



## ACCESS TO HEPATITIS C VIRUS TREATMENT IN MASSACHUSETTS: Identifying Challenges and Exploring Opportunities

### EXECUTIVE SUMMARY

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States, with an estimated 2.7 million people living with chronic HCV nationwide, and approximately 197,000 in Massachusetts. Left untreated, HCV can cause severe morbidity and mortality, including cirrhosis, liver cancer, and liver failure, with concomitant human suffering and high health care costs. As an infectious disease, HCV significantly affects public as well as individual health.

New medications for HCV offer a functional cure, with far fewer adverse side effects than past treatments. The high cost of these medications, however, has led both public and private health insurers to impose eligibility criteria to access the drugs. These restrictions take the form of, among others, prior authorization, exclusivity deals, and adverse tiering, and have created challenges for patients accessing treatment.

This issue brief explores the barriers and challenges to accessing HCV medications, as well as to obtaining concurrent treatment for substance use and HCV. It then offers some recommendations and strategies to improve access to HCV prevention, screening, and treatment, and to better integrate addiction and HCV treatment.

*The Center for Health Law & Policy Innovation provides information and technical assistance on issues related to health reform, public health, and food law. This document should not be considered legal advice. For specific legal questions, consult with an attorney.*

Center for Health Law  
and Policy Innovation

122 Boylston Street  
Jamaica Plain, MA 02130

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

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## ABOUT THE AUTHORS

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. CHLPI works with consumers, advocates, community-based organizations, health and social services professionals, government officials, and others to expand access to high-quality healthcare; to reduce health disparities; to develop community advocacy capacity; and to promote more equitable and effective healthcare systems. CHLPI is a clinical teaching program of Harvard Law School and mentors students to become skilled, innovative, and thoughtful practitioners as well as leaders in health and public health law and policy.

*Access to Hepatitis C Virus Treatment in Massachusetts: Identifying Challenges and Exploring Opportunities* is written by Kellen Wittkop, Amy Rosenberg, Katie Garfield, and Robert Greenwald.

# I. ACCESSING HEPATITIS C VIRUS TREATMENT – WHAT ARE THE ISSUES TO CONSIDER?

## A. SCOPE OF HCV AND URGENCY OF HCV TREATMENT ACCESS

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States, with an estimated 2.7 million people having chronic HCV.<sup>1</sup> In Massachusetts, approximately 197,000 people are estimated to be living with HCV, with 7,963 newly-reported cases in 2013.<sup>2</sup> While the largest number of people living with chronic HCV belong to the “baby boomer” generation (born between 1945 and 1965), young people aged 20-29 comprised the group with the most new reported infections and highest HCV incidence rate in Massachusetts in 2013. A particularly disturbing trend is the rise in HCV among young Massachusetts residents (ages 15 through 24) who inject drugs – a 74% increase in diagnoses from 2002-2009.<sup>3</sup> This trend correlates with the increase of opioid abuse in this cohort.<sup>4</sup>

Left untreated, HCV can cause severe morbidity and mortality, including cirrhosis, liver cancer, and liver failure, with concomitant human suffering and high health care costs. As an infectious disease, HCV affects public as well as individual health. Complications from severe liver damage are expected to peak within the next decade, which creates an urgent need not only to identify but also to treat people living with HCV.<sup>5</sup> A recent study identifying the care continuum for HCV found that nationally, only half of people living with HCV are aware of their status, about one-third are referred to care, and only 5% are successfully treated.<sup>6</sup>

According to both the American Association for the Study of Liver Disease and the Infectious Disease Society of America, every individual living with HCV who has a life expectancy over one year is a candidate for treatment with new therapies that can provide a functional cure.<sup>7</sup> The recent introduction of highly effective, once-daily, oral medications with few adverse side effects should hold great promise to end HCV. Unfortunately, the high cost of the medications has dominated both public discourse and policy making, and has prompted numerous issues with accessing these new treatments.

