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Disclosures

*Hepatitis C: State of Medicaid Access* is supported by AbbVie and Gilead Sciences. The methods, research, and conclusions of this project are those of the Center for Health Law and Policy Innovation of Harvard Law School and National Viral Hepatitis Roundtable and do not necessarily reflect the opinions of AbbVie or Gilead Sciences.
● Overview of Hepatitis C: State of Medicaid Access
● Why Treatment Restrictions Matter
● 2023 Findings & Trends in HCV Treatment Access
● Advocacy Opportunities & Key Takeaways
● Discussion & Q&A
Overview of Hepatitis C: State of Medicaid Access
History of HCV Treatment Access in Medicaid

- **2013**: DAAs come to market at high price, payers impose restrictions on access
- **2014**: Preliminary review of Medicaid coverage shows frequent restrictions*
- **2015**: CMS issues guidance to states suggesting that Medicaid must cover medically-necessary DAAs
- **2016**: WA Medicaid sued for policy requiring severe liver damage before treatment
- **2017**: www.stateofhepc.org launched, detailing Medicaid treatment restrictions

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Hepatitis C: State of Medicaid Access

- Launched in 2017 as a partnership between the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR)
- Documents the current state of Medicaid HCV treatment access across 52 jurisdictions, including state-by-state “report cards”
- Findings are based on publicly available documents, including published clinical criteria, prior authorization forms, meeting minutes, and press releases
Medicaid Treatment Access Restrictions

Historical Restrictions

Fibrosis

Substance Use

Prescriber

Managed Care

Added June 2022

Prior Authorization

Retreatment

Additional Restrictions
Our Website Got a Makeover!

2023 NATIONAL SNAPSHOT REPORT

Since 2014, the Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) have sought to ensure that all people living with hepatitis C (HCV) are able to access treatment through our joint work on the Hepatitis C State of Medicaid Access project.

We’re pleased to report our collective advocacy over the last decade has been working. In particular, the ongoing publication of our State of Medicaid Access reports has successfully supported efforts to eliminate treatment restrictions across the nation. Since we began releasing annual reports in 2017, 21 states have removed prior authorization requirement for most patients, 33 have either eliminated or reduced their fibrosis restrictions, 37 have loosened their sobriety restrictions, and 34 have scaled back their prescriber restrictions.

We celebrate this significant wave of progress, but our work will not be done until the promise of an HCV cure is an accessible reality for all. It is in that spirit that we bring you our 2023 snapshot of Medicaid access. You can click on the categories below to jump to that topic or simply scroll to take it all in.

OVERALL GRADES

A (9): Colorado, Idaho, Michigan, Missouri, Oklahoma, Rhode Island, Virginia, Washington, Wisconsin

A (12): Alaska, California, D.C., Hawaii, Indiana, Louisiana, Massachusetts, New Hampshire, New York, Oregon, Pennsylvania, Texas,

B (15): Alabama, Arizona, Connecticut, Kansas, Kentucky, Minnesota, Mississippi, North Carolina, Tennessee, Utah, Vermont

C (12): Florida, Georgia, Maine, Maryland, Montana, Nevada, New Jersey, New Mexico, Ohio, Puerto Rico, West Virginia, Wyoming

D (6): Delaware, Iowa, Nebraska, North Dakota, South Carolina, South Dakota

F (2): Arkansas, Illinois

Citation: Center for Health Law and Policy Innovation & National Viral Hepatitis Roundtable. Hepatitis C: State of Medicaid Access (2023), www.stateofhepc.org

Check out your state’s most up-to-date report card and our latest national snapshot report at www.stateofhepc.org
Why Treatment Restrictions Matter
HCV Infections are Rising

- The incidence rate of acute hepatitis C has more than doubled since 2013, and increased 15% from 2019.
- Persons aged 20-39 years had the highest incidence of acute hepatitis C.
- 66% of cases with risk information reported injection drug use.

People of Color Have Worse HCV Outcomes

- Native Americans experience higher rates of acute HCV, and higher rates of HCV-related mortality, than any other racial/ethnic group.
- Mortality rates are highest among Native American and Black people (3.2 times and 1.8 times, respectively) compared to white people.

Rates* of reported cases of acute hepatitis C virus infection, by race/ethnicity
United States, 2005–2020

As HCV Cases Rise, Treatment Rates are Declining

- To eliminate hepatitis C, more than 260,000 people should be treated every year.
- The number of people treated was highest in 2015 and declined to its lowest level in 2020.

