Thank you for joining: HepVu's Visualizing Hepatitis C Treatment Restrictions

Subscribe to HepVu's newsletter and blog updates at <u>HepVu.org/email-signup</u>

The webinar will begin at 3:00 pm ET/ 12:00 pm PT

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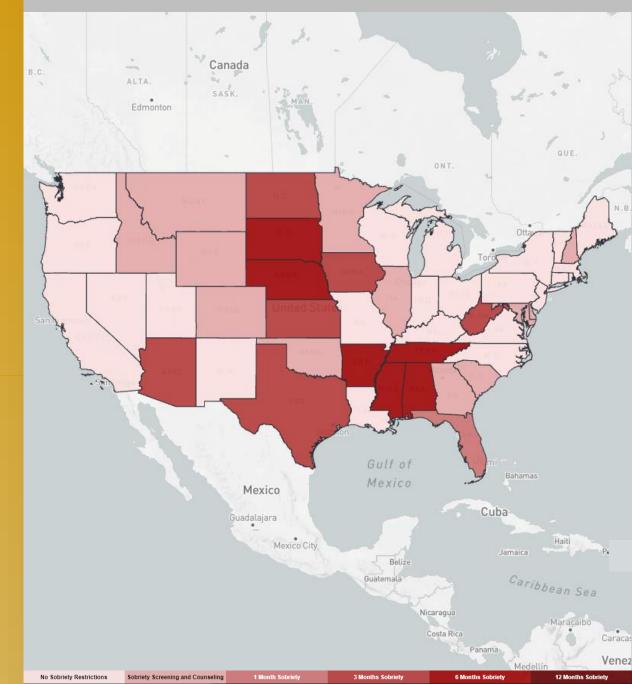
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Visualizing Hepatitis C Treatment Restrictions

Heather Bradley, PhD HepVu Project Director Assistant Professor of Epidemiology Georgia State University



Sobriety Treatment Restrictions, 2021 (as of April 2021)





Webinar Panelists



Phil Waters, J.D., Staff Attorney, Center for Health Law and Policy Innovation (CHLPI), Harvard Law School



Adrienne Simmons, PharmD, MS, BCPS, AAHIVP, Director of Programs, National Viral Hepatitis Roundtable (NVHR)



Lynn E. Taylor, MD, Director of HIV and Viral Hepatitis Services, CODAC Behavioral Healthcare; Research Professor, University of Rhode Island; Director, RI Defeats Hep C



Agenda

HepVu & Treatment Restrictions Overview

Hepatitis C: The State of Medicaid Access

Advocacy & Removing Treatment Restrictions

Discussion: Challenges and Moral Dilemmas of Treatment Restrictions

Q&A



HepVu & Treatment Restrictions Overview

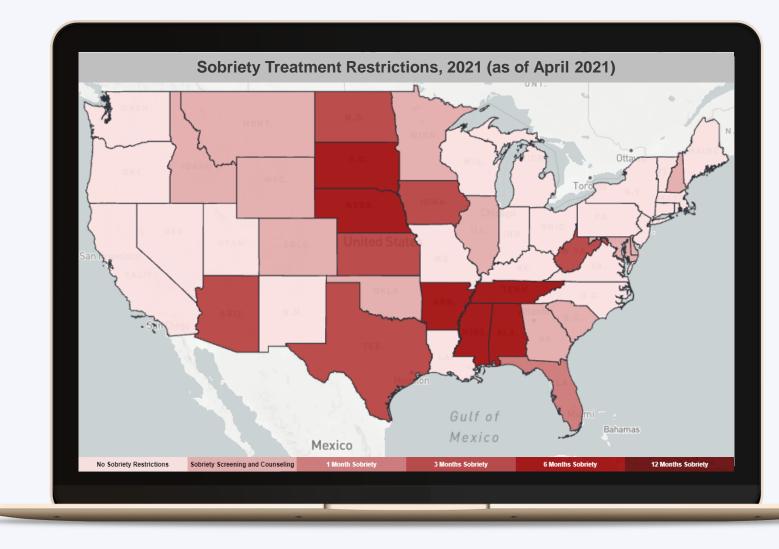
Heather Bradley, PhD, HepVu Project Director, Assistant Professor of Epidemiology, Georgia State University

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Making data on the viral hepatitis epidemic widely available, easily accessible, and locally relevant to inform public health decision making.