## B. OVERVIEW OF HCV TREATMENT ACCESS CHALLENGES

As noted, new HCV medications, including Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), and Viekira Pak (ombitasvir/paritaprevir/ritonavir), come at a high cost –the wholesale acquisition costs for a 12-week course of Sovaldi and Harvoni are \$84,000 and \$94,500, respectively.<sup>8</sup> While payers have gotten discounts averaging nearly 50% on wholesale costs, the high price of the medications and the potential number of individuals who could seek treatment has led both public ( e.g., Medicaid) and private health insurers to impose eligibility criteria to access the drugs. These restrictions fall into three main categories, discussed below: prior authorization requirements, exclusivity agreements, and adverse tiering.

### 1. PRIOR AUTHORIZATION REQUIREMENTS

#### a. Medical need restrictions

Payers commonly limit treatment to those individuals with advanced fibrosis (a Metavir score of F3 or F4) as evidenced by a liver biopsy or other evaluative tests. About 40% of individuals living with HCV score F0/F1, which means they are recently infected, and their liver scarring progresses slowly. Another 20% score an F2, and 40% of individuals with advanced fibrosis score in the F3/F4 range. Note that liver biopsies

are +/- 1 fibrosis stage, and non-invasive tests are the best indicators of advanced fibrosis. Since no test is able to precisely distinguish F2 from the higher scores, this limitation in practice results in restricting treatment to cirrhotic patients. Waiting until the patient develops advanced fibrosis also requires life-long screening for hepatocellular carcinoma (HCC) every six months, even after the patient is cured of HCV.<sup>9</sup>

#### **b. Restrictions based on substance abuse**

Payers will also require that patients abstain from substance use (either drugs, alcohol, or both) for a set period of time, usually between three and twelve months. Some states require prescriber assessment and documentation of abstinence, which is difficult for a patient who may need to retroactively obtain documentation. Negative drug screening results may be required, either before the beginning of treatment or periodically throughout the course of treatment. Patients may also be required to complete or concurrently enroll in a treatment program, especially if they have a past history of substance abuse. Some states require counseling services or engagement in care with an addiction specialist.

#### **c. Provider limitations**

The third type of common restriction involves provider limitations – requiring that only specialists are able to prescribe treatment or that a specialist must be consulted. The term “specialist” usually includes gastroenterologist, infectious disease specialist, or hepatologist. This restriction can be especially limiting for patients located in areas with only a small number of care providers.

#### **d. Other restrictions**

Several states include an HIV co-infection limitation. For example, in New York, those coinfecting with HIV must have had an undetectable viral load for the past six months prior to treatment.<sup>10</sup> A handful of states also limit patients to “one treatment per lifetime,” and certain states impose limitations based on a patient’s history of previous treatment adherence (HCV or any medical treatment generally).

## **2. EXCLUSIVITY DEALS BETWEEN PAYERS AND MANUFACTURERS**

Another challenge to patient access to new treatments is the emergence of exclusivity agreements between payers and drug manufacturers (Gilead and AbbVie). These agreements limit patient/provider treatment options in exchange for increased discounts for the payer. Both health insurers and pharmacy benefits management companies have formed exclusivity agreements with manufacturers of HCV treatments. Examples include:

- Exclusive agreement with AbbVie (Viekira Pak)
  - Express Scripts
- Exclusive agreement with Gilead (Harvoni)
  - Anthem
  - Cigna
  - CVS Caremark
  - Wellcare
  - Optum Rx
  - Aetna
  - Catamaran
  - Humana
  - Wellcare
  - United Health
  - Envision Rx
- Exclusive agreement with both AbbVie and Gilead
  - Prime Therapeutics

