HCV Treatment
Access Restrictions
&
Coverage Obligations under the Law

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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

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

### 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

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
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Fibrosis</td>
<td>F3-4</td>
<td>F3-4</td>
<td>F3-4</td>
<td>F4</td>
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<tr>
<td>Not abused substances for 6 months</td>
<td>Abstain from use for 6 months and participation in supportive care</td>
<td>No substance abuse within past 6 months OR receiving counseling services</td>
<td>Must be referred to specialist; abstinence for 6 months; ongoing participation in treatment; psychosocial supports</td>
<td></td>
</tr>
<tr>
<td>Prescriber Limitations</td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
</tr>
<tr>
<td>HIV Co-Infection</td>
<td>Yes, with non-suppressable viral load or elevated MELD scores</td>
<td>Not without meeting additional requirements above</td>
<td>Not without meeting additional requirements above</td>
<td>Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load</td>
</tr>
<tr>
<td>Additional Adherence Requirements</td>
<td>No history of nonadherence; enrollment in monitoring program</td>
<td>Must demonstrate understanding of proposed treatment and display ability to adhere</td>
<td>Must be assessed for potential non-adherence</td>
<td>No record of non-adherence and willing to commit to monitoring</td>
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<tr>
<td>Condition</td>
<td>Fallon Health</td>
<td>Tufts</td>
<td>Harvard Pilgrim</td>
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<td>F3-4</td>
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<tr>
<td>Requirements Related to Substance Use</td>
<td>Not engaged in any habits that would negate the efficacy of the medications</td>
<td>No illicit abuse within past 6 months OR receiving counselling services/seeing addiction specialist</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Prescriber Limitations</td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
<td>Prescribed or supervised by specialist</td>
<td></td>
</tr>
<tr>
<td>HIV Co-Infection</td>
<td>Must meet other criteria</td>
<td>Must meet other criteria</td>
<td>Must meet other criteria</td>
<td></td>
</tr>
<tr>
<td>Additional Adherence Requirements</td>
<td>Must have history of adherence and a psychological and behavioral habits assessment to determine if therapy is appropriate</td>
<td>Must be assessed for potential non-adherence</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
**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
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
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