Partnership between Gilead Sciences and Rollins School of Public Health at Emory University.





To inform public health decision making

Fibrosis Restrictions By year from 2017 to 2021

Sobriety Restrictions By year from 2017 to 2021

Prescriber Restrictions By year from 2017 to 2021





Hepatitis C Testing & Care



Infected with Hepatitis C Diagnosed and Aware Access to antibody testing. Hepatitis C RNA Confirmed Confirmatory testing. Underwent Liver Disease Staging Liver disease stage assessed.

Prescribed Hepatitis C treatment Access to DAAs. Achieved Cure Complete treatment retained

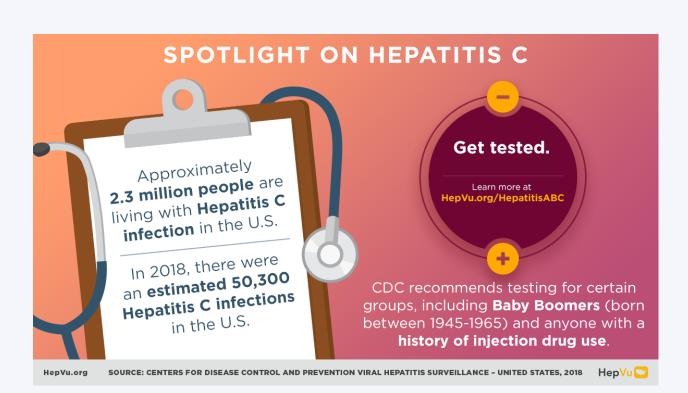
in care.



Testing

Testing...to Treatment?

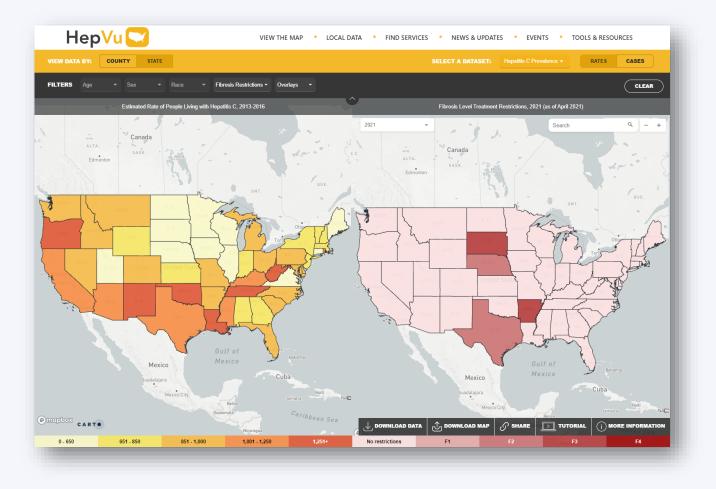
- 2.3 million people are living with Hepatitis C...half are undiagnosed
- CDC recommends all adults get tested for Hepatitis C, especially anyone with a history of injection drug use
- Journal of Primary Care and Community Health: Boston Medical Center (BMC), found that hospital-wide, total Hepatitis C testing decreased by 49.6% over a 3.5-month period from March 16 – June 30, 2020





Comparison Map

Fibrosis Restrictions

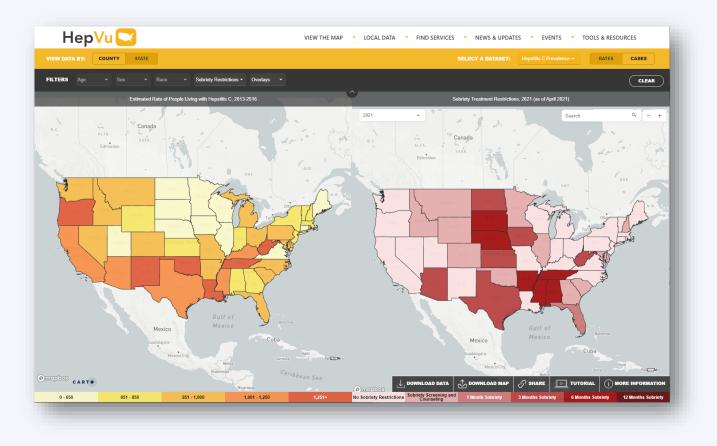


Fibrosis restrictions require patients to wait until Hepatitis C severely damages their liver before receiving Hepatitis C treatment.



