Disparities in Absolute Denial of Modern Hepatitis C Therapy by Type of Insurance


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BACKGROUND & AIMS: The high costs of direct-acting antiviral (DAA) agents to treat chronic hepatitis C virus (HCV) infection have resulted in denials of treatment, but it is not clear whether patients’ access to these therapies differs with their type of insurance.

METHODS: We conducted a prospective cohort study among all patients who had a DAA prescription submitted between November 1, 2014 and April 30, 2015 to Burman’s Specialty Pharmacy, which provides HCV pharmacy services to patients in Delaware, Maryland, New Jersey, and Pennsylvania. We determined the incidence of absolute denial of DAA prescription, defined as a lack of approval of a prescription fill by the insurer, according to type of insurance (US Medicaid, US Medicare, or commercial insurance). Multivariable Poisson regression was used to estimate adjusted relative risks of absolute denial associated with patient characteristics.

RESULTS: Among 2321 patients prescribed a DAA regimen (503 covered by Medicaid, 795 covered by Medicare, and 1023 covered by commercial insurance), 377 (16.2%) received an absolute denial. The most common reasons for absolute denial were insufficient information to assess medical need (134 [35.5%]) and lack of medical necessity (132 [35.0%]). A higher proportion of patients covered by Medicaid received an absolute denial (233 [46.3%]) than those covered by Medicare (40 [5.0%]; P < .001) or commercial insurance (104 [10.2%]; P < .001). Medicaid insurance (adjusted relative risk, 4.14; 95% confidence interval, 3.38–5.08) and absence of cirrhosis (adjusted relative risk, 1.96; 95% confidence interval, 1.53–2.50) were associated with absolute denial.

CONCLUSIONS: There are significant disparities in access to DAA-based treatments for HCV infection among patients with different types of insurance. Nearly half of Medicaid beneficiaries in Delaware, Maryland, New Jersey, and Pennsylvania were denied access to these drugs for chronic HCV infection.

Keywords: Hepatitis C; Direct-Acting Antiviral; Insurance.

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More than 3.2 million people in the United States are chronically infected with hepatitis C virus (HCV) infection.1 If left untreated, chronic HCV can cause progressive liver fibrosis and cirrhosis, leading to hepatic decompensation and hepatocellular carcinoma.2 Viral eradication after antiviral therapy reduces the risk of liver complications and death, even with advanced hepatic fibrosis.3 Consequently, HCV treatment guidelines are currently directed towards achieving sustained viral response (SVR) among patients with HCV infection. Antiviral therapies are highly effective and well tolerated, with SVR achieved in nearly 90% of patients.4 However, these therapies are expensive. Most current article

Abbreviations used in this paper: CI, confidence interval; DAA, direct-acting antiviral; HCV, hepatitis C virus; HIV, human immunodeficiency virus.

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Most current article
have recommended antiviral therapy for all chronic HCV-infected patients.\(^4,5\)

Highly efficacious direct-acting antiviral (DAA) agents were approved by the US Food and Drug Administration in 2014 to treat chronic HCV.\(^6–8\) However, their high costs have led insurers to restrict access to these medications,\(^9–12\) requiring that patients meet insurer-specific criteria for approval, such as evidence of advanced liver fibrosis, consultation with a specialist, or abstinence from alcohol or illicit drug use.\(^13,14\) Two recent reports highlighted the restrictions on reimbursement of DAAs across the US state Medicaid programs and showed considerable heterogeneity by state in the criteria for approval.\(^15,16\) Little is known about restrictions to HCV treatment among US Medicare and commercial insurance beneficiaries.

As a consequence of these varying restrictions, insurers have required that DAA prescriptions undergo prior authorization, a preapproval process to determine if the patient meets insurer-specific criteria for HCV treatment. Prescriptions may be denied after this review, but the decision can be appealed by the provider. The insurer may overturn the denial, if given sufficient supporting information, or uphold the decision. DAA prescriptions that ultimately are not filled because of a lack of insurer approval are considered absolutely denied. Data are lacking on the incidence of absolute denial of DAA prescription and factors associated with this outcome in clinical practice settings. These data are important because absolute denial of HCV treatment by insurers might have adverse outcomes on patients and could harm patient-provider relationships.