### 3. ADVERSE TIERING

“Adverse tiering” is the practice of placing certain classes of medications on coverage levels that require higher cost sharing from the consumer—often in the form of coinsurance (a percentage of the cost of the drug). Enrollees in plans that use adverse tiering have much higher out of pocket drug costs—on average more than triple those of individuals enrolled in non-adverse tiering plans.<sup>11</sup> The authors of a 2015 New England Journal of Medicine article noted that “our findings suggest that many insurers may be using benefit design to dissuade sicker people from choosing their plans.”<sup>12</sup>

A recent review of selected plans in the Massachusetts health insurance Marketplace, ConnectorCare, and MassHealth found that the use of adverse tiering is particularly prevalent with HCV medications. More than half of silver-level Marketplace qualified health plans (QHPs) and ConnectorCare plans placed 75% or more of HCV drugs on the highest formulary tiers or did not cover the drugs at all.<sup>13</sup>

### 4. RECENT CHANGES TO GILEAD’S PATIENT ASSISTANCE PROGRAM

Support Path is Gilead’s patient assistance program (PAP) for its HCV medications (Sovaldi and Harvoni), which helps individuals facing access barriers to these treatments to obtain them affordably. As of July 1, 2015, Gilead has changed the criteria for Support Path so that people who are insured, but who do not meet their insurer’s eligibility requirements for HCV treatment in some way, cannot get medication through the PAP. Examples include insurers imposing fibrosis score limitations, having Viekira Pak as a preferred brand, and having drug and alcohol testing.<sup>14</sup> Gilead’s action is intended to pressure insurers that have received discounts on Sovaldi and Harvoni to grant broader access to the drugs; according to Gilead, “some payers have continued to restrict access despite the discounts.”<sup>15</sup> The upshot of the battle between Gilead and payers is that patients are caught in the crossfire, and can lose access to their medications.

## C. HCV TREATMENT ACCESS NATIONALLY AND IN MASSACHUSETTS

### 1. ACCESS IN THE U.S.

The broader trends across the nation illustrate the generally restrictive character of prior authorization criteria for HCV treatment (looking specifically at state Medicaid programs). Of 42 states (including the District of Columbia) with known Medicaid reimbursement criteria for Sovaldi:

- 81% have liver disease stage restrictions, with 74% limiting access to individuals with advanced fibrosis (a Metavir score of F3 or above).
- 88% have some sort of drug and/or alcohol-related criteria, with half requiring a period of abstinence (ranging from 3 to 12 months), and 64% mandating drug screening prior to and/or during treatment. Some states also require enrollment – either prior to treatment or concurrently – in a substance use treatment programs.
- 69% require prescription by, or in consultation with, a specialist.
- 24% require people living with both HCV and HIV to be on antiretroviral therapy and/or have suppressed HIV RNA levels.<sup>16</sup>

### 2. TREATMENT ACCESS IN MASSACHUSETTS

Criteria to access HCV treatment in Massachusetts vary widely among the Medicaid (MassHealth) fee-for-service program, MassHealth managed care organizations (MCOs), ConnectorCare and Marketplace QHPs.

While MassHealth fee-for-service does require prior authorization for HCV medications, the criteria are among the least restrictive in the country. For example, Sovaldi is covered as a preferred drug, and there are no apparent restrictions for fibrosis, substance use, prescribers, HIV co-infection, or adherence.<sup>17</sup>

MassHealth managed care organizations are significantly more restrictive than the fee-for-service counterpart. A recent CHLPI report found that of the four MCOs with publicly available prior authorization criteria at the time of the report:

- all require F3 or F4 Metavir scores (with one plan limited only to F4);
- all require at least six months abstinence from substance use (with three of the four plans requiring some type of concurrent treatment component);
- all require prescription by (or a consultation with) a specialist;
- all discuss some variation of HCV treatment adherence requirement; and
- 2 of 4 plans (Boston Medical Center HealthNet, and Health New England) also require additional criteria for individuals co-infected with HIV.<sup>18</sup>

Marketplace QHPs and ConnectorCare plans also broadly require prior authorization (using similar restrictions as MassHealth MCOs), and impose other criteria that challenge access, such as considering HCV medications as non-preferred brands, mandating use of specialty pharmacies, or not covering a medication.<sup>19</sup>

## **II. OBTAINING EFFECTIVE CONCURRENT ADDICTION AND HCV TREATMENT – WHAT ARE THE BARRIERS?**

*Note: Because HCV is so closely associated with injection drug use –the estimated prevalence of HCV among people who inject drugs (PWID) is 65%, and over 80% for long-term PWID<sup>20</sup> – particularly of opioids like heroin, this section focuses primarily on treatment for opioid misuse and people who inject drugs. However, many of the potential barriers to addiction treatment can also apply to users of other substances and those who do not use injection as an administration method.*

### **A. POTENTIAL BARRIERS TO CONCURRENT TREATMENT FOR SUBSTANCE USE AND HCV**

There is ample evidence that there are almost no clinical contraindications for treating individuals living with HCV who also use substances, and that people who use substances show comparable adherence and success rates to those who do not.<sup>21</sup> However, barriers to effective concurrent treatment for addiction and HCV can exist on multiple levels: treatment setting/health system, treatment provider, and individual/patient.<sup>22</sup>

#### **1. TREATMENT SETTING/HEALTH SYSTEM-LEVEL BARRIERS**

Studies have found that there is a lack of treatment settings adapted for people who inject drugs (PWID) who also need treatment for HCV. Addiction treatment facilities may lack knowledge and infrastructure for treating HCV; conversely, primary care or specialized HCV clinical settings may lack the “cultural competence” to effectively engage PWID and may be stigmatizing.

Health systems in the U.S. (both care delivery and financing) are complex to navigate, and may require a level of self-advocacy that is difficult for individuals trying to manage multiple health issues. Additionally, past abuses of vulnerable populations within the health system (e.g., the Tuskegee experiments) have left legacies of mistrust.

## **2. PROVIDER-LEVEL BARRIERS**

Barriers identified at the physician/provider level include concerns about the ability of people with substance use disorders to adhere to HCV treatment, the possibility of reinfection after treatment in PWID if relapse occurs, biases against PWID/addicts, and the perception that addicts are difficult patients because they have high levels of comorbidities (like mental health conditions).<sup>23</sup>

## **3. PATIENT-LEVEL BARRIERS**

One significant patient-level barrier is the lack of knowledge among PWID about HCV, with 65-75% of patients unaware of their HCV status, and also unaware that new HCV therapies are curative.<sup>24</sup> Older HCV treatment modalities had severe side effects, and a perception persists among PWID that “the treatment is worse than the disease.” Similarly, patients express concern about having to undergo the invasive procedure of liver biopsy before starting treatment, despite there being noninvasive diagnostic methods available. Injection drug use still carries a significant social stigma, which can discourage PWID from seeking treatment. Finally, while this is certainly not universally applicable, PWID are more likely to be poor, dually-diagnosed, unemployed, and lacking insurance and social supports.

## **B. MASSACHUSETTS — GOVERNOR’S OPIOID WORKING GROUP**

On June 22, 2015, Massachusetts governor Charlie Baker released the findings and recommendations of the Opioid Working Group and an Action Plan to implement the recommendations, organized by initiatives in prevention, intervention, treatment, and recovery support.<sup>25</sup> While the report and action plan do not specifically mention HCV or concurrent treatment for addiction and HCV, a number of the recommendations would help foster an environment that is more conducive to concurrent treatment. For example, the report urges education efforts for the public and providers to decrease the stigma associated with substance use and acknowledge addiction as a chronic medical condition. It calls for creating more pathways to treatment, making information about treatment options easier to access, and eliminating insurance barriers (e.g., “fail first” and prior authorization requirements). The report also recognizes that addressing the opioid epidemic will require coordination and collaboration among numerous state agencies, other branches of government, community-based stakeholders, and the private sector.

Some items in the action plan specifically directed at MDPH lend themselves to incorporating information and education about HCV prevention, testing, and treatment. The plan calls on DPH to pilot programs for both walk-in access for urgent addiction assessment and referral to care, and for recovery coaches in emergency departments and “hot spots.” MDPH is also tasked with increasing office-based opioid treatment (OBOT) programs in community health centers and integrating medication-assisted treatment into clinical stabilization services (CSS) care settings. All of these offer opportunities to introduce information about HCV and linkages to prevention, testing, and treatment.

### **III. RECOMMENDATIONS AND STRATEGIES**

#### **A. SHIFT THE CONVERSATION FROM COST OF TREATMENT TO VALUE OF CURE**

While recognizing payer concerns, it is crucial to accurately assess the value of curing HCV. With supplemental rebates and discounts, treatment cost is now approximately \$40,000-\$50,000, compared to roughly \$250,000 during the former interferon treatment period. Looking to other chronic illnesses, HIV (for which there is no cure) costs approximately \$10,000 per year for life just for medications. Greater treatment access may result in increased pharmacy budgets up front, but cost savings will be seen in other areas, particularly if much more expensive interventions like liver transplants are later averted.

#### **B. REDUCE NEGATIVE EFFECTS OF PRIOR AUTHORIZATION CRITERIA AND ADVERSE TIERING**

Removing burdensome prior authorization criteria is necessary in order to promote greater access to and uptake of HCV treatment, and ensure that curative medications are available to all who need them in line with current treatment guidelines. To address the impact of restrictive criteria, DPH, in collaboration with MassHealth and the Division of Insurance, should: (1) examine how prior authorization requirements in MassHealth managed care plans, ConnectorCare plans, and ACA qualified health plans contravene current clinical treatment guidelines, and (2) assess the “on the ground” impact of prior authorization and adverse tiering on people’s access and adherence to HCV treatment (e.g., approval/denial rates, wait time to get medications, patient cost burdens). Obtaining this information will likely require participation by multiple state agencies as well as other stakeholders (e.g., health provider and consumer groups, community health centers, community-based organizations).

#### **C. DEVELOP A PLAN FOR INCREASING HCV SCREENING AND TREATMENT**

As an entitlement program, Medicaid is specifically designed to have the flexibility to grow to respond to demand created by medical innovation, like new HCV treatments. Fears of an overwhelming demand for HCV treatment (given the number of people living with HCV), combined with the medications’ high cost, have prompted public (and private) payers to institute measures to limit access. These fears may be exaggerated – in Massachusetts, with relatively unencumbered access to HCV medications in the MassHealth fee for service program, only 14% of MassHealth enrollees known to be diagnosed with HCV are engaged in treatment, and it is “unrealistic...to expect that all potential candidates will immediately seek HCV treatment.”<sup>26</sup> While screening and treating more people for HCV may initially increase Medicaid costs, the upfront expenditures will avert much more expensive interventions later (e.g., the average cost of a liver transplant in the U.S. is more than \$739,000<sup>27</sup>).

The increased attention on addressing the Commonwealth’s opioid epidemic and apparent prioritization of the issue by the current administration (Governor Baker reportedly plans to seek \$27.8 million in the fiscal year 2016 budget and redirect \$6.7 million from other sources<sup>28</sup>) make this an opportune time to develop an innovative plan to improve access to HCV screening and treatment. Such a plan should be approached holistically, integrating recommendations from the Governor’s Opioid Working Group, involving key stakeholders, and being informed by current clinical treatment guidelines and best practices.

#### **D. EXPLORE CREATING A MEDICAID HEALTH HOME**

The Affordable Care Act provides financial incentives for states to develop Medicaid health homes to support integrated care for people living with chronic conditions (see CHLPI Issue Brief on Medicaid Health Homes). MDPH could work with MassHealth, the Department of Mental Health (DMH), and other stakeholders to explore creating a health home focusing on people living with HCV and opioid dependency (and possibly other comorbid conditions like mental illness and HIV). