plans, including standalone prescription drug plans (PDPs) or Medicare Advantage plans with prescription drug

Take-Away Points

The high prices of new hepatitis C virus (HCV) drugs are bringing fiscal pressures onto Medicare. The current coverage designs for HCV drugs by Medicare Part D plans are:

- All Part D plans cover at least 1 new, expensive HCV drug.
- Nearly all plans charge relatively high coinsurance and require prior authorization.
- Expected out-of-pocket spending for enrollees with no subsidy to complete a course of treatment ranges from \$6297 to \$10,889; for enrollees eligible for a low-income subsidy, total expected out-of-pocket spending varies between \$10.80 and \$1191.
- Under the current Part D benefits, HCV drug users with no subsidy face sizable financial burdens.

coverage (MAPDs). Medicare specifies a standard Part D benefit package, but plans can modify the benefits as long as their schemes are equal in value to the standard package.

The standard benefit has 3 phases: initial coverage, coverage gap, and catastrophic coverage. Initial coverage includes an annual deductible (\$320 in 2015) followed by 25% coinsurance. After total drug spending of \$2960 (in 2015), beneficiaries enter the coverage gap, where they are responsible for 45% of the spending on brand name drugs and 65% of spending on generic drugs, with in-gap discounts specified by the Affordable Care Act. Catastrophic coverage kicks in when patient OOP spending reaches \$4700 (total spending of \$6680); beneficiaries pay 5% of drug spending above the catastrophic threshold.

Most Part D plans have developed their own schemes, particularly in initial coverage, and use multi-tiered formularies with low cost sharing for preferred drugs and high cost sharing for nonpreferred drugs.¹³ Part D plans can place drugs with monthly spending over \$600 in a separate “specialty” tier and charge higher cost sharing than other tiers. The prices of most HCV drugs are high enough to be placed in a specialty tier.

Cost-sharing subsidies are available for Medicare Part D beneficiaries who are dually eligible for Medicaid (dual eligibles) and/or have low incomes.¹⁴ Noninstitutionalized dual eligibles with incomes \leq 100% of the federal poverty line (FPL) had 2015 co-payments of \$1.20 for generics and \$3.60 for brand name drugs; those with incomes $>$ 100% FPL had 2015 co-payments of \$2.65 for generics and \$6.60 for brand name drugs. Other individuals with incomes \leq 135% FPL and limited resources paid \$2.65 for generics and \$6.60 for brand name drugs. Neither the deductible nor coverage gap was applied to these 2 groups. Individuals with incomes $<$ 150% FPL had a \$66 deductible followed by 15% coinsurance until OOP spending reached \$4700; after that, they paid \$2.65 and \$6.60 co-payments for generic and brand name drugs, respectively.

A large share of patients with HCV in Medicare qualify for these low-income subsidies, which help mitigate

■ **Table 1.** Hepatitis C Virus Treatments^{a,b}

Drug	Usage	Duration of Therapy
Traditional therapy		
Peginterferon + ribavirin (PR therapy)	Once a week (peginterferon) + twice daily (ribavirin)	48 weeks
DAAs		
New DAAs (approved in/after late 2013)		
Olysio (simeprevir)	Once daily	12 weeks
	Used with Sovaldi	12 weeks
	Used with PR therapy ^c	24 weeks
Sovaldi (sofosbuvir)	Once daily	
	Used with PR therapy or Olysio	12 weeks
	Used with ribavirin only	24 weeks
Harvoni (ledipasvir/sofosbuvir)	Once daily	12 weeks
Viekira Pak (ombitasvir/paritaprevir/ritonavir co-packed with dasabuvir) ^d	Twice daily	12 weeks
First DAAs (prior to Olysio/Sovaldi); discontinued in 2015		
VICTRELIS (boceprevir)	3 times daily	
	Used with PR therapy	28-36 weeks ^e
INCIVEK (telaprevir) ^e	3 times daily	
	Used with PR therapy	24-48 weeks ^e

DAA indicates direct-acting antiviral.
^aInformation based on the drug package inserts and the guidelines from the American Association for the Study of Liver Diseases.
^bTreatment approaches are for genotype 1 and may not apply to those with other genotypes and patients who experience relapse or who have failed to respond previously.
^cUsed with PR therapy for the first 12 weeks and then PR therapy only for the remaining treatment period.
^dWith and without ribavirin for genotypes 1a and 1b, respectively.
^eDuration of therapy depends on patient's response to the drug.

applying prior authorization/quantity limits to the drug and placing the drug in a specialty tier. We then examined the type and amount of cost sharing for the drug. Because several peginterferon and ribavirin products are available, we used cost sharing of the product covered by most plans. At the time of the study, Victrelis and Incivek were discontinued and no Part D plan listed Incivek in its formulary. We used the December 2013 formularies to compare benefit coverage of these first DAAs and newer HCV drugs.