We evaluated the incidence of absolute denial of DAA therapy among a sample of US chronic HCV-infected patients by type of insurance. Because the criteria for reimbursement of DAA medications may be more restrictive within the Medicaid program than within other types of insurance,\(^15,16\) we hypothesized that absolute denial of DAA treatment would be more common among Medicaid beneficiaries. We also evaluated the reasons for absolute denial given by the insurers, factors associated with absolute denial, and time to fill among those whose prescription was approved.

**Methods**

**Study Design and Data Source**

We conducted a prospective cohort study using data from Burman’s Specialty Pharmacy, which provides HCV pharmacy services to community and academic medical practices across Delaware, Maryland, New Jersey, and Pennsylvania. DAAs often are dispensed by specialty pharmacies because of their high costs and requirements for special handling and delivery.\(^17\) Burman’s Specialty Pharmacy obtains medical information from clinicians to complete the prior authorization request and submits the prescription and request to the insurer. Burman’s Specialty Pharmacy uses an electronic record system to collect data on demographics, health insurance, and prescribed medications. Clinical information submitted to the pharmacy by the clinician for the prior authorization request, including documentation of hepatic fibrosis stage, human immunodeficiency virus (HIV) co-infection, and previous HCV treatment and response, also is recorded electronically. Burman’s Specialty Pharmacy collects information from prescribing clinicians on alcohol or drug use when requested for the prior authorization. This study was approved by the University of Pennsylvania Institutional Review Board.

**Study Patients**

Patients were included if they were infected with HCV genotypes 1, 2, or 3 (the most common HCV genotypes in the United States\(^16\)) and had a DAA prescription submitted to the pharmacy between November 1, 2014 and April 30, 2015 (the first 6 months that interferon-containing regimens were no longer recommended as first-line therapy\(^5\)). Patients were excluded if their prior authorization was completed by an outside pharmacy (because medical information might not be available to Burman’s Specialty Pharmacy), their insurer mandated use of a different pharmacy, or they had no health insurance. If a patient had multiple DAA treatment courses prescribed during the period of interest, only the first regimen was included.

**Main Study Outcomes**

The primary outcome was absolute denial of a DAA prescription, defined as a lack of approval of a DAA fill by the insurer, even after appeal. Burman’s Specialty Pharmacy ascertained the status of all prescriptions with the insurers through September 30, 2015.

As secondary outcomes, we evaluated the following: (1) the reason given by the insurer for absolute denial, (2) denial preceding prescription approval, (3) any denial (composite of either absolute denial or denial preceding insurer approval), (4) time to DAA fill (days from receipt of the DAA prescription by the pharmacy to the date of fill), and (5) time to absolute denial (days from receipt of the DAA prescription by the pharmacy to the date of absolute denial).

**Data Collection**

Demographic and clinical data collected from Burman’s Specialty Pharmacy electronic records at the time the DAA prescription was received by the pharmacy included the following: age; sex; race; insurance; HCV RNA; HCV genotype; presence of cirrhosis (based on clinician report from liver biopsy or noninvasive test); history of HCV treatment and response (based on prior
prescription fills for antiviral therapy and/or clinician report); HIV status (reported by clinician); DAA regimen prescribed; and date of DAA prescription receipt by the pharmacy. Insurance was classified as US Medicaid (joint federal- and state-funded programs for medical care and drug benefits for low-income and special-needs individuals\textsuperscript{19}), US Medicare (federal health insurance program available to Americans aged \( \geq 65 \) years and those \(< 65 \) years with certain disabilities or chronic health conditions\textsuperscript{20}), or commercial insurance (health benefits that are employer-sponsored, privately purchased, or obtained via health exchange through the Affordable Care Act\textsuperscript{21}). Patients were classified according to the insurance plan to which the DAA prescription was submitted. Patients covered by Medicaid fee-for-service or Medicaid managed care were classified as having Medicaid insurance.

Data collected after receipt of the DAA prescription included dates of completion of prior authorization, insurer denial preceding approval, absolute denial by insurer, appeal of the insurer’s decision by the clinician, and DAA fill.

**Statistical Analysis**

Follow-up evaluation began on the date that the DAA prescription was received by the specialty pharmacy and continued until the pharmacy ascertained the final outcome for the prescription (ie, absolute denial, DAA prescription fill) or determined that the prior authorization request was incomplete (ie, after 60 days of inactivity). Patients who had an incomplete prior authorization were excluded from analyses because a completed prior authorization is required for insurer review and a decision to either approve or deny the DAA prescription.

