CENTER FOR HEALTH LAW
& POLICY INNOVATION
Harvard Law School

HCV Treatment Access Restrictions & Coverage Obligations under the Law

Robert Greenwald, JD
Clinical Professor of Law
Faculty Director, Center for Health Law & Policy Innovation
Harvard Law School

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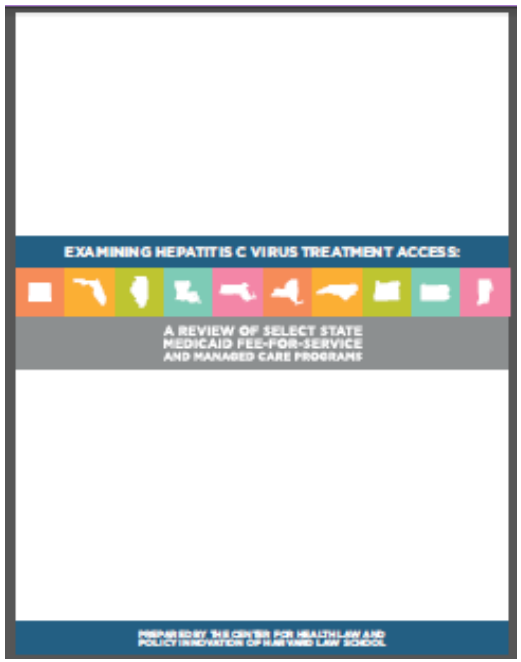
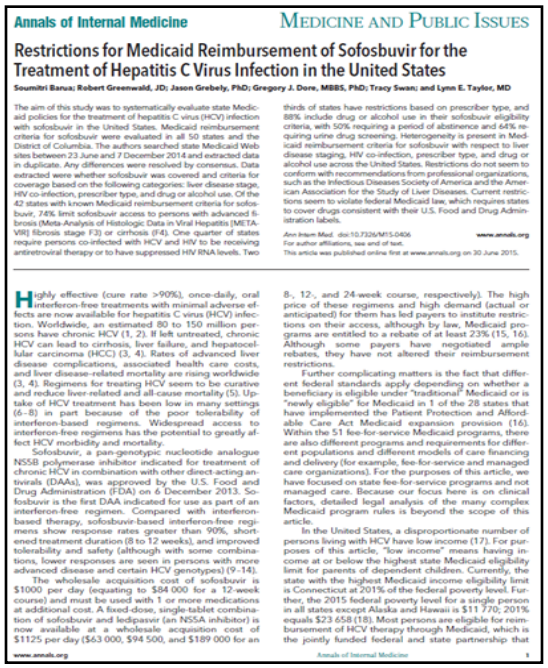
Center for Health Law
and Policy Innovation

chlpi@law.harvard.edu
www.chlpi.org

Comments Based on Findings of Relatively Recently Released Reports




Annals of Internal Medicine — Medicine and Public Issues

Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States

Soumitri Barua; Robert Greenwald, JD; Jason Grebely, PhD; Gregory J. Dore, MBBS, PhD; Tracy Swan; and Lynn E. Taylor, MD

- Examines accessibility of Sovaldi through Medicaid fee-for-service in 10 states
- Also examines Sovaldi access in 5 select states Medicaid managed care plans
- Report and corresponding webinar available at www.chlpi.org

