Economic burden associated with sobriety restrictions to second-generation direct acting antiviral (2G-DAAs) access among Medicaid patients with hepatitis C virus (HCV): A Retrospective analysis of Claims from States with and without restrictions

Poster 137166

Michelle Martin,[1] Krithika Rajagopalan,[2] Dilip Makhija,[3] Fatema Turkistani,[2] Caroline Burk,[3] Marvin Rock,[3] and Nancy Reau[4]

1. University of Illinois at Chicago College of Pharmacy, Chicago, IL, 2. Anlitiks, Inc., Dover, MA, United States, 3. Gilead Sciences, Inc., Foster City, California, United States, 4. Rush University Medical Center, in Chicago, IL

Conclusions

- In this analysis, patients initiating direct-acting antiviral agents (DAAs) in states with no restrictions (S/no-SR) had nearly 20% and 50% lower per patient per month (PPPM) pharmacy and medical costs, respectively compared to states with sobriety restrictions (S/SR)
  - Lower medical costs driven by 40% fewer inpatient visits.
- These results suggest that cohort S/SR may have increase in overall costs potentially due to
  - Increased costs of sobriety treatment, addiction management, and
  - Greater adverse long-term patient outcomes, including extra-hepatic manifestations
- These findings suggest that sobriety restrictions that may delay DAAs access for the vulnerable hepatitis C virus (HCV) population in state Medicaids may have unintended cost consequences, potentially due to increased HCRU.

Plain Language Summary

- In this research, we studied the cost impact of compulsory restrictions in state Medicaids that require patients with HCV to show proof that they are sober from drug/alcohol abuse before they can receive life-saving DAA medications.
- For this analysis, we used the Medicaid sample from the All Payor Claims Data to compare data of HCV patients in states with Medicaid S/SR and states without Medicaid S/no-SR.
- Results show that people in S/SR used healthcare more often, which made their treatment more expensive; patients treated with DAAs in S/no-SR had 20% lower medication costs and 50% medical visit costs, including hospitalization compared to those in S/SR.
- This shows that having sobriety rules might have the unintended results of increasing costs rather than decreasing costs, with potentially greater spending for treating addiction as well as increasing clinical problems.

Abbreviations: 2G-DAAs, second generation direct acting anti-viral; APCD, all payor claims data; AUD, alcohol use disorder; CI, confidence interval; ED, emergency department; HCV, hepatitis C virus; IP, in-patient; IQR, inter-quartile range; LSM, least square mean; OP, out-patient; PPPM, per patient per month; S/no SR, states with no sobriety restrictions; S/SR, states with sobriety restrictions; SD, standard deviation; SUD, substance use diagnosis; US, United States.

References: 1. 2021 Hepatitis C | Viral Hepatitis Surveillance Report | CDC. (n.d.). https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-c.htm. Access March 14, 2024. 2. Poster 2954 EAS 2022.c. 3. Thompson WW, Symum H, Sandul A, et al. Vital Signs: Hepatitis C Treatment Among Insured Adults — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:1011-1017.doi: http://dx.doi.org/10.15585/mmwr.mm7132e1

Acknowledgments: to Sharyu Deshmukh and Vamshidhar Taduka for their programming support, as well as to Richa Goyal and Goutam Solanki who are employees of Anlitiks for their support of this work. We acknowledge that this study was funded by Gilead Sciences, Inc..

Disclosures: This study was funded by Gilead Sciences, Inc., Foster City, California, United States

Correspondence: Dilip Makhija (dilip.makhija@gilead.com)

Introduction

- In 2021,107,300 new cases of chronic hepatitis C virus (HCV) infection were identified in the United States (US) with a rate of 39.8 cases per 100,000 individuals. [1,2]
- HCV is known to mainly impact the underserved population, who are often insured through state Medicaids.[1,2]
- With the advent of 2nd generation direct-acting antiviral agents (DAAs) in 2013, many state Medicaids have implemented mandatory restrictions associated with liver disease severity, prescriber specialty, as well as sobriety that delay access to DAAs.
- Additionally, state Medicaids have implemented other DAA access restrictions that require:
  - (i) individuals to have worsened liver function (ii) only specialists such as hepatologists/GI/infectious disease specialists to prescribe/counsel DAA use (iii) prior authorization, and (vi) use of a specific specialty pharmacy.[3]

Objectives

- To estimate differences in all-cause and HCV-related medical, pharmacy, and overall total health care costs of Medicaid population initiating 2nd generation DAAs in states with no restrictions (S/no-SR) versus states with sobriety restrictions (S/SR).