The incidence of absolute denial of a DAA prescription was determined, overall and by type of insurance, cirrhosis status, and HCV genotype. The reason given by the insurer for the absolute denial was evaluated. We also calculated the incidence of denial preceding prescription approval and of any DAA denial by insurance type.

Next, we used multivariable Poisson regression with a robust error variance to estimate the relative risks with 95% confidence intervals (CIs) of absolute denial associated with patient factors.\textsuperscript{22} We used Poisson, rather than logistic, regression because odds ratios may overestimate relative risks when the outcome of interest is common, as in this study.\textsuperscript{23} We hypothesized that Medicaid coverage and absence of cirrhosis would be the strongest determinants of absolute denial. Other variables evaluated within the multivariable model included age, sex, race, genotype, prior HCV treatment, HIV, and time period of DAA prescription (DAA prescribed within the first 3 months of the observation period vs the latter 3 months). To avoid bias from missing data, we implemented multiple imputations using chained equations.\textsuperscript{24} Twenty imputed data sets were created using all of the variables from the Poisson model, including absolute denial status. Results across the 20 data sets were combined to arrive at CIs that accounted for within- and across-data set variances.\textsuperscript{25}

Finally, we determined the median time to DAA fill by insurance type. Results were stratified according to receipt of insurer denial before approval. The median time to absolute denial also was calculated. Data were analyzed using Stata 12.1 (Stata Corporation, College Station, TX).

**Results**

**Study Patients**

Between November 1, 2014 and April 30, 2015, Burman’s Specialty Pharmacy received DAA prescriptions for 3791 patients. After exclusions (Figure 1), 2342 patients remained. Among these, 21 (0.9%) patients had an incomplete prior authorization after 60 days and were excluded, leaving 2321 patients (503 with Medicaid [492 (97.8%) with Medicaid managed care and 11 (2.2%) with Medicaid fee-for-service], 795 with Medicare, and 1023 with commercial insurance). Medicaid patients were younger, more commonly black, and more frequently HCV treatment-naïve than patients with Medicare or commercial insurance (Table 1). Cirrhosis and HIV co-infection were more frequent among patients with Medicaid and Medicare than commercial insurance (\( P < .01 \) for all comparisons). HCV genotype 1 was the most common genotype across the insurance types.

**Incidence of Absolute Denial**

Among these 2321 patients, 377 (16.2%; 95% CI, 14.8%–17.8%) were absolutely denied their DAA prescription. Absolute denial was more common for patients with Medicaid (233 [46.3%]) than Medicare (40 [5.0%]; \( P < .001 \)) or commercial insurance (104 [10.2%]; \( P < .001 \)) (Figure 2). When the analysis was restricted to the 715 patients with cirrhosis, the incidence of absolute denial remained higher for patients with Medicaid (42 of 165 [25.4%]) than Medicare (4 of 281 [1.4%]; \( P < .001 \)) or commercial insurance (8 of 269 [3.0%]; \( P < .001 \)). Among Medicaid beneficiaries, no statistically significant difference in absolute denial rate was observed by state (Delaware: 8 of 14 [57.1%]; Maryland: 8 of 17 [47.1%]; New Jersey: 35 of 94 [37.2%]; and Pennsylvania: 182 of 378 [48.2%]; \( P = .06 \)). Absolute denial of DAA prescription was more frequent among patients with HCV genotype 3 (24 of 76 [31.6%]) than genotype 1 (327 of 2114 [15.5%]; \( P < .001 \)), but not significantly different compared with genotype 2 (26 of 131 [19.9%]; \( P = .06 \)). There was no difference in the incidence of absolute denial between patients with genotypes 1 and 2 (\( P = .18 \)).

Table 2 reports the incidence of DAA denial preceding insurer approval. When the composite of either absolute
denial or denial preceding approval (ie, any denial) was evaluated, 690 patients (29.7%; 95% CI, 27.9%–31.6%) received a denial of DAA treatment. Receipt of any denial was nearly 4-fold more common for Medicaid (356 [70.8%]) than Medicare (143 [18.0%]; \( P < .001 \)) or commercially insured patients (191 [18.7%]; \( P < .001 \)) (Figure 2). Among patients issued any denial, an appeal of the insurer’s decision by the clinician was less commonly filed for patients with Medicaid (38 of 356 [10.7%]) than Medicare (39 of 143 [27.3%]; \( P < .001 \)) or commercial insurance (41 of 191 [21.5%]; \( P < .001 \)).