Comparison Map

Sobriety Restrictions



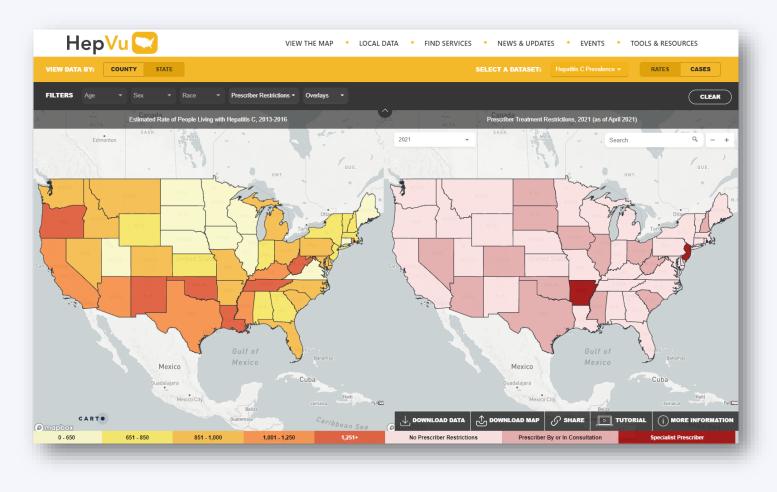
Sobriety restrictions require individuals to abstain from using alcohol and/or drugs for a specified timeframe prior to starting Hepatitis C treatment.





Comparison Map

Prescriber Restrictions



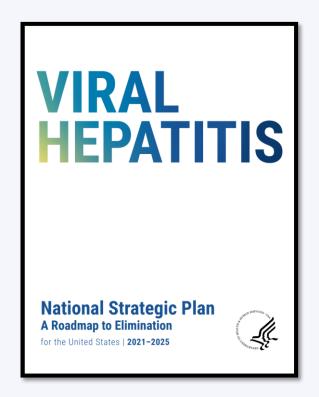
Prescriber restrictions limit the type of clinicians that can prescribe Hepatitis C treatment.





Why Map Treatment Restrictions?







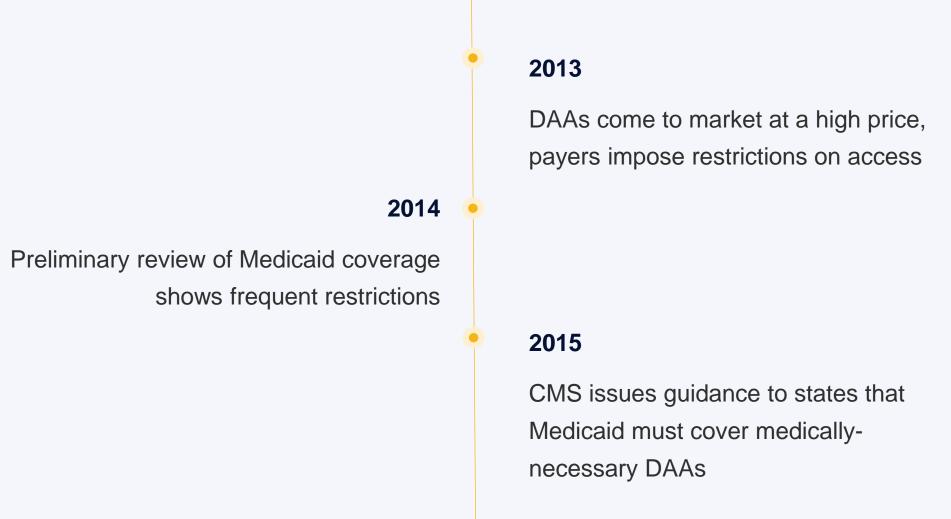
Hepatitis C: The State of Medicaid Access

Phil Waters, J.D., Staff Attorney, Center for Health Law and Policy Innovation (CHLPI), Harvard Law School

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HCV Treatment Access in Medicaid





2016

WA Medicaid sued for policy requiring severe liver damage before treatment

Continued advocacy results in removal of restrictions entirely in 21 states

2017

StateofHepC.org launched, detailing Medicaid treatment restrictions

2021

Movement of restrictions by year mapped on HepVu



Hepatitis C: The State of Medicaid Access

Documents the current state of Medicaid fee-for-service Hepatitis C treatment access policies.

