HCV TREATMENT ACCESS: A NATIONAL PERSPECTIVE AND CASE STUDIES

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COMMENTS BASED ON FINDINGS OF RECENTLY RELEASED REPORTS

- 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

RESTRICTIONS BASED ON SUBSTANCE ABUSE

- 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 treatment decisions made by a non-specialist 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, required 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 MCOs Sovaldi Prior Authorization Criteria

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Fibrosis</strong></td>
<td>F3-4</td>
<td>F3-4</td>
<td>F3-4</td>
<td>F4</td>
</tr>
<tr>
<td><strong>Requirements Related to Substance Use</strong></td>
<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>
</tr>
<tr>
<td><strong>Prescriber Limitations</strong></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><strong>HIV Co-Infection</strong></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><strong>Additional Adherence Requirements</strong></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>
</tr>
</tbody>
</table>
## Massachusetts Affordable Care Act Qualified Health Plans – Prior Authorization Criteria

<table>
<thead>
<tr>
<th></th>
<th>Fallon Health</th>
<th>Tufts</th>
<th>Harvard Pilgrim</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fibrosis</strong></td>
<td>F3-4</td>
<td>F3-4</td>
<td>F3-4</td>
</tr>
<tr>
<td><strong>Requirements</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>
</tr>
<tr>
<td><strong>Prescriber Limitations</strong></td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
<td>Prescribed or supervised by specialist</td>
</tr>
<tr>
<td><strong>HIV Co-Infection</strong></td>
<td>Must meet other criteria</td>
<td>Must meet other criteria</td>
<td>Must meet other criteria</td>
</tr>
<tr>
<td><strong>Additional Adherence Requirements</strong></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>
</tr>
</tbody>
</table>
Coverage
+ Non-preferred drug

Fibrosis
+ Biopsy indicating Metavir score of $\geq$F3

Substance Use
+ Provider must confirm no substance abuse and/or alcohol abuse within the past 12 months
+ Drug and alcohol screen 30 days prior to start of treatment, at start, and every 30 days during treatment

Prescriber Limitations
+ Prescribed by specialist

Additional Restrictions
+ Must sign “Hepatitis C Therapy Agreement”
# Bayou Health MCOs Sovaldi Prior Authorization Criteria

<table>
<thead>
<tr>
<th>Requirements Related to Substance Use</th>
<th>Aetna</th>
<th>United Healthcare Community Plan</th>
<th>Amerigroup</th>
<th>Louisiana Healthcare Connections</th>
<th>AmeriHealth Caritas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrosis F3-4</td>
<td>Biopsy indicating F3-4</td>
<td>Covered but no form</td>
<td>“Evidence of advanced liver disease”</td>
<td>Biopsy indicating Metavir score of ≥ F2</td>
<td></td>
</tr>
<tr>
<td>Requirements Related to Substance Use</td>
<td>No alcohol or illicit drug use within 6 months (and compliance with treatment program)</td>
<td>Must “discuss drug/alcohol abuse” and drug screen within past 3 months</td>
<td>--</td>
<td>Documented sobriety from alcohol and/or illicit IV drug for 6 months</td>
<td>No “substance abuse”</td>
</tr>
<tr>
<td>Prescriber Limitations</td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
<td>--</td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
</tr>
<tr>
<td>HIV Co-Infection</td>
<td>None listed</td>
<td>None listed</td>
<td>--</td>
<td>Form inquires</td>
<td>HIV testing, serology, and treatment required</td>
</tr>
<tr>
<td>Additional Adherence Requirements</td>
<td>Must agree to remain compliant; no history of noncompliance</td>
<td>None listed</td>
<td>--</td>
<td>Must agree to medication adherence program</td>
<td>No “unresolved barriers to successful treatment”</td>
</tr>
</tbody>
</table>
I am browsing various insurance plans on the LA Marketplace, and I would like to find out your Prior Authorization criteria for Sovaldi 400 mg tablets.

<table>
<thead>
<tr>
<th>Plan</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humana</td>
<td>• Required member ID #</td>
</tr>
<tr>
<td></td>
<td>• Eventually connected to sales rep, then transferred to sales specialist, all were busy, then disconnected</td>
</tr>
<tr>
<td></td>
<td>• Called again, given connected to sales specialist, transferred to benefits department, agent did not know if could provide info, brought pharmacy rep. on the line, told only info could give out was general PA form</td>
</tr>
<tr>
<td></td>
<td>• Told could not see PA criteria without having a policy first</td>
</tr>
<tr>
<td>BlueCross BlueShield</td>
<td>• Told they cannot give advice without first accessing a member account</td>
</tr>
<tr>
<td>Vantage</td>
<td>• Told not on the formulary</td>
</tr>
<tr>
<td>United HealthCare</td>
<td>• Told could not access specific PA criteria without selecting a plan first</td>
</tr>
<tr>
<td>LA Marketplace</td>
<td>• Told have to do an application first, which doesn’t open until Nov 1, 2016</td>
</tr>
</tbody>
</table>
NEXT STEPS

LEGISLATION, REGULATION, AND ADVOCACY
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 - 50,000
+ 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
Both public and private health insurance laws preclude restrictive, unfair and discriminatory HCV treatment access practices

- State medical necessity laws and contracts in private insurance often require coverage of effective, life-saving medications where no other reasonable alternative exits

- 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 the ACA differential treatment of HCV rises to the level of a discriminatory insurance practice
Federal and State laws and regulations can be strengthened to protect the chronic disease communities, including the HCV community

- **Co-Pay Limits (LA, DE, MD):** Most commonly limit OOP to $150 for a 30 day supply of a single prescription.

- **Right to Treatment (LA, MS, and 18 other states):** Currently in the context of providing experimental treatments to terminally ill patients but could be modified for important chronic treatments.

- **Formulary Lock (NV Regulation):** Require insurers to get approval from regulators before changing formulary coverage or tiering during non-open enrollment periods.
Federal and State laws and regulations can be strengthened to protect the chronic disease communities, including the HCV community

• **Equalize Medicaid FFS and MCOs Drug Access (FL, NH, TX):** Require Medicaid MCOs to cover the same medications at the same costs as the corresponding Medicaid FFS formulary.
  
  – In a Nov 5, 2015 guidance on HCV, HHS stated that Medicaid programs must ensure that MCOs offer the same access to HCV drugs as do their FFS programs

• **Billing Reimbursement for Provider’s Prior Authorization Time:** Insurers must be held accountable for unreasonable demands on providers’ time by making prior authorization work billable when the demands are excessive.