Table 2 reports the frequency of DAA prescription approval and absolute denial categorized by reason reported by the insurer, according to type of insurance. Overall, the most common reasons for absolute denial were insufficient information to assess medical need (134 [35.5%]) and lack of medical necessity (132 [35.0%]), and these were the most frequently reported reasons among Medicaid beneficiaries as well.

Factors Associated With Absolute Denial

In the multivariable analysis, Medicaid insurance, absence of cirrhosis, and DAA prescription in the initial 3 months of the 6-month observation period were associated with a higher risk of absolute denial (Table 3). Older age and Medicare coverage were associated with a lower risk of absolute denial. Sex, race, HCV genotype, prior HCV treatment, and HIV co-infection were not associated with absolute denial. HCV genotype 3 was not associated with an increased risk of absolute denial in multivariable analysis.

Median Time to Prescription Fill

The median time to DAA fill was longer for Medicaid than Medicare or commercially insured patients (Table 4). Among patients who had a denial preceding insurer approval, the median time to fill was substantially longer for all insurance types, but remained longer for Medicaid patients. The median time to absolute denial was shorter for patients with Medicaid and Medicare than commercial insurance.

Discussion

In this study of chronic HCV-infected patients prescribed DAA-based HCV therapy across Delaware, Maryland, New Jersey, and Pennsylvania between November 2014 and April 2015, 16% were absolutely denied treatment by their insurance carrier. Notably, 46% of Medicaid beneficiaries from these states did not have their prescription approved for fill, and this was substantially higher than patients with Medicare or commercial insurance. The disparity was even more evident among patients with cirrhosis, with 25% of Medicaid beneficiaries absolutely denied treatment compared with almost none of those with other types of insurance. Lack of medical necessity and incomplete data to determine medical need were the most frequently reported reasons for absolute denial among Medicaid beneficiaries. Finally, Medicaid patients experienced a longer time to prescription fill than patients with Medicare or commercial insurance. These data confirm the effects of restrictive preapproval policies for new HCV
treatments and provide concerning evidence of a disparity in access to HCV treatment.

The high incidence of DAA prescription denials among Medicaid beneficiaries in this study, along with the longer time to fill, is likely a direct consequence of the restrictive criteria for approval of these drugs that have been implemented across state Medicaid programs, which has been highlighted in recent reports.15,16 Faced with the high cost of DAAs, limited budgets, and the potential that future regimens currently being studied in Table 1.

Table 1. Characteristics of Chronic HCV-Infected Patients for Whom a DAA Prescription Was Received by the Pharmacy, Overall and by Type of Insurance