Methods

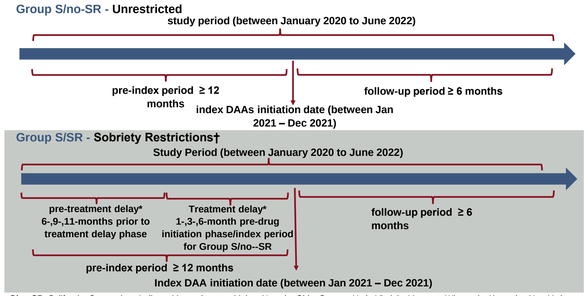
Study Design and Data Source

- A retrospective cohort analysis of claims data sourced from Anlitiks All Payor Claims Data (APCD), representing all state Medicaids from January 2020 – June 2022 (study period).
- The APCD provides insight into over 80% of the US population eligible for health insurance.

Study Population

- Adult patients, aged 18-64 years, who initiated a 2nd generation DAA (≥1 pharmacy claim for a DAA regimen) between 01/01/21-12/31/21(i.e., patient identification period) based on National Drug Code (NDC) codes in outpatient pharmacy claims, and continuously enrolled for ≥12-months pre- and ≥6-months post-index enrolment (i.e., ≥1 medical claim) were categorized based on "state of residence" into S/no-SR and S/SR.
  - ***S/no-SR:*** the date for initiated a 2nd generation DAA was indexed as the index date
  - ***S/SR:*** States with 1-,3-, or 6-month sobriety restrictions (where patients must abstain from substance use for at least 1-,3-, or 6- months prior to receiving DAA treatment).
    - The 1-,3-, 6-month pre-drug initiation phase was considered as a "treatment delay" and the first date of "treatment delay" was indexed as the index date and included in the cost calculations **(Figure 1).**

Figure 1: Study Design & Schema



S/no-SR: California, Connecticut, Indiana, Massachusetts, Maine, Nevada, Ohio, Oregon, Utah, Virginia, Vermont, Wisconsin, Kentucky, New York, North Carolina, Pennsylvania; **S/SR**:1 Month, Florida; 3 Months, Arizona, Iowa, Kansas, North Dakota, Texas, West Virginia; 6 Months, Arkansas, Mississippi, Nebraska, South Dakota, Tennessee, Alabama
*Patients with history of pre-index and/or post-index for alcohol use disorder (AUD); substance use diagnosis (SUD) related to opioid use disorder; other drug-related disorders such as cocaine, heroin, sedatives based on ≥1 inpatients (IP) or outpatients (OP) claim was flagged for inclusion; †For patients residing in restricted states (S/SR), both pre-index and post-index history of methadone, buprenorphine, or naltrexone used for treatment of SUD or AUD was identified to determine sobriety levels or status to determine washout period

Study Measures and Definitions

- Baseline Measures (S/no-SR: 12-months pre-index, S/SR: 12-months pre-index includes both "pre- treatment delay/pre-washout period" and "treatment delay/washout period")
  - Demographic characteristics (e.g., age) and clinical characteristics (e.g., substance use, HCV diagnosis rate), and comorbidity characteristics (e.g., Charlson comorbidity) index were examined.
- Follow-up Cost Outcome Measures (post-index)
  - Total and PPPM all-cause and HCV-specific medical (IP, ED, OP, professional visit, other visits) and pharmacy costs between S/no-SR vs. S/SR were measured for patients with at least one claim with cost (≥ 0).

Methods

Statistical Methods

- Demographics, clinical characteristics, and cost were reported as frequencies and percentages for categorical variables; mean (SD) and median (IQRs), as well as 95% confidence interval (CIs) for continuous variables
- Gamma regressions with log link were used to assess report differences in all cause and HCV-related total and PPPM costs, adjusting for baseline characteristics that was significantly different between the cohorts.
  - Percentages, unadjusted least square (LS) mean, and adjusted LS mean total and PPPM costs with 95% CI are presented.

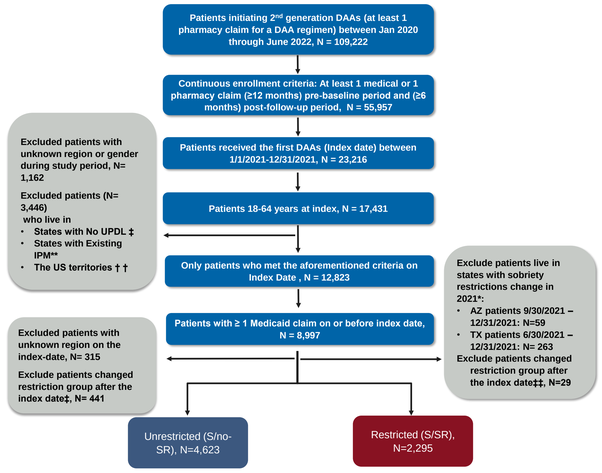
Results

- Patient selection attrition table and demographic, clinical, and comorbidity characteristics are provided in **Figure 2 and Table 1,** respectively.
- Overall S/no-SR were significantly younger (43 vs. 45; p<0.001) years; more likely to be male (58.1% vs. 50.28%; p<0.001), and had higher rates of substance use, **Table 1**.

All-cause Cost; Cost Per Patients:

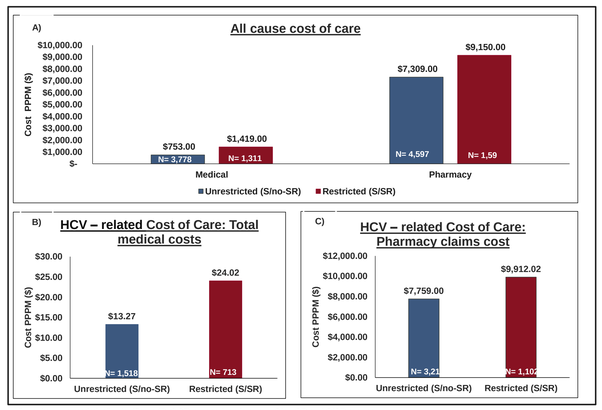
- All-cause medical PPPM costs were significantly lower (p<0.05) for S/no-SR vs. S/SR cohort and were mainly driven by IP visits, **Figure 3:**
  - IP [$3,441.04 vs. $5,680.1], OP [$42.66 vs. $83.60], ER [$97.86 vs. $155.73], and office visits [$65.74 vs. $80.11].

Figure 2: Patient Identification



‡ States with No Uniform Preferred-Drug List (UPDL): (Hawaii, Maryland, New Jersey, New Mexico, Rhode Island); ** Existing Integrated Pricing/Payment Model (IPM): Louisiana, Washington, Michigan, and Missouri; † † The US territories District of Columbia and Puerto Rico; *States with sobriety restrictions change in 2021 (AZ patients 1/1/2021-9/30/2021, TX patients 1/1/2021-6/30/2021); ‡‡Patients who switch their state of residence within the same restriction group after the index date was included in the analysis. However, patients who switch their state of residence and fall into a different restriction group after the index date was excluded from the analysis.

Figure 3. Unadjusted Cost of Care PPPM



All results were statistically significant (P<0.05) comparison between S/no-SR and S/SR groups.