We measured price by the wholesale acquisition cost (WAC) for a 4-week supply of each drug from the Wolters Kluwer Health Medi-Span Electronic Drug File (MED-File) v.2 (2015).¹⁶ WAC is the manufacturer's list price to wholesalers before any discounts or rebates. It approximates what pharmacies pay wholesalers for brand name drugs¹⁷ and captures payments by both plans and enrollees. Based on this price, we calculated total spending on a single

financial difficulties.¹⁵ However, patients with no subsidy bear significant financial burdens for expensive HCV drugs. Although they reach catastrophic coverage with the first few pills, high prices of HCV drugs can result in sizable OOP spending even with only 5% coinsurance.

METHODS

The primary data source was the July 2015 Prescription Drug Plan Formulary and Pharmacy Network Files from CMS, which contains information on plan characteristics and benefits for drugs covered by each Part D plan. We excluded special needs plans (n = 540) because they serve certain specific beneficiaries (eg, institutionalized patients) and may have special benefit schemes. After this exclusion, we identified 1635 MAPDs and 1013 PDPs.

We examined formulary and cost-sharing structures used by MAPDs and PDPs for the HCV drugs shown in **Table 1**. We analyzed the percentages of plans covering each drug,

drug therapy and on a combination of drugs. We collected information on drug usage (such as combined drug therapies) and expected therapy duration from the drug package inserts and the guidelines from the American Association for the Study of Liver Diseases (AASLD).¹⁸ We then estimated annual OOP spending needed for enrollees in a plan to complete a course of treatment. We used the plan's cost sharing for the drug in each benefit phase (initial coverage, coverage gap, and catastrophic coverage) in 2015.

RESULTS

All Part D plans covered 2 new HCV drugs, Olysio and Sovaldi, and 98% of plans covered Harvoni (**Table 2**). Only 33% of MAPDs and 30% of PDPs covered Viekira Pak. Nearly every plan that covered these new drugs used prior authorization and nearly half of the plans used quantity limits. Almost all plans placed new HCV agents in a specialty tier and required coinsurance rather than

■ **Table 2.** Coverage for Hepatitis C Virus Drugs in Medicare Part D^a

	% Plans												Coinsurance Rate, ^b Mean (range)
	Covering the Drug		Using PA		Using Quantity Limit		Placing Drug in Specialty Tier		Using Coinsurance ^b		Coinsurance Rate, ^b Mean (range)		
	MAPD ^c	PDP ^d	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	
Traditional therapy													
Peginterferon + ribavirin therapy													
Peginterferon	100.0	100.0	83.2	88.4	33.9	21.72	94.9	99.6	99.5	99.6	31.4 (20-50)	28.8 (25-33)	
Ribavirin	100.0	100.0	29.6	44.3	22.9	13.5	14.4	9.9	18.0	30.6	31.0 (20-50)	25.4 (10-50)	
DAAs													
New DAAs (approved in/after late 2013)													
Olysio (simeprevir)	100.0	100.0	100.0	100.0	64.2	61.6	95.3	100.0	99.9	100.0	31.4 (20-50)	28.7 (25-33)	
Sovaldi (sofosbuvir)	100.0	100.0	100.0	100.0	64.7	61.7	95.3	100.0	99.9	100.0	31.4 (20-50)	28.7 (25-33)	
Harvoni (ledipasvir/ sofosbuvir)	97.1	99.6	99.4	100.0	73.0	76.3	95.3	100.0	100.0	100.0	31.3 (20-50)	28.7 (25-33)	
Viekira Pak (ombitasvir/ paritaprevir/ritonavir with dasabuvir)	33.0	30.3	97.6	98.7	46.5	79.2	95.9	98.7	99.4	98.7	31.6 (25-45)	28.4 (25-33)	
First DAAs (prior to Olysio/Sovaldi); discontinued in 2015 ^e													
Victrelis (boceprevir)	89.9	89.2	96.3	89.2	50.9	54.4	96.1	85.1	98.6	99.1	31.9 (20-45)	28.3 (25-48)	
Incivek (telaprevir)	98.6	100.0	58.3	90.4	52.9	94.5	95.5	83.4	97.9	99.9	31.9 (20-45)	29.3 (25-50)	

DAA indicates direct-acting antiviral; MAPD, Medicare Advantage prescription drug plan; PA, prior authorization; PDP, prescription drug plan.

