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Coverage for Hepatitis C Drugs in Medicare Part D

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Abstract

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

Study Design—A cross-sectional analysis of the Centers for Medicare and Medicaid Services July 2015 Part D Plan Formulary File and the Wolters Kluwer Health Medi-Span MED-file v.2.

Methods—We analyzed the type and amount of cost-sharing for hepatitis C 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 one recently introduced hepatitis C drug as of July 2015. Nearly all plans charged relatively high coinsurance and required prior authorization for new hepatitis C drugs. For enrollees with no subsidy, the mean out-of-pocket spending needed to complete a course of treatment is substantial, ranging from $6,297 to $10,889. For enrollees with a low-income subsidy, OOP spending varies between $10.80 and $1,191.

Conclusions—Under the current Part D benefits, hepatitis C 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 hepatitis C, join Medicare, efforts should be made to ensure patient access to needed drugs.

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Precise: This study analyzes the current coverage designs for hepatitis C drugs by Medicare Part D plans.

Keywords

Hepatitis C drugs; Medicare Part D; benefit designs

Introduction

Prescription drug spending in the United States increased by 13.1% in 2014 – the highest rate for the decade – 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] Since its arrival, this new hepatitis C drug has drawn intensive attention from the media, policy makers, and researchers. Despite the drug'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 hepatitis C drugs– Harvoni and Viekira Pak – entered the market with similarly high prices in the late 2014. These hepatitis C drugs are not an isolated case. Highly effective yet highly expensive drugs are increasingly introduced. However, hepatitis C drugs present a clear example of the fiscal pressures that new drugs are imposing on the health care system.

The financial impact of the new hepatitis C drugs has been particularly salient in Medicare Part D. Spending on hepatitis C drugs in Part D jumped from $283 million in 2013 to $4.5 billion in 2014.[2] Spending on Sovaldi alone exceeded $3 billion – the most expensive drug in Part D. [3] Hepatitis C drug spending in Part D is expected to reach $9.2 billion in 2015.[4] With this alarming trend, strategies or benefit designs to effectively manage hepatitis C drug spending are being sought.[5,6,7]

Coverage decisions on these drugs are challenging because they require a balance between ensuring patients' access to needed drugs and controlling health care expenditures. Examination of benefit designs currently used for hepatitis C drugs can be informative in exploring tools to manage hepatitis C drug spending and refining benefit designs to improve patients' access. We analyzed the current Part D coverage for hepatitis C drugs and calculated expected out-of-pocket (OOP) spending for beneficiaries to complete a course of treatment.

Background

Hepatitis C and its treatments

More than 3 million Americans are infected with hepatitis C virus (HCV).[8] Its prevalence is concentrated among baby-boomers, who were born between 1945 and 1965.[8] HCV causes more deaths in the US than HIV/AIDS.[9] Chronic hepatitis C is a cause of serious and costly liver diseases such as cirrhosis and liver cancer. Hospitalizations and costs related to HCV and liver diseases have increased during the past decade.[10] While the burden of HCV can be reduced through screening and treatments, the implementation of recommended screening is limited and half of the infected population is not diagnosed.[10]

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. The “cure” rate measured by sustained virologic response (SVR), defined as having no HCV RNA in blood 24 weeks after a treatment, was about 50%.[11] Due to side effects of interferon, some patients could not tolerate this therapy.

The first “direct acting antivirals” (DAAs) – telaprevir (Incivek) and boceprevir (Victrelis) – were approved in 2011. With these drugs, SVR reached 75-80%[11] however, patients had to be on the PR regimen and were required to dose every 7-9 hours.

Sofosbuvir (Sovaldi), introduced in December 2013, has several innovative aspects: convenient administration (once-a-day pill); a short treatment period (12 weeks); and a high cure rate (90%).[11] But sofosbuvir came with a price tag of $1,000 per pill, which immediately caught the attention of the media and payers. Two competing drugs entered the market in the late 2014: ledipasvir/sofosbuvir (Harvoni) and ombitasvir/partiaprevir/ritonavir co-packaged with dasabuvir (Vikiera Pak). An additional drug, simeprevir (Olysio), was introduced in 2013 to be used with PR therapy, but its utilization increased after it was approved for combined usage with sofosbuvir in November 2014.[12] The first DAAs were discontinued after these new drugs arrived.

Medicare Part D benefits

Medicare Part D provides outpatient prescription drug coverage to the elderly and disabled. It is delivered through private plans – stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs). 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 three 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 $ 2,960 (in 2015), beneficiaries enter the coverage gap, where they are responsible for 45% (65%) of the spending on brand-name (generic) drugs with in-gap discounts specified by the Affordable Care Act. Catastrophic coverage kicks in when patient OOP spending reaches $4,700 (total spending of $6,680), and 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 (high) cost-sharing for preferred (non-preferred) drugs.[13] Part D plans can place drugs with monthly spending > $600 in a separate “specialty” tier and charge higher cost-sharing than other tiers. Prices of most HCV drugs are high enough to be placed in a specialty tier.