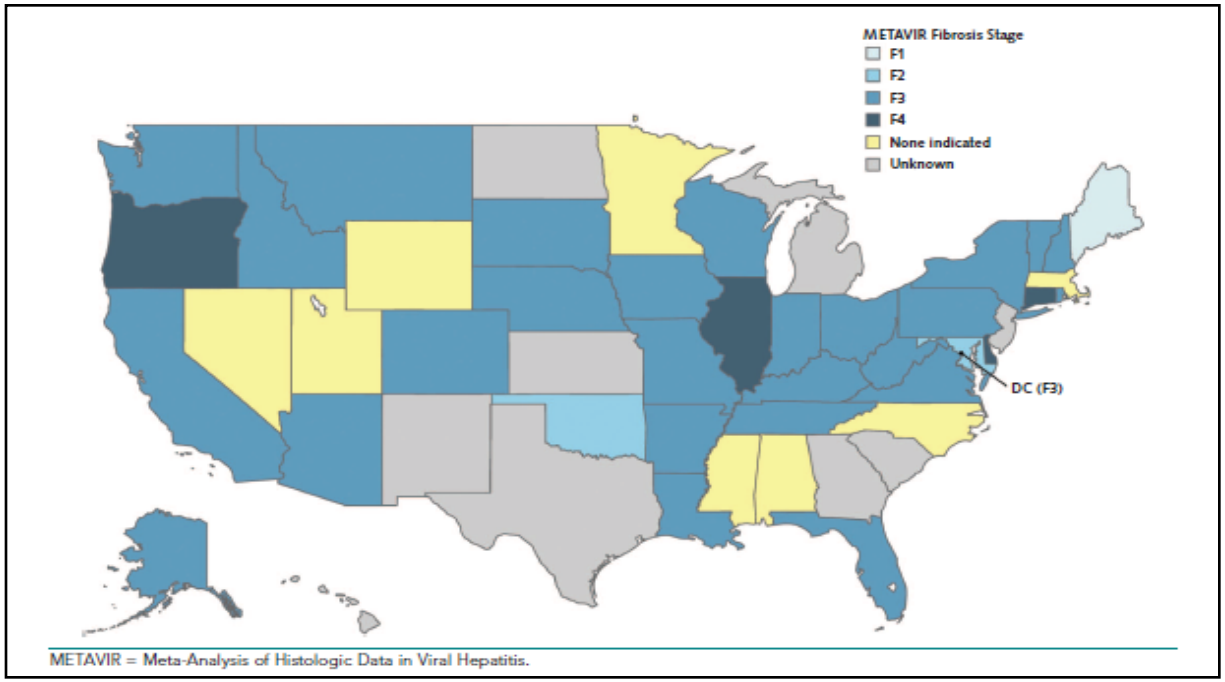
- Evaluates state Medicaid policies for Sovaldi access in 42 states and DC
- Assesses policies in light of treatment guidelines
- Article available online at www.annals.org

Limitations on Access to HCV Treatments

- **Limits Based on Stage of Fibrosis**
- **Restrictions Based on Substance Use**
- **Prescriber Limitations**
- **Other restrictions**
  - HIV Co-Infection limitations
  - “Once per lifetime” limitations
  - Genotype limitations
  - Previous history of treatment adherence requirements
  - Specialty pharmacy restrictions
  - Exclusivity agreements with insurers