^aInformation based on the July 2015 Part D plan formulary except for first DAAs, whose data are based on the December 2013 Part D plan formulary.

^bDuring the initial coverage phase for enrollees with no subsidy.

^cMedicare Advantage Prescription Drug plans (n = 1635).

^dStandalone prescription drug plans (n = 1013).

^eBased on the December 2013 formulary information.

co-payment. The average coinsurance rate was slightly higher among MAPDs than PDPs (31.4% vs 28.7%), but it varied more among MAPDs (20%-50%) than PDPs (25%-33%).

Cost-sharing type and amount for the new HCV drugs is fairly similar to that for the first DAAs. However, utilization management was tightened for the new drugs; for example, only 58% of MAPDs required prior authorization for Incivek.

Total spending on a single new drug for the expected therapy duration was high: \$84,000 for Sovaldi; \$94,500 for Harvoni; and \$83,319 for Viekira Pak (Table 3). These estimates, based on 2015 WAC, appear to closely reflect total Part D spending. For example, in 2014, Part D spending on Sovaldi was \$94,000 per user (the average amount paid by all Part D plans to pharmacies without incorporating manufacturers' rebates or other price concessions).³

Harvoni and Viekira Pak can be used alone. However, Sovaldi is used with either Olysio (AASLD recommendation) or PR therapy for 12 weeks; it can also be used in combination with ribavirin for 24 weeks. Total spending for a combination of Sovaldi + Olysio was \$150,360, and total spending for Sovaldi + PR therapy was \$94,950.

Total spending for both single and combination new-drug therapy is significantly higher than that of the 48-week PR therapy (\$43,801). Our estimate of PR therapy spending is close to what prior literature reported, considering inflation and therapy duration: a study using 2002 to 2006 commercial claims data found that 24-week spending on PR therapy was about \$18,963.¹⁹

Enrollees with low-income subsidies spend between \$10.80 and \$1191 OOP for a full course of HCV treatment with new drugs. However, those with no subsidy need to spend much more, ranging from \$6297 for Viekira Pak used

■ **Table 3.** Total Spending and Beneficiary Out-of-Pocket Spending for a Full Course of Hepatitis C Virus Treatment^{a,b}

	Total Spending, \$	Enrollees With No Subsidy				LIS Enrollees	
		Total OOP Spending, \$ Mean (range)		Number of 4-Week Supply Needed to Hit CC	Mean OOP in CC, \$		Total OOP Spending, \$ Range
		MAPD ^c	PDP ^d		MAPD	PDP	
Traditional therapy							
Peginterferon + ribavirin [PR]	43,801	4466 (2636-5221)	4600 (4147-4717)	2-3	1787	1826	57.60-1204
New DAAs							
Olysio (simeprevir)	66,360	5570 (2646-6022)	5711 (5403-5716)	1	2901	2974	10.80-1155
Sovaldi (sofosbuvir)	84,000	6432 (2646-6904)	6593 (6285-6598)	1	3763	3856	10.80-1155
Harvoni (ledipasvir/sofosbuvir) (monotherapy)	94,500	6942 (2646-7429)	7118 (6810-7123)	1	4273	4381	10.80-1155
Viekira Pak (ombitasvir/paritaprevir/ritonavir with dasabuvir) (monotherapy)	83,319	6297 (2646-6870)	6551 (6237-6564)	1	3563	3821	10.80-1155
Combined drug therapy							
Sovaldi + PR therapy	94,950	7271 (2688-8252)	7399 (7045-8049)	1	4602	4662	25.20-1183
Sovaldi + Olysio	150,360	9750 (5964-10,222)	9911 (9603-9916)	1	7904	8014	21.60-1175
Sovaldi + ribavirin	169,955	10,635 (2700-11,200)	10,889 (10,581-10,894)	1	7966	8152	38.40-1191

CC indicates catastrophic coverage; DAA, direct-acting antiviral; LIS, low-income subsidy; MAPD, Medicare Advantage prescription drug plan; OOP, out-of-pocket; PDP, prescription drug plan.

^aAll spending was based on wholesale acquisition cost reported in the June 2015 Medi-Span Electronic Drug File (MED-File) v.2 by Wolters Kluwer Health.