Cost-sharing subsidies are available for beneficiaries who are dually eligible for Medicaid (dual eligibles) and/or have low incomes.[14] Non-institutionalized dual eligibles with incomes ≤100% FPL (>100% FPL), have 2015 copayments of $1.20 ($2.65) for generics and $3.60 ($6.60) for brand-name drugs. Other individuals with incomes ≤ 135% FPL and limited resources pay $ 2.65 for generics and $ 6.60 for brand-name drugs. Neither the deductible nor coverage gap is applied to these two groups. People with incomes below 150% FPL have a $66 deductible followed by 15% coinsurance until OOP spending reaches

$4,700; after that, they pay $2.65 and $6.60 copayments for generic and brand-name drugs, respectively.

A large share of HCV patients in Medicare qualify for these low-income subsidies (LIS), which help mitigate 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 in catastrophic coverage.

Methods

The primary data source is the July 2015 Prescription Drug Plan Formulary and Pharmacy Network Files from the Centers for Medicare and Medicaid Services. This file 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 (e.g., institutionalized people) and may have special benefit schemes. After this exclusion, we identified 1,635 MAPDs and 1,013 PDPs.

We examined formulary and cost-sharing structures used by MAPDs and PDPs for HCV drugs shown in Table 1. We analyzed the percentages of plans covering each 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 products of peginterferon and ribavirin are available, we used cost-sharing of the product covered by most plans. At the time of the study, boceprevir and telaprevir were discontinued, and no Part D plan listed telaprevir 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 MED-file v.2 (2015). WAC is the manufacturer's list price to wholesalers before any discounts or rebates. It approximates what pharmacies pay wholesalers for brand-name drugs[16] and captures payments by both plans and enrollees. Based on this price, we calculated total spending on a single drug therapy and a combination of drugs. We collected information on drug usage (such as combined drug therapies) and expected therapy duration from the drug package insert and the guidelines from the American Association for the Study of Liver Diseases (AASLD).[17] 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 two new HCV drugs, simeprevir and sofosbuvir, and 98% of plans covered ledipasvir/sofosbuvir (Table 2). Only 33% of MAPDs and 30% of PDPs covered Vikiera 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 copayment. 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 MA-PDs required prior authorization for telaprevir.

Total spending on a single new drug for the expected therapy duration was high: $84,000 for sofosbuvir; $94,500 for lediparsir/sofosbuvir; 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 sofosbuvir per user was $94,000 (the average amount paid by all Part D plans to pharmacies without incorporating manufacturers' rebates or other price concessions).[3]

Lediparsir/sofosbuvir and Viekira Pak can be used alone. However, sofosbuvir is used with either simeprevir (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 sofosbuvir + simeprevir was $150,360, and total spending for sofosbuvir + 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 2002-2006 commercial claims data found that 24-week spending on PR therapy was about $18,963.[18]

Enrollees with low-income subsidies spend between $10.80 and $1,191 out-of-pocket (OOP) for a full course of HCV treatment with new drugs. However, those with no subsidy need to spend more, ranging from $6,297 for Viekira Pak used alone to $10,889 for sofosbuvir plus ribavirin. Average OOP spending for each therapy was slightly higher in PDPs than in MAPDs, but 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 out-of-pocket spending in catastrophic coverage, where patients pay only 5% coinsurance, ranges from $3,563/$3,821 (MAPDs/PDPs) for Viekira Pak to $7,966/$8,152 for sofosbuvir + ribavirin.

Discussion

Part D plans charge relatively high coinsurance for new HCV drugs and 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) when offering 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 out-of-pocket spending for patients with no subsidy to complete a new HCV therapy is significant, reaching up to about $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.[19,20] 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 effectiveness or 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 that of existing expensive but less-effective HCV drugs. It is also surprising that integrated MAPDs charge slightly higher cost-sharing on average for new HCV drugs than 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 health care expenditures, so plans may have naturally turned to high cost-sharing for all costly drugs as drug spending rises. While 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 lower cost-sharing selectively for high-value drugs – and 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.[21,22] Applying it to new drugs can be challenging because defining/measuring value is difficult and evidence on real-world effectiveness or cost-saving effects is yet not 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 post-therapy health care 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 we showed 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.

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.

Despite these limitations, our analysis is the first to describe the current Part D benefits for HCV drugs and examine their financial implications for HCV patients. 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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Take-Away Points

High prices of new hepatitis C drugs are bringing fiscal pressures on Medicare. The current coverage designs for hepatitis C drugs by Medicare Part D plans are:

- All Part D plans cover at least one new expensive hepatitis C 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 $6,297 to $10,889; for enrollees eligible for a low-income subsidy, total expected out-of-pocket spending varies between $10.80 and $1,191.
- Under the current Part D benefits, hepatitis C drug users with no subsidy face sizable financial burdens.