Limits Based on Liver Disease Stage

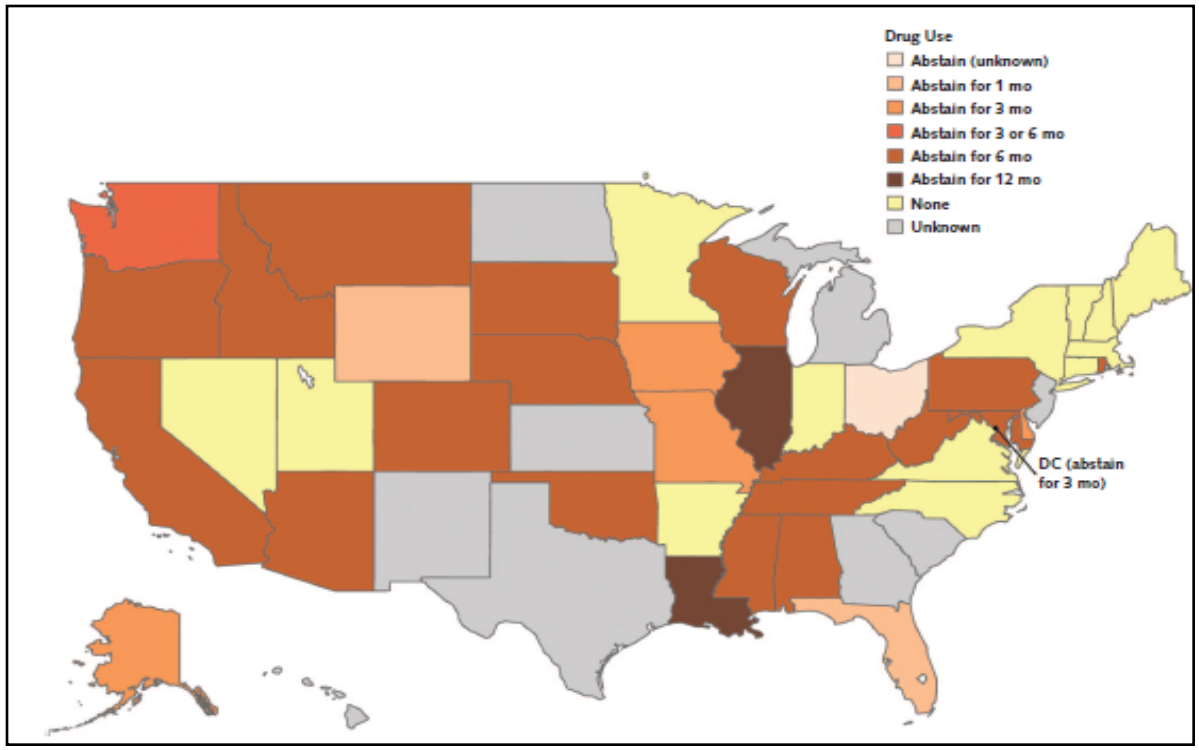
- 10% of state Medicaid programs with known criteria (n=42) limited Sovaldi access to people with Metavir score of F4
- 74% of state Medicaid programs limit access to METAVIR score of F3 and higher



Source: S. Barua, et al. "Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States," ANN INTERN MED, published online 30 June 2015

Restrictions Based on Substance Abuse

- 50% of states require periods of abstention (range = 1 - 12 months)



Source: Barua, Greenwald et al. "Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States," Ann Intern Med, published online 30 June 2015

Prescriber Limits

- 33% of states (14 states) limit prescriber type to only a specialist (Gastroenterology, Hepatology, Infectious Diseases or Liver Transplant)

- 36% of states (16 states) limit prescriber type to specialists or non-specialists if there is consultation with a specialist

- Such policies are in direct contrast to the broader prescribing policies associated with historic HCV treatment with pegylated interferon and ribavirin

Source: Barua, Greenwald et al. "Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States," Ann Intern Med, published online 30 June 2015

Illinois Sovaldi Prior Authorization Criteria: More Restrictive Than Most States

Coverage

+ Preferred drug

Fibrosis

+ Metavir score of F4

Substance Use

+ No evidence of substance abuse in past 12 months

Prescriber Limitations

+ If prescriber is not a specialist, requires one-time written consultation within past 3 months

MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive Than Most States

Coverage

+ Preferred drug

Fibrosis

+ No restrictions (form inquires)

Substance Use

+ No restrictions (form inquires about current use)

Prescriber Limitations

+ No restrictions

Additional Restrictions

+ No additional restrictions based on HIV Co-infection or previous adherence

MassHealth Managed Care Organizations
Sovaldi Prior Authorization Criteria

	Boston Med. Ctr. Health Net Plan	Neighborhood Health Plan	Tufts Health Plan Network Health	Health New England
Fibrosis	F3-4	F3-4	F3-4	F4
Requirements Related to Substance Use	Not abused substances for 6 months	Abstain from use for 6 months and participation in supportive care	No substance abuse within past 6 months OR receiving counseling services	Must be referred to specialist; abstinence for 6 months; ongoing participation in treatment; psychosocial supports
Prescriber Limitations	Prescribed by or in consultation with specialist	Prescribed by or in consultation with specialist	Prescribed by specialist	Prescribed by specialist
HIV Co-Infection	Yes, with non-suppressable viral load or elevated MELD scores	Not without meeting additional requirements above	Not without meeting additional requirements above	Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load
Additional Adherence Requirements	No history of nonadherence; enrollment in monitoring program	Must demonstrate understanding of proposed treatment and display ability to adhere	Must be assessed for potential non-adherence	No record of non-adherence and willing to commit to monitoring

Massachusetts Affordable Care Act Qualified Health Plans – Prior Authorization Criteria

	Fallon Health	Tufts	Harvard Pilgrim
Fibrosis	F3-4	F3-4	F3-4
Requirements Related to Substance Use	Not engaged in any habits that would negate the efficacy of the medications	No illicit abuse within past 6 months OR receiving counselling services/seeing addiction specialist	None
Prescriber Limitations	Prescribed by specialist	Prescribed by specialist	Prescribed or supervised by specialist
HIV Co-Infection	Must meet other criteria	Must meet other criteria	Must meet other criteria
Additional Adherence Requirements	Must have history of adherence and a psychological and behavioral habits assessment to determine if therapy is appropriate	Must be assessed for potential non-adherence	None

Next Steps: Reframe the Response

Shifting the focus from cost to cure

- Recognize payor concerns, but accurately assess value of cure
- With supplemental rebates the cure is now ~$45,000
- Comparative effectiveness matters
  - We paid over ~$250,000 per HCV cure in interferon age
  - In HIV, no cure and we pay ~$10,000 per year for life
- Pharmacy budgets may increase but others will decrease
- U.S. govt sets pharma laws with varying perspectives if effective – if not, change laws, rather than deny access to HCV cure
- Medicaid is an entitlement program in part to grow to meet the demands created by innovation

Next Steps: Respond to Treatment Advances from a Public Health Perspective

Addressing HCV as a serious public health issue

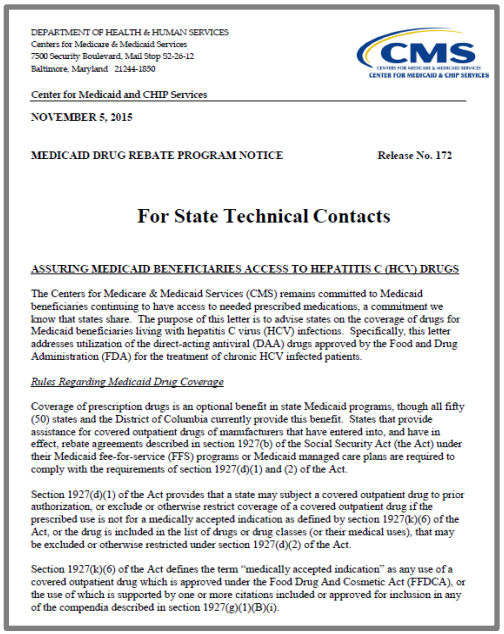
+ Screening and treatment have significant individual and public health benefits
+ Baby boomer generation is not the end of the epidemic, with increasing evidence of growing incidence in young people
+ Other serious diseases are not similarly treated (i.e., requiring disease progression or sobriety) and this undermines the public health response
+ Insurers should adopt, not ignore, lessons learned from HIV treatment guidelines, where early and unrestricted access is the rule

Next Steps: Follow Insurance, Medicaid and ACA Law

Precluding restrictive, unfair and discriminatory HCV treatment access practices under the law

+ State medical necessity laws and contracts in private insurance require coverage of medications with clinically meaningful therapeutic advantage over other treatments
+ Under the Medicaid Act all prescription drugs of a manufacturer with rebate agreements must be covered, with only exceptions allowed for safety and clinical effectiveness
+ While states have discretion under prior authorization, courts have supported challenges when access is severely curtailed
+ Under the ACA differential treatment of HCV may rise to the level of a discriminatory insurance practice

CMS Guidance To States Outlines HCV Treatment Access Requirements



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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

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 Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term "medically accepted indication" as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

Complying with explicit CMS Guidance

+ Encourages negotiation on pricing arrangements
+ Recommends using AASLD, IDSA, and IAS-USA's guidelines to guide coverage policies
+ Cites as examples of unreasonable practices restrictions limiting access based on a fibrosis score of F3/4, sobriety, provider type
+ Clarifies that services provided by Medicaid managed care organizations cannot be less in amount, duration, and scope than fee-for- service
+ Confirms CMS will monitor State compliance

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

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