Understanding Hepatitis C Treatment Access

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Comments Based on Findings of Recently Released Report

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS

A REVIEW OF SELECT STATE MEDICAID FEE-FOR-SERVICE AND MANAGED CARE PROGRAMS

- 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

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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

Illinois Sovaldi Prior Authorization Criteria: More Restrictive Then Most States

Coverage

+ Non-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, required one-time written consultation within past 3 months

MassHealth FFS Sovaldi Prior Authorization Criteria: Less Restrictive Then 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 MCOs 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	(For members with past/current issues) abstain from use for 6 months and participation in supportive care	No substance abuse within past 6 months OR receiving counseling services	(Known substance abusers) must have been referred to specialist; abstinence from substance abuse for 6 months; ongoing participation in treatment program; adequate 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 compliance monitoring program	Individual must demonstrate understanding of the proposed treatment, and display the ability to adhere to clinical appointments	"[M]ember has been assessed for potential nonadherence."	No ongoing non-adherence to previously scheduled appointments, meds or treatment; adherence counseling; 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	"[N]ot engaged in any habits that would negate the efficacy of the medications."	No illicit substance abuse within past 6 months OR receiving substance or alcohol abuse counselling services/seeing addiction specialist	None
Prescriber Limitations	Prescribed by specialist	Prescribed by specialist	Prescribed or supervised by specialist
HIV Co-Infection	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.	None. Must meet other criteria as listed on this chart.
Additional Adherence Requirements	Must have been adherent to past therapies; must be prepared/motivated to start treatment. Application "require[s] a member's psychological and behavioral habits assessment to determine if therapy is right for him/her."	"[M]ember has been assessed for potential nonadherence."	None

NEXT STEPS

Reframe the Response

Shift the focus from cost to cure

- Recognize payor concerns, but accurately assess the value of cure
- With supplemental rebates the cure is now ~$40,000
- 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 for HAART
- Pharmacy budgets may increase but others will decrease
- U.S. government 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

Respond to Treatment Advances From a Public Health Perspective

Hepatitis must be addressed 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

Follow Medicaid and ACA Law

Both public and private health insurance laws preclude restrictive, unfair and discriminatory HCV treatment access practices

- Under the Medicaid Act all prescription drugs of a manufacturer who enters into rebate agreements must be covered, with only exceptions allowed for safety and clinical effectiveness
- While states have more discretion under prior authorization, even here courts have supported challenges when access is severely curtailed or final authority to provide drugs does not rest with the prescribing health care providers
- Under Massachusetts law, as well as in other states, state medical necessity laws require even fewer restrictions on access to effective, life-saving medications
- Under the ACA differential treatment of HCV rises to the level of a discriminatory insurance practice

Advocate for Broader Access for Many People Living with Hepatitis By Securing Adequate Coverage

Federal

+ Urge Congressional support of increased funding for hepatitis research, prevention, screening and vaccination, linkage to care, and surveillance
+ Urge Congressional support for viral hepatitis testing law that will expand education and testing for Hepatitis B and C
+ Urge CMS to advise State Medicaid Programs regarding the appropriate coverage of prescription drugs for patients with hepatitis C

State

+ Advocate for Medicaid expansion
+ Advocate before the Pharmacy and Therapeutics Committee in your state as the members decide which drugs are included on formularies and what prior authorization criteria are attached to each drug
+ Monitor state Medicaid fee-for-service and managed care organizations and advocate for strong and consistent coverage criteria