Table 1

Hepatitis C treatments

Drug	Usage	Duration of therapy
Traditional therapy		
Peginterferon + Ribavirn (PR therapy)	Once a week (peginterferon) + twice daily (ribavirin)	48 weeks
Direct Antiviral Agents (DAAs)		
New DAAs (Approved in/after the late 2013)		
Simeprevir (Olysio)	Once daily	12 weeks
	Used with sofosbuvir	12 weeks
	Used with PR therapy[a]	24 weeks
Sofosbuvir (Sovaldi)	Once daily	
	Used with PR therapy or simeprevir	12 weeks
	Used with ribavirin only	24 weeks
Lediparsir/sofosbuvir (Harvoni)	Once daily	12 weeks
Ombitasvir/paritaprevir/ritonavir co-packed with dasabuvir (Viekira Pak)[b]	Twice daily	12 weeks
First DAAs (prior to simeprevir/sofosbuvir; discontinued in 2015)		
Boceprevir (Victrelis)	Three times daily	
	Used with PR therapy	28-36 weeks[c]
Telaprevir (Incivek) [a]	Three times daily	
	Used with PR therapy	24~48 weeks[c]

Note) Information based the drug package insert and the guidelines from the American Association for the Study of Liver Diseases (AASLD); Treatment 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;

[a] used with PR therapy for the first 12 weeks and then PR therapy only for the remaining treatment period;

[b] with and without ribavirin for genotype 1a and 1b, respectively;

[c] duration of therapy depends on patient response to the drug.

Table 2

Coverage for Hepatitis C drugs in Medicare Part D

	% plans										Coinsurance rate[c] Mean (range)	
	covering the drug		using prior authorization		using quantity limit		placing drug in specialty tier		using coinsurance[c]			
	MAPD[a]	PDP[b]	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP	MAPD	PDP
Traditional therapy (Peginterferon + Ribavirn; PR 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)
Direct Antiviral Agents (DAAs)												
New DAAs (Approved in/after the late 2013)												
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)
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)
Lediparsir/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)
Ombitasvir/paritaprevir/ rito- navir 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 simeprevir/sofosbuvir; discontinued in 2015)[d]												
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)
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)

Note) Information based on the July 2015 Part D plan formulary;

[a]Medicare Advantage Prescription Drug Plans (N=1,635);

[b]stand-alone Prescription Drug Plans (N=1,013);

[c]during the initial coverage phase for enrollees with no subsidy;

[d]based on the December 2013 formulary information.

Table 3

Total spending and beneficiary out-of-pocket (OOP) spending for a full course of Hepatitis C treatment

	Enrollees with no subsidy						LIS[d] enrollees
	Total spending	Total OOP spending ($) Mean (range)		# of 4-week supply needed to hit CC[c]	Mean OOP in CC[c] ($)		Total OOP spending ($) Range
		MAPD[a]	PDP[b]		MAPD	PDP	
Traditional therapy (Peginterferon + Ribavirin; PR therapy)	43,801	4,466 (2,636-5,221)	4,600 (4,147-4,717)	2-3	1,787	1,826	57.60-1,204
New Direct Antiviral Agents (DAAs)							
Simeprevir	66,360	5,570 (2,646-6,022)	5,711 (5,403-5,716)	1	2,901	2,974	10.80-1,155
Sofosbuvir	84,000	6,432 (2,646-6,904)	6,593 (6,285-6,598)	1	3,763	3,856	10.80-1,155
Lediparsir/sofosbuvir (monotherapy)	94,500	6,942 (2,646-7,429)	7,118 (6,810-7,123)	1	4,273	4,381	10.80-1,155
Ombitasvir/paritaprevir/ritonavir with dasabuvir (monotherapy)	83,319	6,297 (2,646-6,870)	6,551 (6,237-6,564)	1	3,563	3,821	10.80-1,155
Combined drug therapy							
Sofosbuvir + PR therapy	94,950	7,271 (2,688-8,252)	7,399 (7,045-8,049)	1	4,602	4,662	25.20-1,183
Sofosbuvir + simeprevir	150,360	9,750 (5,964-10,222)	9,911 (9,603-9,916)	1	7,904	8,014	21.60-1,175
Sofosbuvir + ribavirin	169,955	10,635 (2,700-11,200)	10,889 (10,581-10,894)	1	7,966	8,152	38.40-1,191

Note: All spending was based on wholesale acquisition cost reported in the June 2015 MediSpan MED-file v.2 by Wolters Kluwer Health. OOP was estimated based on total spending of a drug, and each plan's benefit information from the July 2015 Part D plan formulary file;

[a] Medicare Advantage Prescription Drug Plans (N=1,635);

[b] stand-alone Prescription Drug Plans (N=1,013);

[c] catastrophic coverage;

[d] low-income subsidy.