Findings are based on surveys of Medicaid officials, publicly available documents, and official press or media releases.

HEPATITIS C: THE STATE OF MEDICAID ACCESS May 2021 National Progress Report

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) share a commitment to ensuring that all individuals living with hepatitis C (HCV) are able to access the cure for HCV, one of the deadliest infectious disease in the United States. We are pleased to report that our collective advocacy is working.

In particular, the launch of our Hepatitis C: The State of Medicaid Access report in 2017 has successfully supported efforts to eliminate treatment access restrictions. Since 2014, access to direct-acting antivirals (DAAs) in state Medicaid programs has been incrementally expanded, often in response to advocacy and impact litigation. Importantly, there has been immense progress in transparency. In 2014, 18 states had unclear fibrosis restrictions, 15 states had unclear sobriety restrictions, and 23 states had unclear prescriber restrictions. Now, all states have known criteria, in part due to pressure from advocates for this information to be publicly available.

Since 2017, 32 states have either eliminated or reduced their fibrosis restrictions, 21 have loosened their sobriety restrictions, and 25 have scaled back their prescriber restrictions. There are also now 7 states that, in addition to removing all restrictions, have removed prior authorization for treatment entirely: Washington, Louisiana, New York, California, Indiana, Wisconsin, and most recently Michigan. In these states the barriers to getting treatment in Medicaid have been paved over with a road to treatment.

We have made tremendous progress in removing barriers to treatment since the launch of the State of Hep C in 2017, particularly with fibrosis restrictions. But our work continues. Discriminatory sobriety restrictions persist and continue to undermine our collective efforts to address both hepatitis C and the growing opioid epidemic. CHLPI and NVHR remain committed to capitalizing on the momentum we enjoy today and to advocating for the removal of all states' HCV treatment access restrictions.

We have the tools to eliminate HCVin the US, but it requires the removal of all discriminatory HCV treatment access restrictions as well as leadership and resources to turn the promise of the cure into a reality for all.

For more information about Hepatitis C: The State of Medicaid Access please go to www.stateofhepc.org.

Published: May 19, 2021



NAVHR National Viral Hepatitis Roundtable





Medicaid Treatment Access Restrictions





Sobriety

Fibrosis

Disease progress as measured by liver scarring (fibrosis). Periods of abstinence from substance and/or alcohol use prior to treatment.



Prescriber

Limiting which health care providers can prescribe treatment.



Fibrosis



The U.S. has seen the biggest progress to date in removing fibrosis restrictions.

Since 2017, 32 states have either eliminated or reduced their fibrosis restrictions.

Only 4 states have restrictions remaining.

Fibrosis Level Treatment Restrictions, 2017 Fibrosis Level Treatment Restrictions, 2021 (as of April 2021)

No restrictions

F1



F4

Sobriety

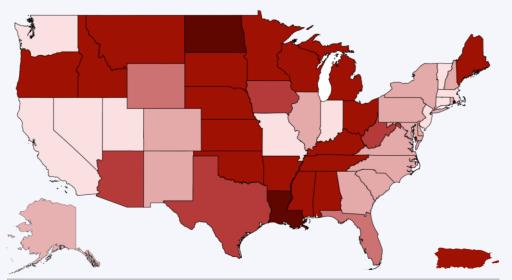


Since 2017, 21 states have loosened their sobriety restrictions.

