Treatment Access Update

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HCV Treatment History

• Historically, HCV treatment was difficult, had low rates of success (40-50%) and significant side effects. This led many to opt out of treatment.

• In 2013, the first direct-acting antivirals (DAAs) receive FDA approval and achieve 95-98% cure rates.

• Infectious Disease Society of America and the American Association for the Study of Liver Diseases guidelines call for treatment of all patients, with limited exceptions.

• However, the cure came with significant cost: List price of $84,000/course of treatment. The actual cost was lower for most insurers, but still expensive.

Insurer Response to DAAs

• Despite the virtual certainty of curing patients, many public and private insurance payors restricted HCV treatment access.

• **Unprecedented restrictions** include:
  - Disease severity
  - Sobriety
  - Prescriber specialty

Center for Health Law and Policy Innovation (CHLPI) and National Viral Hepatitis Roundtable (NVHR) at https://stateofhepc.org/.
Disease Severity Restrictions

- The progression of HCV is measured in terms of liver damage (fibrosis) on a 0-4 scale (F0 absent or mild fibrosis, F4 cirrhosis or liver failure).
- Many Medicaid programs withhold treatment until patients reach advanced stages of the disease (F3-F4).

FYI

Medicaid is a government-funded insurance program that helps with medical costs for some people with limited income and resources.

Even though the federal government helps fund the program, states make decisions about how it is run.
Sobriety

- Many Medicaid programs require mandated periods of abstinence from drugs/alcohol prior to approving treatment.

- Periods range from 1-6 months, with 6 months being most common.

- Evidence shows no difference in treatment adherence or cure rates compared to people who are not using drugs.
• Many state Medicaid programs restrict prescribing authority to certain specialists: hepatologists, gastroenterologists, infectious disease specialists.

• In both urban and rural areas enrollees often lack access to scarce specialists in narrow networks, thereby creating a treatment bottleneck.
Federal Guidance to States

• **Centers for Medicare and Medicaid Services (CMS)**, the federal agency that administers Medicaid, issues guidance on access to HCV drugs to State Medicaid Directors in November 2015

• States...
  – Must cover HCV drugs of manufacturers with rebate agreements
  – **Cannot impose coverage conditions** that unreasonably restrict access
  – Must provide same coverage across all Medicaid plans within a state

*However, following the 2015 guidance, there was little movement to eliminate restrictions!*

Court Cases against Medicaid Programs

Litigated Results
- **Washington**: BE vs Teeter (injunction granted; settlement approved, April 2017)
- **Missouri**: JEM vs Kinkade (policy reformed, November 2017)
- **Michigan**: JV vs Lyon (settlement reached, March 2018)
- **Colorado**: Ryan vs Birch (disease severity criteria removed and settlement pending, April 2018)

Pre-Litigation **Settlements** as a result of legal advocacy
- CT, DE, FL, IL, MA, NJ, NY, PA, RI, VT

More cases in development!

The Research: Medicaid Access

**Hepatitis C: The State of Medicaid Access**, regularly updates HCV treatment access research.

- The research evaluates treatment access in all 50 states, Washington, D.C., and Puerto Rico.

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

See state-specific reports at [www.StateofHepC.org](http://www.StateofHepC.org)
The Research: Medicaid Access

CHLPI and NVHR release state-specific report cards assigning ‘grades’ based on the severity of restrictions on an interactive webpage.

www.StateofHepC.org

CHLPI and NVHR at https://stateofhepc.org/
Report Card Comparison

Connecticut
Liver Damage Minimum: None
Sobriety: None
Prescriber: None
Grade: A+

Texas
Liver Damage Minimum: F3
Sobriety: 3 Months
Prescriber: Specialist must consult
Grade: D
Mapping Progress: Disease Severity

2014

2019

*Data current as of 7/15/19. For the most up to date information, visit www.StateofHepC.org
Mapping Progress: Sobriety

2014

2019

*Data current as of 7/15/19. For the most up to date information, visit www.StateofHepC.org
Mapping Progress: Specialty

2014

2019

*Data current as of 7/15/19. For the most up to date information, visit [www.StateofHepC.org](http://www.StateofHepC.org)*
What about Medicaid ‘managed care’?

• In some states, Medicaid pays private insurance companies to run the insurance program, or ‘manage’ the healthcare for enrollees

• These private programs are called Managed Care Organizations, or MCO’s

• This model can save states money, so it is becoming more popular every year

• About 75% of all people on Medicaid are covered by an MCO
Puzzle Piece: MCOs

• In some states, managed care organizations serve over 99% of Medicaid enrollees

• While most MCOs follow their state’s rules, some impose more restrictive treatment criteria

• 42 CFR § 438.210: “Each contract between a State and an MCO. . .must. . .[r]equire that. . .services. . .be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid . . .”
HCV Treatment Restrictions in Correctional Facilities

By extension, this requires that all people who are incarcerated are supposed to receive the medical standard of care for any condition.
# HCV in Prison: 8th Amendment Class Actions

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Conclusion

• Progress made in reducing access restrictions to the HCV cure.

• However, restrictions persist as many states continue to violate Medicaid law and national medical guidelines.

• States are hiding behind cost despite the ~75% reduction in cost over the past 3 years.

• Stigma continues to drive access barriers: In what other disease would we withhold a cure that costs ~ $10,000 or fail to treat due to alcohol or drug use?

• The law is clear: litigation and advocacy has resulted in elimination of access restrictions.

To reach the goal of eliminating hepatitis C in the United States, all treatment access restrictions must be removed!
What can we do?

HCV Treatment Restrictions

• Stay informed on your state (and nearby states’) Medicaid restrictions
  • StateOfHepC.org

• If your state has treatment restrictions, apply pressure on your state Medicaid program
  • We can help with this!

• If your state does not have treatment restrictions, try to find any reports about the budget impact or decision-making process.
  • This can help with our advocacy in other states!

• If you hear of any patients who are denied treatment, keep track of it and let us know! This can be important for litigation.
What can we do?

HCV Treatment In Correctional Facilities

• Stay informed on your state’s testing and treatment policies
  • You can ask the Dept of Corrections or Public Health for this. We will be tracking it too.

• If your state does not test or treat people who are incarcerated apply pressure on policymakers
  • We can help with this! The threat of a lawsuit is sometimes sufficient.

• Join the National Hepatitis Corrections Network (NHCN) if you would like to do more in this area
  • HCVinPrison.org
Questions? Ideas?
Connect for more information

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