^bOOP was estimated based on total spending of a drug and on each plan's benefit information from the July 2015 Part D plan formulary file.

^cMedicare Advantage Prescription Drug plans (n = 1635).

^dStandalone prescription drug plans (n = 1013).

alone to \$10,889 for Sovaldi plus ribavirin to complete a therapy. Average OOP spending for each therapy was slightly higher in PDPs than in MAPDs; however, it varied widely among MAPDs while differing little among PDPs.

With the current Part D benefit, new HCV drug users without a subsidy reach catastrophic coverage with their first 4-week fill, regardless of their plan's initial benefit. The mean OOP spending in catastrophic coverage, in which patients pay only 5% coinsurance, ranges (MAPDs/PDPs) from \$3563/\$3821 for Viekira Pak to \$7966/\$8152 for Sovaldi + ribavirin.

DISCUSSION

Part D plans charge relatively high coinsurance for new HCV drugs, and they require rigorous utilization management, including prior authorization and quantity limits for those drugs. Little variation in coverage exists across plans, leaving few options for beneficiaries to choose a plan with better benefits. This is likely because plans are concerned

about adverse selection (attracting more and sicker HCV patients) if they were to offer more generous coverage for HCV drugs than their competitors.

The analysis indicated that the current Part D cost-sharing subsidies help mitigate financial hardship for low-income patients who need expensive new drugs; however, total OOP spending for patients with no subsidy to complete a new HCV therapy is significant, reaching almost \$10,000. This suggests that the presence of catastrophic coverage, which was designed as a stop-loss in Part D, and the recent in-gap discount for brand name drugs, do not offer significant financial protection to Part D enrollees requiring high-price drugs.

These findings are consistent with recent reports on Part D coverage for high-price rheumatoid arthritis and cancer drugs.^{20,21} This implies that the strategies of high cost sharing and use of prior authorization are not unique to HCV drugs but are applied to many high-price drugs. It is discouraging that the effectiveness or the therapeutic values of drugs are not considered in benefit decisions.

New HCV drugs are highly efficacious, but Part D plans' coverage for them differs little from coverage for less-effective HCV drugs, such as the first DAAs. It is also surprising that integrated MAPDs charge slightly higher cost sharing on average for new HCV drugs than do stand-alone PDPs, although they could expect potential cost savings from reduced use of medical services by offering generous coverage for those drugs.

Cost sharing is commonly used to contain healthcare expenditures, so plans may have naturally turned to high cost sharing for all costly drugs as drug spending rose. Although not surprising, this raises a concern that patients' access to needed medications may be limited, which can lead to worsened health outcomes. It also raises an important but difficult question of how to design benefits for high-price drugs. One approach would be to selectively lower cost sharing for high-value drugs—particularly for beneficiaries with financial difficulties—to ensure patients' access to effective drugs.

Linking cost sharing to value is not a new strategy. It has been adopted for drugs used to treat common chronic conditions, such as diabetes or hypertension.^{22,23} Applying it to new drugs can be challenging, however, because defining and measuring value is difficult, and evidence on real-world effectiveness or cost-saving effects has not yet been established for new HCV drugs. Little is known about their impact on patients' health outcomes, such as incidence or progress of liver diseases, and on posttherapy healthcare utilization. A value-based approach based on clinical efficacy (using currently available information) would be limited, but it could be a good starting place while implementing procedures to update information on value/effectiveness as more evidence is gathered.

In addition, reducing financial stress on beneficiaries who need expensive but effective drugs can help improve patients' access to those drugs. As discussed above, the current Part D coverage may not offer adequate financial protection to some beneficiaries because high prices of recently introduced drugs far exceed the initial coverage limit and OOP maximum thresholds in Part D. Expanding eligibility for low-income cost-sharing subsidies for certain costly, yet effective, drugs might be an option to explore.

Limitations

Our analysis is limited to examining coverage for HCV drugs without assessing its impact on drug utilization. It does not tell us how many patients would not initiate new drug therapies or discontinue therapies due to financial burdens. We could not examine protocols for prior authorization and how many cases are denied. Future research

should address those questions as utilization data for the post-Sovaldi period become available.

CONCLUSIONS

Our analysis is the first to describe the current Part D benefits for HCV drugs and examine their financial implications for HCV patients. It indicates that Part D enrollees using new HCV drugs with no subsidy face sizable financial burdens, even with catastrophic coverage and the recent in-gap discount for brand name drugs. As baby boomers—the group most likely to have HCV—join Medicare, efforts should be made to ensure patients' access to needed drugs.

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