Only 1 in 3 of Insured Receive Timely HCV Treatment

Timely Hepatitis C Treatment* by Insurance Type

<table>
<thead>
<tr>
<th>Insurance Type</th>
<th>Timely Treatment</th>
<th>Not Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>23%</td>
<td>77%</td>
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<tr>
<td>Medicare</td>
<td>28%</td>
<td>72%</td>
</tr>
<tr>
<td>Private</td>
<td>35%</td>
<td>65%</td>
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*Hepatitis C treatment started within 12 months of diagnosis during January 30, 2019 to October 31, 2020

Timely treatment rates drop to 1 in 4 among Medicaid Beneficiaries

HCV Treatment Access is a Health Equity Issue

- Certain communities are disproportionately impacted by the HCV epidemic and have poorer treatment outcomes, including:
  - Black communities and other communities of color;
  - Rural communities;
  - People who are unhoused or housing insecure;
  - People who use drugs; and
  - People who have a history of incarceration.

- Treatment access restrictions often disproportionately restrict access to these same communities, widening disparities in both health care access and health outcomes.
Disparities are Widened by Prior Auth Requirements

Treatment access restrictions can widen already-existing disparities for groups that already experience disproportionate rates of infection

- People who use drugs are at higher risk for hepatitis C, but may be denied treatment in states that impose substance use restrictions
- People who are unhoused and without access to reliable transportation may have difficulty meeting prior authorization requirements, like submitting multiple rounds of lab work within a certain timeframe
- Providers who serve rural communities with low populations may face difficulty scheduling a specialist consultation, particularly if there are only a few specialists in network
Federal HCV Elimination Initiative

• Dr. Francis Collins leading development of a proposal for a National HCV Elimination Program
• Early discussions include **financing strategies for direct-acting antivirals** and novel HCV diagnostics
• Funding not yet secured for program and program details not yet finalized
2023 Findings & Trends in HCV Treatment Access
State Grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A+</td>
<td>100</td>
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<tr>
<td>A</td>
<td>90-99</td>
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<tr>
<td>B</td>
<td>80-89</td>
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<tr>
<td>C</td>
<td>70-79</td>
</tr>
<tr>
<td>D</td>
<td>60-69</td>
</tr>
<tr>
<td>F</td>
<td>&lt;60</td>
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</tbody>
</table>

Overall State Grades

- A+: 9 states
- A: 12 states
- B: 10 states
- C: 13 states
- D: 6 states
- F: 2 states
Overall State Grades

Since 2017, 33 states either eliminated or reduced fibrosis restrictions, 36 loosened sobriety restrictions, and 35 scaled back prescriber restrictions.
Noteworthy Progress Since June 2022 Report

**ALABAMA** eliminated 6-month abstinence requirement following DOJ complaint

**ARIZONA** removed prior authorization for most patients, including prescriber restriction

**COLORADO** removed prior authorization for most patients, including retreatment restriction

**DC** removed prior authorization for most patients, including substance use and prescriber restrictions

**MISSISSIPPI** eliminated substance use and prescriber restrictions

**OKLAHOMA** removed prior authorization for most patients, including substance use and prescriber restrictions

**OREGON** removed prior authorization for most patients, including retreatment restriction

**TEXAS** removed prior authorization for most patients, including substance use counseling restriction
• **21 states (40%)** have removed prior authorization for treatment-naive patients and/or preferred drug regimens, significantly reducing administrative barriers to care.

• 7 of those states removed prior authorization after June 2022 report was published.

*Updates since February 2023*
- Florida removed prior authorization by implementing SmartPA
- New Mexico and Pennsylvania may be next to remove PA
• All but two states (Arkansas, South Dakota) have removed restrictions based on liver damage (fibrosis)

• This is a significant change. In 2017, 34 states (65%) imposed some kind of liver damage requirement

Updates since February 2023
• South Dakota removed fibrosis restriction as of April 1, 2023, leaving Arkansas as the only state that imposes a fibrosis restriction.
• **5 states (10%)** require abstinence from alcohol/substances prior to or during treatment, including participation in a substance use treatment program

• **8 states (15%)** require a provider to counsel or address substance use issued prior to treatment

• **39 states (75%)** have no substance use restriction

**Updates since February 2023**

• South Dakota removed substance use requirement as of April 1, 2023

**Substance Use Restrictions**
6 states (12%) impose prescriber restrictions for initial treatment:

- **Arkansas** requires that the prescription written be a specialist; all other states require specialist consultation.
- **Puerto Rico** allows primary care physicians to prescribe only if they undergo additional training and certification.

