6th International Symposium on Hepatitis Care in Substance Users
September 8, 2017

Third-Party Payor Restrictions as a Barrier to HCV Elimination among People who Inject Drugs

CENTER FOR HEALTH LAW & POLICY INNOVATION
Harvard Law School

Kevin Costello
Director of Litigation
617-390-2578
kcostello@law.harvard.edu

Overview

1. **Consensus on Open Access**
2. **Surveying the Landscape**
3. **Informal Enforcement**
4. **Litigation**

Open Access

Open Access = Necessary but not Sufficient

- AASLD / IDSA Guidelines are the standard of care – treat all with few exceptions
- Restrictions still vary -- disease severity, abstinence, prescriber credential
- Elimination is the goal; open access is a preliminary step.
- Quickly Evolving

After Open Access – De Facto Barriers

- Identifying those who will benefit - Outreach
- Engagement in Care
- Testing
- Prior Authorization process
- Continuing Connection to Care

National Academies of Science, Engineering & Medicine
A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report (2017)

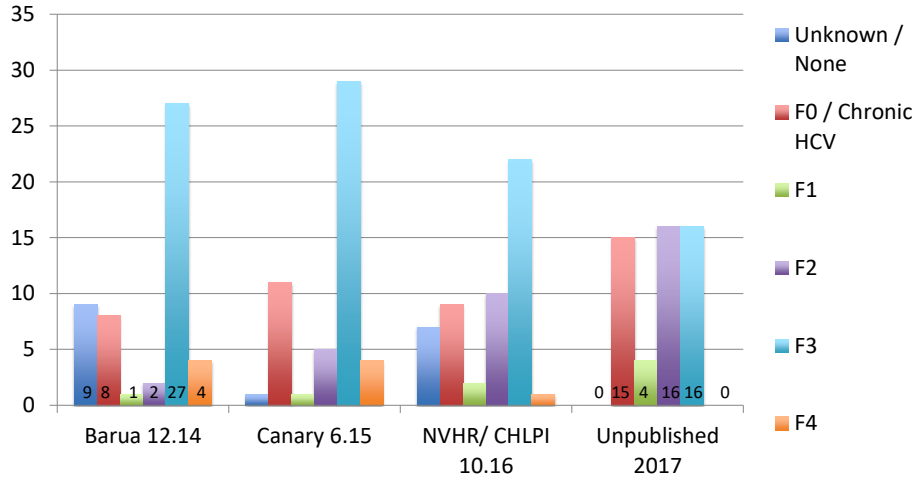
"Treating everyone with chronic HCV infection, regardless of disease stage, would avert considerable suffering and anxiety. It is also a financially sensible course of action in the long run. [...] The ability of these drugs to eradicate HCV infection in nearly all infected people has made the prospect of eliminating viral hepatitis in the United States plausible. Public and private health plans should not interfere with this goal. They should remove restrictions on direct-acting antiviral treatment for hepatitis C patients."

Surveying the Landscape

Medicaid Policy Surveys

- 2014: Barua S., Greenwald, R., Grebely, J., Dore, G., Swan, T., and Taylor, L. "Restrictions for Medicaid Reimbursement of Sofosbuvirfor the Treatment of Hepatitis C Virus Infections in the United States," Ann. Intern Med.2015; 163:215-223
- 2015: Canary, L. A., R. M. Klevens, and S. D. Holmberg. 2015. Limited access to new hepatitis C virus treatment under state Medicaid programs. Annals of Internal Medicine 163(3):226-228.
- 2016: National Viral Hepatitis Roundtable & Center for Health Law & Policy Innovation, *Hepatitis C: The State of Medicaid Access* (Preliminary Report) (November 2016), available at http://www.chlpi.org/wp-content/uploads/2013/12/HCV-Report-Card-National-Summary_FINAL.pdf
- 2017 – Continuous update of this work. Publication forthcoming.

The Trend in Medicaid Restrictions



Center for Health Law and Policy Innovation of Harvard Law School

Medicaid – No FS Restriction States

1. Massachusetts
2. Connecticut
3. New York
4. Maine
5. Georgia
6. Washington
7. Mississippi
8. Nevada
9. Delaware
10. Florida
11. Pennsylvania
12. South Carolina
13. Minnesota
14. Virginia
15. New Hampshire
16. Wyoming

Center for Health Law and Policy Innovation of Harvard Law School

Other Third Party Payors without Fibrosis Score Restrictions

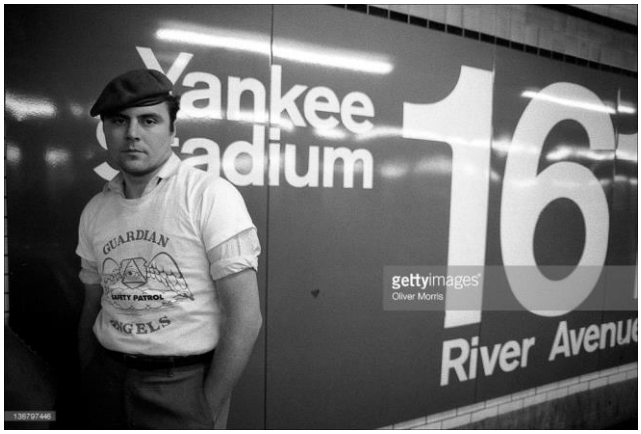
- Public Insurers:
  - Medicare
  - Veterans' Administration
- Major Commercial Insurers
  - Anthem
  - Aetna
  - United
  - Humana
  - Cigna
  - Kaiser Permanente