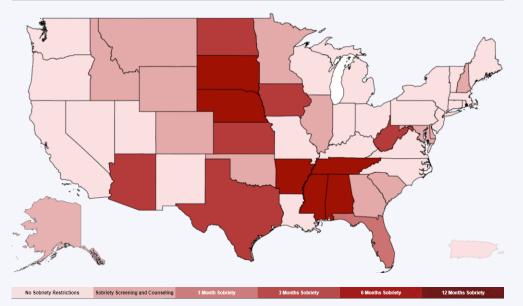
39 states impose no minimum period of abstinence.

Length required has shortened overall.

Sobriety Treatment Restrictions, 2017



Sobriety Treatment Restrictions, 2021 (as of April 2021)





Prescriber

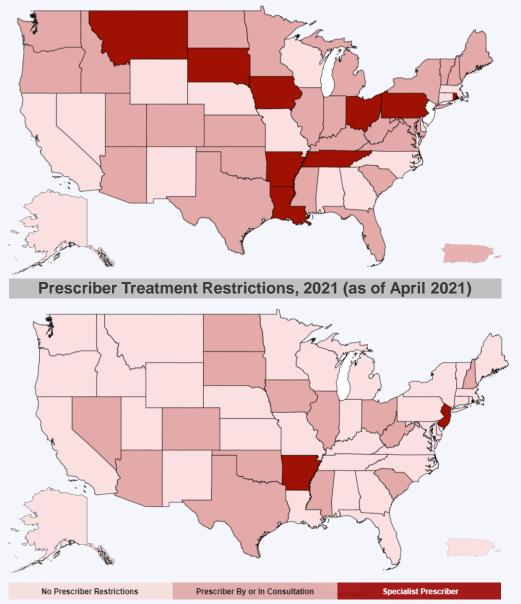


Since 2017, 25 states have scaled back their prescriber restrictions.

18 states require specialist involvement, only 2 require prescription written by specialist

Training programs for primary care providers and mid-level practitioners on Hepatitis C.

Prescriber Treatment Restrictions, 2017

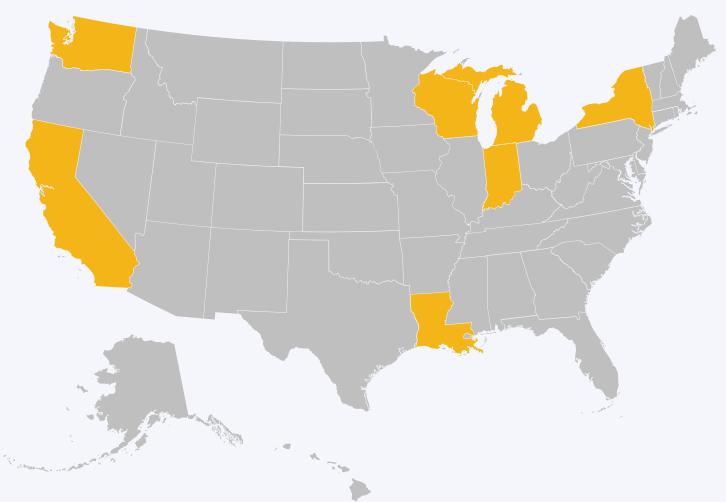




Prior Authorization

Seven states now allow access to DAAs in their Medicaid programs without requiring prior authorization at all.

This obviates the need for burdensome paperwork and streamlines treatment.





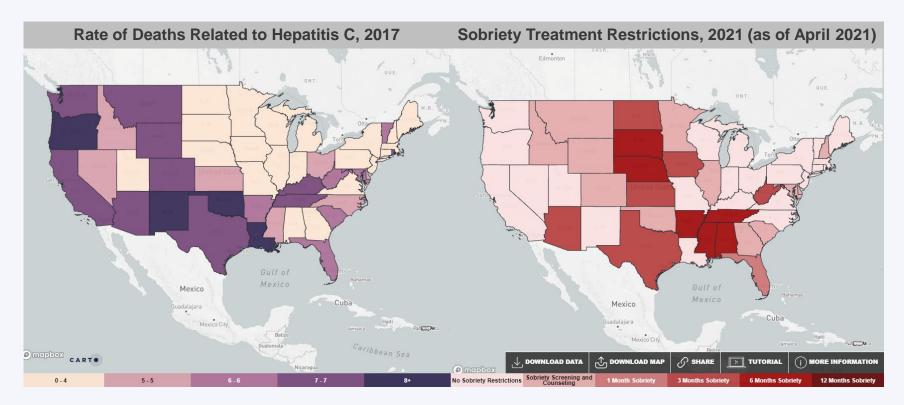
Advocacy & Removing Treatment Restrictions