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (n = 2321)</th>
<th>US Medicaid (n = 503)</th>
<th>US Medicare (n = 795)</th>
<th>Commercial insurance (n = 1023)</th>
<th>P value Medicaid vs Medicare</th>
<th>P value Medicaid vs commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, y (IQR)</td>
<td>58 (52–63)</td>
<td>55 (49–60)</td>
<td>60 (54–66)</td>
<td>58 (52–62)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>918 (39.6)</td>
<td>218 (43.3)</td>
<td>323 (40.6)</td>
<td>377 (36.8)</td>
<td>.33</td>
<td>.02</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Black or African American</td>
<td>608 (26.2)</td>
<td>166 (33.0)</td>
<td>233 (29.3)</td>
<td>209 (20.4)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>White</td>
<td>1416 (61.0)</td>
<td>208 (41.4)</td>
<td>480 (60.4)</td>
<td>728 (71.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>17 (0.7)</td>
<td>8 (1.6)</td>
<td>4 (0.5)</td>
<td>5 (0.5)</td>
<td></td>
<td></td>
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<tr>
<td>Other/unknown</td>
<td>280 (12.1)</td>
<td>121 (24.1)</td>
<td>70 (9.8)</td>
<td>81 (7.9)</td>
<td></td>
<td></td>
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<tr>
<td>HCV genotype, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2114 (91.1)</td>
<td>445 (88.5)</td>
<td>733 (92.2)</td>
<td>936 (91.5)</td>
<td>.02</td>
<td>.06</td>
</tr>
<tr>
<td>2 or 3</td>
<td>207 (8.9)</td>
<td>58 (11.5)</td>
<td>62 (7.8)</td>
<td>87 (8.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median HCV RNA level, log IU/mL (IQR)</td>
<td>6.3 (5.8–6.7)</td>
<td>6.2 (5.8–6.6)</td>
<td>6.3 (5.8–6.7)</td>
<td>6.3 (5.8–6.7)</td>
<td>.11</td>
<td>.24</td>
</tr>
<tr>
<td>Cirrhosis, n (%)</td>
<td>715 (30.8)</td>
<td>165 (32.8)</td>
<td>281 (35.4)</td>
<td>269 (26.3)</td>
<td>.30</td>
<td>.01</td>
</tr>
<tr>
<td>Prior HCV treatment response, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>No prior treatment</td>
<td>1572 (67.7)</td>
<td>391 (77.7)</td>
<td>510 (64.2)</td>
<td>671 (65.6)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Nonresponse</td>
<td>366 (15.8)</td>
<td>40 (8.0)</td>
<td>153 (19.2)</td>
<td>173 (16.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial response</td>
<td>89 (3.8)</td>
<td>11 (2.2)</td>
<td>34 (4.3)</td>
<td>44 (4.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapse</td>
<td>180 (7.8)</td>
<td>26 (5.2)</td>
<td>65 (8.2)</td>
<td>89 (8.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>114 (4.9)</td>
<td>35 (7.0)</td>
<td>33 (4.2)</td>
<td>46 (4.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV co-infection, n (%)</td>
<td>92 (4.0)</td>
<td>29 (5.8)</td>
<td>41 (5.2)</td>
<td>22 (2.2)</td>
<td>.66</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Regimen prescribed, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sofosbuvir-ledipasvir + ribavirin</td>
<td>1953 (84.1)</td>
<td>399 (79.3)</td>
<td>680 (85.5)</td>
<td>874 (85.4)</td>
<td>.03</td>
<td>.002</td>
</tr>
<tr>
<td>Sofosbuvir + ribavirin</td>
<td>210 (9.0)</td>
<td>57 (11.3)</td>
<td>64 (8.0)</td>
<td>89 (8.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir + simeprevir + ribavirin</td>
<td>66 (2.8)</td>
<td>22 (4.4)</td>
<td>27 (3.4)</td>
<td>17 (1.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paritaprevir/ritonavir-ombitasvir + dasabuvir + ribavirin</td>
<td>62 (2.7)</td>
<td>16 (3.2)</td>
<td>11 (1.4)</td>
<td>35 (3.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pegylated interferon alfa + sofosbuvir + ribavirin</td>
<td>30 (1.3)</td>
<td>9 (1.8)</td>
<td>13 (1.6)</td>
<td>8 (0.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IQR, interquartile range.

Figure 2. Incidence of any denial of a DAA prescription by the insurer (overall height of bar), insurer denial of a DAA prescription preceding approval (white bar), and absolute denial of a DAA prescription by the insurer (black bar), overall and by insurance status.
clinical trials may decrease drug prices through competition, state-run Medicaid programs have elected to prioritize certain groups over others when deciding whether to allocate DAA treatments. One review found that 74% of Medicaid programs required evidence of advanced hepatic fibrosis or cirrhosis, 69% requested a prescription by or consultation with a specialist, and 50% required a period of abstinence from drugs and/or alcohol. Study of Liver Diseases and Infectious Diseases Society of America recommended antiviral treatment for all patients with chronic HCV, but prioritized DAA-based HCV therapy for certain subgroups, particularly those with advanced hepatic fibrosis or cirrhosis. As of October 2015, these HCV treatment guidelines no longer provide prioritizations for DAA therapy. DAA treatments also have been shown to be cost effective in recent analyses. Our finding that prescription of DAA treatment in the latter 3 months of our observation period was less likely to be associated with denial may suggest that insurers are relaxing criteria for reimbursement over time.

