Restrictions to HCV Treatment in State Medicaid Programs

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Medicaid Eligibility Basics

• Program for individuals who are low-income AND who meet some other criteria of eligibility: i.e., disabled, parent of a young child

• Eligibility for Medicaid varies widely by state:
  • In Massachusetts, you can be eligible if you have income up to 138% of FPL ($11,670/individual/year) regardless of category;
  • In Alabama, if you’re the parent of a young child, you’ll qualify if you make 18% of FPL ($2,100/individual/year)

• In non-expansion states, essentially a really cruel standard for people with chronic illnesses:
  • Basically you have to be disabled before you can access the care that would’ve prevented you from being disabled in the first place!
Medicaid Benefits- Key Points

• Every state Medicaid program has to cover certain kinds of benefits for its traditional enrollees (non-expansion population)

• Prescription drug benefits are an optional coverage category, but every state has opted to provide them

• In general, states have flexibility with respect to “amount, duration, and scope of coverage,” but they cannot arbitrarily deny or reduce coverage because of a diagnosis, type of illness, or condition

• States also have some flexibility with respect to setting standards for what is “medically necessary”
Variation in How Medicaid Works

- Most states still offer some kind of Fee For Service (FFS) Medicaid program (mostly for traditional categorical enrollees)
  - In this model, you go to a provider, and Medicaid pays the provider directly for the service

- Increasingly states require individuals to enroll in Managed Care Organizations (MCOs)
  - In this model, Medicaid pays MCOs a specific amount of $ per member per month, and then the MCO provides the mandated Medicaid benefits
  - Often characterized by “in-network” and “out-of-network” providers and services
  - MCOs vary as far as the discretion they have to implement medical management techniques (like prior authorization), but for the most part, they have flexibility (and incentive) to keep costs low
Individuals newly eligible for Medicaid in expansion states have access to:

- Ten categories of **essential health benefits (EHB)**, including
  - preventive care
  - substance use disorder services
  - behavioral health services
  - chronic disease management

- **Preventive services without cost-sharing** (all services given an A or B recommendation from the United States Preventive Services Task Force (USPSTF)), including:
  - HCV screening for those at risk
  - one-time HCV test for individuals in the baby-boomer generation

- **Every state**: new rules allow individuals other than medical providers (like Community Health Workers-CHWs) to be reimbursed for providing preventive services

- **Every state**: new reforms also encourage states to better manage populations with chronic illnesses, like the Medicaid Health Home program
Challenge Number One: Advocating for Medicaid Expansion in Every State MUST Also Be a Priority

- Non-expansion states = status quo: many individuals with incomes below 100% FPL will continue to fall through the cracks

Source: http://kff.org/health-reform/state-indicator/state-decisions-for-creating-health-insurance-exchanges-and-expanding-medicaid/#map
Challenge Number Two: Access to HCV Treatment

- State Medicaid programs and/or managed care plans have discretion with regards to utilization management of Medications

- Wide-spread concern about cost of Sovaldi treatment has led states to implement restrictive access requirements

- We examined state Medicaid FFS programs along three categories of potential restrictions:
  - Restrictions based on **substance use or abuse**
  - Restrictions based on **disease progression/fibrosis**
  - Restrictions based on **prescriber limitations** (i.e., who can treat people with HCV)
All states must cover any drug approved by the FDA and whose manufacturer participates in the Medicaid rebate program – this includes Gilead and Sovaldi.

The federal government gets a specific rebate amount for each drug (about 23%), and individual (or groups of) states may then negotiate supplemental rebates.

States can decide to create a formulary with preferred v. non-preferred drugs and may choose to implement prior authorization requirements.

- Mostly, this is about encouraging use of generic products to reduce cost and ensuring against fraud and abuse.

Most states have a Pharmacy and Therapeutics Committee (or similar body) that makes decisions about formulary coverage and what kinds of utilization management policies to implement.

- Often meet on a quarterly or monthly basis.