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP, Director of Programs, National Viral Hepatitis Roundtable (NVHR)



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Data Visualization as an Advocacy Tool



Tells a (Local) Story

Makes Data Accessible

Additional Comparisons

- Overdose Mortality/Sobriety Restrictions
- Hep C Prevalence/Prescriber Restrictions
- Hep C Mortality/Fibrosis Restrictions

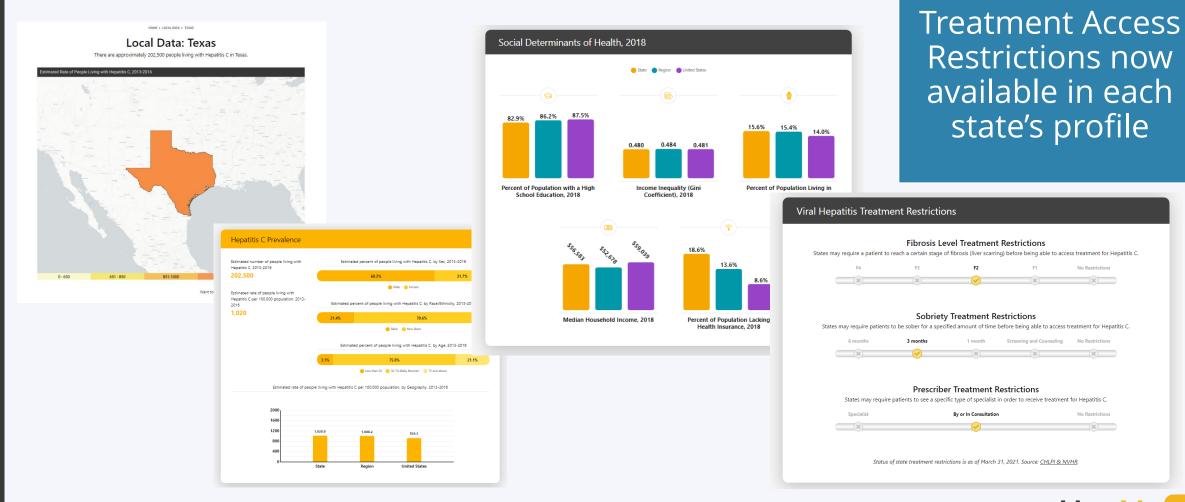


Data Visualization as an Advocacy Tool

No Restrictions

No Restrictions

Hep



Patient Advocacy

- Share your story with legislators and other policymakers such as the Medicaid Director, Secretary of Health, Governor's Office, etc.
- Provide public comment at Medicaid Pharmacy & Therapeutics Committee and/or Drug Utilization Review Board meetings
- Engage in state coalitions and support awareness, education, and advocacy efforts
- Leverage opinion editorials, letters to the editor, and social media to spread awareness about how treatment access restrictions are impacting you

FIRST OPINION

We can't eliminate hepatitis C without removing barriers to treatment

By Nick Voyles Nov. 14, 2020



Paulette Walton, a registered nurse in charge of coordination of hepatitis C treatment at the San Francisco General Hospital Opiate Treatment Outpatient Program, shows a pack of pills used to treat the virus at the clinic.

s Americans fight the Covid-19 pandemic, the epidemic caused by the hepatitis C virus also continues to rage, especially among marginalized communities. And while some barriers to accessing health care have been eliminated during Covid-19,





Provider Advocacy

- Compile examples of treatment access issues and provide public comment at Medicaid Pharmacy & Therapeutics Committee and/or Drug Utilization Review Board meetings
- Send sign-on letters and/or request meetings with the Medicaid Director, Secretary of Health, Governor's Office, etc.
- Leverage opinion editorials, letters to the editor, and social media to spread awareness about how treatment access restrictions impact patients
- Present and publish on treatment access restrictions

November 9, 2020

Stephanie Azar Commissioner Alabama Medicaid Agency 501 Dexter Avenue, PO Box 5624 Montgomery, AL 36103-5624

Re: COVID-19 and Access to Hepatitis C Treatment

Dear Commissioner Azar:

This letter is submitted on behalf of the below signed clinicians to request your immediate attention to the barriers to care that COVID-19 poses to our patients living with hepatitis C virus (HCV) infection.