Results

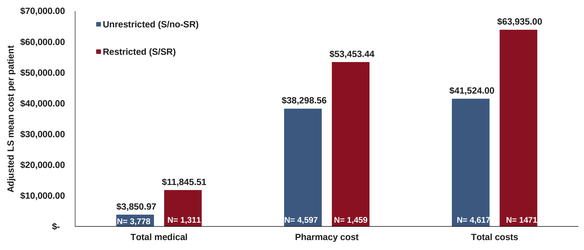
- Overall, S/SR had significantly higher all cause unadjusted and adjusted LS mean cost per patients for medical and pharmacy costs as well as total costs after controlling for potential confounders.
  - Unadjusted ~~LS~~ means cost per patients for S/no-SR vs. S/SR were: total medical cost, $4,522 ($3,590 – $5,454) vs. $8,515 ($6,933 – $10,098); pharmacy cost $43,857 ($42,443 – $45,272) vs. $54,904 ($52,394 – $57,415); overall, $47,368 ($45,748 – $48,988) vs. $62,047 ($59,176 – $64,917)
    - Pharmacy costs were mainly driven by the expenses associated with DAA medications and substance use treatment for both groups
  - The adjusted regression results are displayed in **Figures 4**

Table 1. Demographic, Clinical and Comorbidity Characteristics

Parameters	Unrestricted (S/no-SR), N=4,623	Restricted (S/SR), N=2,295	p-value*
Age			
Mean (SD)	43 (11.51)	45 (12.02)	‡
Sex, n (%)			
Male	2,686 (58%)	1,154 (50.28%)	‡
Race Availability†, n (%)			
Available	1,833 (39.65%)	900 (39.22%)	
Race/Ethnicity, n (%)			
White	101 (5.51%)	230 (25.56%)	‡
African American	45 (2.45%)	53 (5.89%)	‡
American Indian/Alaskan Native	2 (0.11%)	2 (0.22%)	0.85
Asian	1 (0.05%)	0 (0%)	NA
Hispanic	24 (1.31%)	24 (2.67%)	0.02
Other	1,660 (90.56%)	591 (65.67%)	‡
HCV diagnosis rates			
N (%)	3,081 (66.65%)	1,486 (64.75%)	
Time from HCV diagnosis to treatment (in days)			
Mean (SD) / Median (IQR)	mean(SD) = 130.8 (115.4); median (IQR = 90(195)	Mean (SD) = 139.5 (114.8); median (IQR = 106(200)	‡
Quan-Charlson Comorbidity Index, n (%)			
≥3	386 (8.35%)	267 (11.64%)	‡
Other Comorbid Conditions, n (%)			
Mild liver disease	1,053 (22.78%)	622 (27.1%)	‡
Moderate or severe liver disease	1.961 (42.42%)	846 (36.86%)	‡
Substance Use, n (%)			
Any SUD	2,759 (59.68%)	1,012 (44.1%)	‡
1 SUD	225 (4.87%)	118 (5.14%)	
>1 SUD	2,534 (54.81%)	894 (38.95%)	‡

*P-values reported using Two sample independent T Test for comparing means and Chi-Square test for comparing categories; P-values ≤ 0.05 considered statistically difference; ‡ P-values ≤ 0.05; † Available for a subset of patients only
The assessment of substance use encompassed Alcohol Use Disorder, Opioid Use Disorder, Substance-related disorder, and Medication for Opioid Use Disorder. We determined the number of patients and proportions based on whether they were diagnosed with one or more of the following: Alcohol Use Disorder, Opioid Use Disorder, Substance-related disorder, or had a National Drug Code (NDC) associated with Medication for Opioid Use Disorder.

Figure 4: All-cause Adjusted Mean Cost Per Patient



All results were statistically significant (P<0.05) between unrestricted (S/no-SR) and restricted (S/SR) groups
* Covariates in adjusted model: age, gender, opioid use disorder, substance related disorder, Quan-Charlson (less mild/moderate liver disease), smoking & tobacco use, screening & counseling and prescriber restrictions.

Limitations

- Disease definitions rely on ICD-10-CM codes from reimbursement claims, potentially leading to false positives and false negatives in classification.
- This study evaluated a Medicaid claims dataset only, so its findings may not be fully applicable to all insured populations in the US, including those with HCV.
- The study did not evaluate other access barriers beyond sobriety restrictions, which could also impact healthcare costs.
- In addition, it is important to note that there may be other underlying differences between the analytic samples in the states, which could potentially impact the study outcomes