Note that states also vary with respect to MCOs and drug coverage (i.e., whether the MCO must match the state’s FFS formulary, or whether it has flexibility to implement its own PA requirements).
Side note: “Standard of Care” Regimens for Hepatitis C Have Been Expensive for Years

<table>
<thead>
<tr>
<th>Regimen</th>
<th>SVR rates (Genotype 1, Naïve)</th>
<th>2014 WAC Price</th>
<th>Cost per SVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegasys + Ribavirin x 48 weeks¹</td>
<td>41%</td>
<td>$41,758</td>
<td>$101,849</td>
</tr>
<tr>
<td>Telaprevir + Pegasys + Ribavirin x 24 weeks²</td>
<td>75%</td>
<td>$86,843</td>
<td>$115,791</td>
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<tr>
<td>Sofosbuvir + Pegasys + Ribavirin x 12 weeks³</td>
<td>90%</td>
<td>$94,421</td>
<td>$104,912</td>
</tr>
</tbody>
</table>

Created by C. Graham, from McHutchison, NEJM 2009; ²Jacobson, NEJM 2011;³Lawitz, NEJM 2013
Restrictions based on Alcohol and Drug Use and/or Abuse
(Data preliminary and may be subject to change)

- We were able to obtain information for 43 states (including Washington D.C.); 1 other state (MN) has indicated they may be implementing a more restrictive policy in the future
- We were unable to obtain information for 7 states
- Of the 43 state policies, 35 have requirements related to refraining from use or abuse of drugs or alcohol prior to treatment*
  - Of those 35 states:
    - 2 states require a year or more
    - 11 states require a period of 6 months or more (1 of these states (MD) makes an exception for individuals with “significant progression of disease state”)
    - 5 states require a period of 3 months or more
    - 1 state requires a period of 1 month or more
    - 3 states make exceptions if the patient is in treatment
    - 1 state (NY) has proposed that there be “no signs of high risk behavior (recurring alcoholism, IV drug use, etc.)”
      - (exact time unknown for 12 states**)
  - Of those 35 states
    - 15 states do not distinguish between alcohol abuse v. use
    - 8 states do not appear to have a prohibitive policy with respect to drugs or alcohol

*In some states, these requirements apply only to persons with past or present drug or alcohol use disorders
** Data provided by Lauren Canary, CDC/VHAC
States Vary With Respect to Scope of These Policies

Variations in time frame:
South Dakota:
To start treatment, you must provide “documentation showing that patient is drug and alcohol free for the past 12 months”

Delaware:
“Client must not have used any illegal substances 90 days prior to therapy;” “The client must have documented abstinence from alcohol use for 90 days prior to starting therapy”

Variations with respect to differentiating between substances
Oklahoma:
“No illicit IV drug use or alcohol abuse in past 6 months, and must not use IV drugs or alcohol during treatment and post-therapy”

Variations in targeting individuals with past or current substance use disorders
Rhode Island:
For patients with current or past significant alcohol or intravenous drug use disorder, patient must be abuse free for a minimum of 6 months OR actively participating in a substance abuse treatment program.

Restrictions May also Apply for Continuation of Anti-Viral Therapy
Louisiana:
If patient has a past history of alcohol and/or substance abuse: If yes, results of urine drug screen and blood alcohol level required every 30 days during treatment.
Some States Allow For Exceptions If the Patient is in Treatment

Florida:
To start treatment, *one of the following* (regardless of previous history), must apply:

“Patient has abstained from *the use of* illicit drugs and alcohol for a minimum of one month as evidenced by negative urine or blood confirmation tests collected within the past 30 days, prior to initiation of therapy (results must be submitted with request);”

OR

“Patient is receiving substance or alcohol abuse counseling services or seeing an addiction specialist as an adjunct to HCV treatment and it is documented in the medical records”
Another Variation: Illinois

Criteria for approval:

• “The patient does not have evidence of *substance abuse diagnosis or treatment* (alcohol, illicit drugs or prescription opioids and other drugs listed on the schedule of controlled drugs maintained by the Drug Enforcement Administration) in the past 12 months based on department claims records, prescriber’s knowledge, medical record entry, state’s narcotic prescription registry database, reports from a hospital, an Emergency Department visit, an urgent care clinic, a physician’s office or practice or another setting”

• “The patient has a documented negative standard urine drug screen report within 15 days prior to submission of prior approval request”
“There are no published data supporting a minimum length of abstinence as an inclusion criterion for HCV antiviral treatment. Patients with active substance- or alcohol-use disorders should be considered for therapy on a case-by-case basis and care should be coordinated with substance-use treatment specialists.”

Restrictions Based on Disease Progression
(Data preliminary and may be subject to change)

- We were able to obtain information for 42 states (including Washington D.C.); 1 other state (MN) has also indicated they may be implementing a more restrictive policy in the future.

- We were unable to obtain information for 8 states.

- Of those 42 states, 34 states have restrictive criteria with respect to disease progression.*
  - Of those 34 states:
    - 1 (ME) state limits to a metavir score of F1
    - 6 states limit to a metavir score of F2
    - 23 states limit to metavir score of F3
    - 4 states limit to metavir score of F4

- 8 states do not appear to have a prohibitive policy with respect to disease progression.

*Note that this does not necessarily mean these states require a biopsy, many may also allow other equivalent measures.
Prescriber Restrictions
(Data preliminary and may be subject to change)

- We were able to obtain information for 43 states (including Washington D.C.); 1 other state (MN) has also indicated they may be implementing a more restrictive policy in the future

- We were unable to obtain information for 7 states

- Of those 43 states, 32 states require either that a specialist prescribe the medication, or that a specialist be consulted - usually limit to Infectious Disease, GI, or Hepatologist (some states also refer to physicians with specific HCV expertise)
  - Of those 31 States:
    - 18 require either that the prescriber be a specialist, or be in consultation with a specialist
    - 9 only allow specialists to prescribe
    - (exact requirements unknown for 5 states*)

- 11 states do not appear to have a requirement with respect to prescribers

* Data provided by Lauren Canary, CDC/VHAC
Restrictions to Treatment Are Problematic For So Many Reasons . . .

1. Discriminatory with respect to individuals who are living with SUDs (sobriety restrictions are not based on clinical evidence)

2. Discriminates against women who may want to have children but are concerned about vertical transmission

3. Tests can’t accurately distinguish between metavir scores of F2/F3/F4

4. Discourages testing: individuals/providers who think they won’t be able to get/provide treatment will have less motivation to get/provide screening
   • won’t be able to actually identify those who meet Medicaid priority guidelines
   • Missed opportunity to help mitigate deterioration in others who have not progressed as rapidly
   • Missed opportunity to provide education around transmission risk

5. Huge burden on providers who have to spend long periods of time filling out PA forms rather than treating patients

6. Missed public health opportunity: we have potential to eliminate the virus because we have a cure!!
Medicaid Moving Forward: Opportunities for Advocacy

1. Become familiar with your state’s policy (if you are having trouble finding it, get in touch and we’re happy to help)

2. Every state has a Pharmacy and Therapeutics (P &T) Committee (or the equivalent) who makes decisions with respect to how drugs are covered on a state’s Medicaid formulary

3. Figure out when those meetings are happening and be sure to provide input
   1. In particular- individuals who otherwise meet treatment criteria should not be excluded on the basis of past or present substance use

4. Testing is critical – in order to identify those that meet even the most strict PA requirements, must ensure testing for all those at risk

5. Case management programs will also be important to ensure medication adherence and protect investments in treatment (consider e.g. Medicaid health homes)

6. Reach out to your state’s adult viral hepatitis coordinator (AVHC)

7. If you are denied treatment by Medicaid, you can appeal !!
   1. And don’t forget about availability of PAP

8. Systemic litigation may be necessary as a last resort

9. Be in touch with your state and federal legislators