As we seek effective solutions to COVID-19, we must not disregard the pre-existing public health crisis of HCV infection. The response to COVID-19 and HCV share similar barriers, such as limited testing capacity and lack of support for preventive measures. However, one stark contrast between these public health crises is that HCV *can be cured* through a safe and effective 8-to-12-week course of direct acting antiviral (DAA) therapy. Unfortunately, access to curative therapy in Alabama is restricted by prior authorization criteria. These criteria interfere with our ability to provide the medical standard of care to our patients, thereby increasing their risk of death from liver disease. We request that any prior authorization criteria that do not align with the standard of care established by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) guidelines be immediately removed.



Opinion

Opinion: Hepatitis C is a curable disease. Texans shouldn't have to wait for a cure

By Dr. Mamta Jain

Posted Mar 7, 2020 at 5:46 AM

Disproportionately high rates of viral hepatitis and liver cancer are jeopardizing the lives of countless Texans. Unfortunately, discriminatory and illegal restrictions on treatment prevent thousands from accessing necessary care. Current Medicaid restrictions on hepatitis C treatments leave too many patients untreated, leading to further complications and rising liver cancer rates.

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Supporting Broader Advocacy Efforts

- Support federal advocacy efforts led by organizations like NVHR, such as calling on CMS and HHS to hold states accountable in removing treatment access restrictions
- Track denials and engage with NVHR/CHLPI about what you're seeing on the ground - this is helpful for litigation
- Share information about the removal of restrictions and the impact in your community
- Join the NVHR Voices4Hep network and let us know how we can help support your advocacy efforts!

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-26-12 Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 172

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the



Social Advocacy

Hepatitis C treatment restrictions have **lessened** over the last decade since the introduction of direct-acting antivirals (DAAs). Fewer treatment restrictions allow for increased access to Hepatitis C treatment for patients in Medicaid programs.

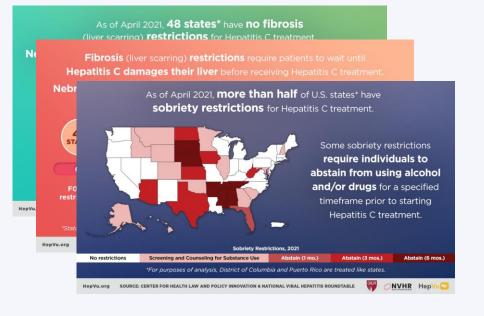
Current Hepatitis C Treatment Restrictions for Medicaid, 2021

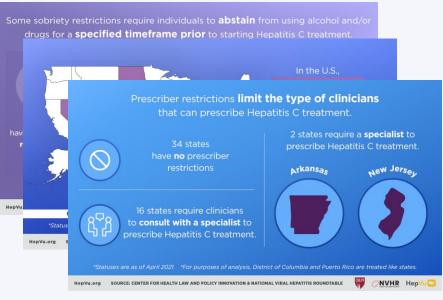
32 states 21 states 25 states FO/No Restrictions No Restrictions Screening and Counseling for Substance Use F1 Abstain (1 mo.) Abstain (3 mos.) Abstain (6 mos.)

No Restrictions By or in Specialist Must Prescribe

HepVu.org SOURCE: CENTER FOR HEALTH LAW AND POLICY INNOVATION & NATIONAL VIRAL HEPATITIS ROUNDTABLE

⊃NVHR HepVu<mark>⊂</mark>





Discussion: Challenges and Moral Dilemmas of Treatment Restrictions

Lynn E. Taylor, MD, Director of HIV and Viral Hepatitis Services, CODAC Behavioral Healthcare; Research Professor, University of Rhode Island; Director, RI Defeats Hep C



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The recording and slides will be available on <u>HepVu.org</u>



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