Context - Cost

Center for Health Law and Policy Innovation
of Harvard Law School

Context - Cost (cont'd)

- Price originally reported in media: $84,000 ($1k / pill x 12 weeks)
- Abbvie's new product (Mavyret) with wholesale price of $26,400 for eight weeks' treatment
- Medicaid program discount: 23%, before supplemental, negotiated rebates.
- Best guess - $20k range and going lower
- Medicaid price impact also must account for federal dollars.
- WA 2016 Supplemental Budget Request
  - Requested ~$77M of Medicaid budget ($20M state portion) (25%)
  - Represented that this would treat 4700 enrollees
  - Math = $16,450 per enrollee per treatment (State portion = ~$4k)



INFORMAL ENFORCEMENT

CMS Guidance

November 5, 2015

- Directed to State Technical Contacts
- Explicitly couched in the posture of the Medicaid statute: States "are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs."
- "CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements . . . by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extend of liver damages has progressed to [a] fibrosis score [of] F3."
- Other issues: Abstinence requirements, Prescriber-type restrictions and Medicaid managed care parity.

State Advocacy

- Pharmacy & Therapeutics Committee
  - New York
  - Pennsylvania
  - Colorado
  - Oregon
- State Budgetary Issues
  - IL emerging from historic crisis.

Demand Letters

Examples

- **CT** - Feb. 2015 – New Haven Legal Assistance Ass'n & CT Legal Services
- **MO** – Jan. 2016 – Legal Services of Eastern Missouri
- **DE** - March 2016 – Center for Health Law & Policy Innovation at Harvard Law School, Tycko & Zavareei, and Community Legal Aid Society
- **FL** - April 2016 - NHeLP, FL Legal Services & Legal Aid Society of Palm Beach County
- **NY** – April 2016 – NY AG Schneiderman issues subpoenas to 7 major insurers.

LITIGATION

Litigation As Last Resort

- Medicaid Cases
  - **IN** – Nov. 2015 (*Jackson*)
  - **WA** – March 2016 (*B.E. v. Teeter)*
  - **CO –** filed September 2016 (*Ryan v. Birch*)
  - **MO** - filed October 2016 (*J.E.M. v. Kinkade*)
- Prisoner Litigation – 8th Amendment
  - **At least 7 states** (MA, PA, MN, TN, FL, MO, CO)
  - January 2017 - Strong decision in individual PA case brought by Mumia Abu Jamal

- Private Insurers
  - **WA** - GroupHealth, BridgeSpan and Regence Blue Cross all agree to remove disease severity restrictions after state ct complaints filed.
  - **CA** - Anthem sued in state court in May 2015 – policy was changed across states in December 2015.
  - **NY** - AG threatened litigation against 7 commercial insurers. Policies changed after investigation.
    - AG filed fraud and consumer-protection based lawsuit against lone holdout: Capital District Physicians' Health Plan. Settled with policy change shortly thereafter.

Federal Medicaid Law

- Federal law requires each state's Medicaid program to provide **"medically necessary"** care according to a state definition that must be approved by CMS. *See Beal v. Doe,* 432 U.S. 438, 444–45 (1977).
  - Typical definition includes services necessary for the prevention, diagnosis, or treatment of a physical or mental health condition, but provides allowances for state discretion on equally effective, cheaper care, and prohibitions on "convenience" care. Some definitions reference the clinical standard of care.
- Federal law allows states significant discretion in determining the **amount, duration and scope** of services to be provided. 42 C.F.R. § 440.230(b). Must **not be arbitrary**. 42 C.F.R. § 230(c).
- Policies must nevertheless be in the **"best interests"** of the recipients. 42 U.S.C. § 1396a(a)(19).
- Medical assistance must be furnished with **"reasonable promptness."** 42 U.S.C. § 1396a(a)(8).
- Coverage must be **comparable** as between similarly-situated Medicaid enrollees. 42 U.S.C. § 1396a(a)(10)(B)(i) and (ii); 42 C.F.R. § 440.240.

Teeter Case

Medical Necessity

- "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."

Teeter Case

Irreparable harm

- Deprivation of medically necessary care.
- "Plaintiffs argue, persuasively, that without an injunction "they are at imminent risk of deteriorating health, liver damage and even death."
- Example of L.B. – missed treatment window during "observation period."

Teeter Case

Public Interest

- "[T]he 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."
- PI favors enforcement of existing law.
- "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."

CENTER FOR HEALTH LAW & POLICY INNOVATION
Harvard Law School

122 Boylston Street • Jamaica Plain, MA 02130
chlpi@law.harvard.edu

Connect with us online

www.chlpi.org
HarvardCHLPI
HarvardCHLPI