Medicaid patients also commonly were denied treatment owing to insufficient information to assess medical need. It is unclear why so many patients were denied for this reason because these patients had complete prior authorization requests that should have contained the materials needed to justify approval. In most instances, the specific information that was missing was not reported in the denial letter to the clinician, making it difficult to appeal the decision. This lack of specificity might have been the reason that fewer appeals were filed by providers caring for Medicaid patients. Future studies also should investigate whether providers for Medicaid patients are less able to navigate through the prior authorization process and if information required from Medicaid patients is different from those with other types of insurance.
The implications of absolute denial of DAA treatment remain unknown. However, patients denied access to new DAA therapies may have continued progression of hepatic fibrosis and remain at risk for the development of cirrhosis, end-stage liver disease, and hepatocellular carcinoma. Indeed, a recent analysis using data from the Veterans Health Administration suggested that deferring anti-HCV therapy until the development of advanced hepatic fibrosis/cirrhosis reduces treatment effectiveness and increases the risk of liver-related complications and death. A separate analysis among HIV/HCV-co-infected patients in the Swiss HIV Cohort Study found that deferring treatment from meta-analysis of histological data in viral hepatitis stage F2 until stages F3 or F4 increased the risk of liver-related death 2-fold and 5-fold, respectively. Denial of DAA treatment also can lead to ongoing HCV-associated inflammation, which might increase the risk of extrahepatic complications, including bone, kidney, cardiovascular, and neuropsychiatric disease. Furthermore, failure to treat and cure chronic HCV can lead to continued risk of HCV transmission. Denial of DAA therapy also might promote anxiety and stress about HCV disease progression and provoke distrust among patients of the health care system and their providers. Clinicians then are challenged to explain the denial, and important opportunities for patient engagement, education, and cure could be irrevocably lost.

This study had several potential limitations. Because Medicaid programs have different criteria for DAA prescription, our findings among the Medicaid patients within Delaware, Maryland, New Jersey, and Pennsylvania might not be generalizable to beneficiaries in other states. Our results also might not be generalizable to patients covered by integrated health plans. Furthermore, our analysis included a sample of chronic HCV-infected patients from one specialty pharmacy in the US Mid-Atlantic region and may not be representative of chronic HCV patients nationally or reflect prescription outcomes at other pharmacies dispensing DAA therapy. However, the characteristics of the patients in this study are similar to those within recent DAA treatment trials and observational studies of chronic HCV-infected patients.

Moreover, this study evaluated access to DAA therapy during the period when the first all-oral DAA regimens were available and the market was dominated by one supplier. The recent release of several new DAs (eg, daclatasvir, elbasvir/graftoprevir) appears to be resulting in greater price competition, which could allow greater access to these agents in the future. In addition, on November 5, 2015, the Centers for Medicare and Medicaid Services notified states that restricting access to DAA drugs is contrary to the statutory requirements within section 1927 of the Social Security Act. They also sent letters to DAA drug manufacturers inquiring about opportunities for discount or value-based purchasing arrangements to make these medications more affordable. The long-term effects of an expanding supply of agents and pressure from government sources on treatment access remain to be seen.

In conclusion, most Medicare and commercial insurance beneficiaries have access to DAA-based treatment for chronic HCV infection, but nearly half of the Medicaid beneficiaries within Delaware, Maryland, New Jersey, and Pennsylvania were denied access. Notably, nearly one quarter of Medicaid recipients with cirrhosis experienced treatment denial. Medicaid patients from these states also experienced a longer time to prescription fill than those with Medicare or commercial insurance. These data show that the restrictive preapproval policies for DAA therapies among Medicaid beneficiaries have led to an important disparity in access to HCV therapy that must be addressed.

References


Reprint requests
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Conflicts of interest
These authors disclose the following: Vincent Lo Re has received investigator-initiated research grant support (to the University of Pennsylvania) from AstraZeneca; Jody Gilmore has served on the advisory boards of AbbVie, Bristol-Myers Squibb, and Gilead Sciences; Jalpa Doshi has served on the advisory boards of Alkermes, Boehringer Ingelheim, Forest, Ironwood Pharmaceuticals, Merck, and Shire, has received research grant support (to the University of Pennsylvania) from Amgen, Merck, Pfizer, PhRMA, and the National Pharmaceutical Council, and has a spouse who holds stock in Merck and Pfizer; Peter Reese has received investigator-initiated research grant support from Merck; K. Rajender Reddy has served on the advisory boards of Merck, AbbVie, Bristol-Myers Squibb, Gilead Sciences, and Janssen, and has received research grant support (to the University of Pennsylvania) from AbbVie, Bristol-Myers Squibb, Gilead Sciences, Janssen, and Merck; Jay Kostman has served on the advisory board of Gilead Sciences; and Paul Urick, Joshua Halladay, Kathryn Battista, and Cassandra Peleckis are employees of Burman’s Specialty Pharmacy. The remaining authors disclose no conflicts.

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