A PATH TOWARDS HCV ELIMINATION: ADDRESSING DISCRIMINATORY BARRIERS TO HCV TREATMENT

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HCV 101
Cure Is Feasible

• **2013**: The first direct-acting antiviral for treatment of chronic HCV infection receives FDA approval and achieves 95%–98% cure rates

• The American Association for the Study of Liver Diseases and Infectious Diseases Society of America 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
  • Actual cost lower, but still expensive

RESPONSE TO DAAs?

Unprecedented Restrictions

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

• Unprecedented restrictions include
  – Disease severity
  – Sobriety
  – Prescriber specialty

The progression of HCV is measured in terms of liver damage (fibrosis) on a 0–4 scale (F0 no damage, F4 cirrhosis/liver failure)\(^1\)

Many state Medicaid programs withhold treatment until patients reach advanced stages of the disease (F3–F4)\(^2\)


SOBRIETY RESTRICTIONS

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

- Evidence shows no difference in treatment adherence or cure rates compared with nonusers.

PRESCRIBER RESTRICTIONS

• 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 creating a treatment bottleneck

FEDERAL GUIDANCE TO STATES

• Centers for Medicare and Medicaid Services (CMS) issued guidance on access to HCV drugs to State Medicaid Directors in November 2015

• States…
  – Must cover HCV drugs of manufacturers who have entered into rebate agreements
  – Cannot impose coverage conditions that unreasonably restrict access
  – Must provide parity between Medicaid fee-for-service and managed-care programs

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

MEDICAID LITIGATION

• Litigated results
  – **WA**: *BE v Teeter* (injunction granted; settlement approved, April 2017)
  – **MO**: *JEM v Kinkade* (policy reformed, November 2017)
  – **MI**: *JV v Lyon* (settlement reached, March 2018)
  – **CO**: *Ryan v Birch* (settlement pending)

• Prelitigation settlements
  – **PA, DE, MA, FL, VT, NY, RI, NJ, CT**

• Several states in development

The Court is satisfied that Plaintiffs’ evidence will likely establish that the [Defendant] is failing to follow its own definition of medical necessity by refusing to provide DAAs to monoinfected enrollees with a F0–F2 score.
IRREPARABLE HARM

**BE et al v Teeter**

“Plaintiffs argue persuasively that without an injunction “they are at imminent risk of deteriorating health, liver damage, and even death.

- Patient LB: Missed treatment window during ‘observation period’”
“The balance of hardship favors beneficiaries of public assistance who may be forced to do without needed medical services over a state concerned with conserving scarce resources.”

“Faced with such a conflict between financial concerns and human suffering, we have little difficulty concluding that the balance of hardships tips decidedly in plaintiffs’ favor.”
THE RESEARCH
Medicaid Access to HCV Cure

- **Hepatitis C: The State of Medicaid Access**, updates initial 2014 Medicaid research published in *Annals of Internal Medicine*
- The research evaluates Medicaid HCV-treatment access in all 50 states, Washington, DC, and Puerto Rico, focusing on liver damage, sobriety, and prescriber restrictions

MAPPING PROGRESS
Prescriber Specialization

2014

2018

HCV ADVOCACY IS ONGOING

• CHLPI and NVHR release state-specific report cards assigning “grades” based on the severity of restrictions

• An interactive webpage: www.StateofHepC.org

IT’S NOT JUST MEDICAID

- **Prisoner litigation: 8th Amendment**
  - At least 7 states: MA, PA, MN, TN, FL, MO, and CO\(^1,2,3\)
  - January 2017: Strong decision in individual PA case brought by Mumia Abu Jamal; treatment ordered\(^4\)
  - March 2018: Settlement in MA with restrictions reduced to F2 and 6-month screening cycle\(^1\)
  - July 2018 – Strong summary judgment decision in favor on incarcerated plaintiffs from federal district court in PA\(^9\)

- **Private-insurer litigation**
  - WA: Group Health, BridgeSpan, and Regence Blue Cross all removed disease-severity restrictions after state court complaints filed\(^5\)
  - CA: Anthem sued in state court in May 2015; policy was changed across the state in December 2015\(^6\)
  - NY: AG settles with 7 commercial insurers to immediately eliminated coverage restrictions\(^7\)
  - Nationwide class settlement reached with United Healthcare in 2016\(^8\)

WHERE WE GO FROM HERE

• Progress has been made in reducing access restrictions to the HCV cure
• Yet, despite the fact that the law is clear, restrictions persist in many states
• States are hiding behind cost and stigma continues to drive access barriers
  – In what other disease would we withhold a cure that costs ~$10-15,000, or fail to treat due to alcohol or drug use?
• Advocacy and litigation will continue until all discriminatory restrictions are eliminated

To reach the goal of eliminating HCV in the United States, Medicaid and other insurers must end treatment-access restrictions