Prescriber Restrictions
• **20 states (38%)** impose retreatment restrictions

• Such restrictions include lifetime restrictions on retreatment and policies that are otherwise more restrictive than those for treatment-naive patients (e.g., denying retreatment based on past treatment adherence, substance use, SVR12 documentation)
In states that operate managed care programs, **16 states** have at least one managed care organization (MCO) that imposes more stringent criteria to treatment access or does not provide publicly available HCV treatment criteria. Some states have strong FFS policies, but poor MCO enforcement (e.g., New Hampshire).
Additional Restrictions

- **18 states** require documentation of genotype
- **10 states** require documentation of chronic HCV infection
- **9 states** require labs to be collected within a certain timeframe
- **10 states** impose adherence requirements
- **6 states** impose barriers to replacing lost/stolen meds
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Solutions</th>
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<tr>
<td>• Mail order and lock-in requirements</td>
<td>• Allow medication to be filled by non-specialty pharmacies</td>
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<tr>
<td>• Dispensing limitations (often 30-days’ supply)</td>
<td>• Louisiana and Virginia allow retail pharmacies to fill Rx</td>
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<tr>
<td>• Two states (Connecticut and Maine) have 14-day limits</td>
<td>• Improve specialty pharmacy processes around communication and delivery</td>
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<td>• Specialty pharmacy processes vary by plan</td>
<td>• Dispense full treatment course at treatment initiation</td>
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<tr>
<td>• Intake forms often mimic PA forms</td>
<td>• Colorado allows 90-day fills</td>
</tr>
<tr>
<td>• Signature/phone call requirements are challenging for historically</td>
<td>• Engage pharmacy benefit managers about data requirements</td>
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<tr>
<td>marginalized communities</td>
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Innovative PA Mechanisms are on the Rise

- States are looking to automatic prior authorization processes referred to as Auto PA or SmartPA.
- System automated criteria check for specific requirements (e.g., diagnosis, age, previous therapies, etc.). If all requirements are found, the claims will pay at the pharmacy counter without need of manual prior authorization submission.
- To date, Indiana and Massachusetts use these processes. Florida is in the process of implementing Auto PA.

Auto PA may be an alternative strategy in states that are hesitant to remove prior authorization altogether.
Growing # of States have Single Preferred Agent

- 10 states have a **single** preferred agent (Mavyret OR generic Epclusa) on their Preferred Drug List
  - DC, Louisiana, Michigan, Minnesota, Missouri, Montana, Oklahoma, Puerto Rico, Texas, Washington
- 5 of these states use an innovative payment model (subscription model)
  - Louisiana, Michigan, Missouri, Texas, Washington
- Oklahoma appears to use an outcomes-based contract
- Other states may be purchasing through multi-state purchasing agreements

Policies Change, Awareness Lags

- When states change policies, patients and providers are often unaware
- States should send letters to providers and conduct outreach to patients who were previously diagnosed and may be untreated
- Clinics, medical societies & professional associations, provider training programs, community-based organizations, and coalitions can also be effective messengers
Opportunities, Advocacy, & Key Takeaways
Opportunities and Threats

**Opportunities**

- National HCV Elimination Program
- MINMON Study
- Treatment access in correctional facilities
  - California 1115 Waiver for Medicaid eligibility 90 days pre-release
- COVID-19 pandemic innovations (e.g., rapid diagnostics, telehealth)

**Threats**

- Public Health Emergency expiration
- Medicaid expansion holdout states
- Manufacturer restrictions on 340B Program
- Treatment access in Medicare & commercial insurance
Call to Action

• **Patients**: Tell your story! Join our Voices4Hep Network & see our Prior Auth and Letter to the Editor toolkits

• **Advocates**: Share your state’s grade & call for action! Use social media & advocacy events to publicize the need for change

• **Providers**: Use your voice! Make the case for removing burdensome barriers through written or oral testimony to your state Medicaid P&T Committee or Drug Utilization Review Board

• **Viral Hepatitis Coordinators**: Link to elimination planning! Convene stakeholders in charting a path to full access to cure

• **State Medicaid Officials**: Review and update your policies!

• **CMS**: Issue updated guidance to State Medicaid Directors!
Key Takeaways

• Prior authorization removal offers an exciting opportunity for state Medicaid programs to increase HCV treatment access and advance health equity.

• Substantial progress has been made since 2017 in reducing the number of states that impose fibrosis, substance use, and prescriber restrictions on HCV treatment access.

• Many restrictions rooted in stigma and discrimination remain. Restrictions must be removed to eliminate HCV by 2030.
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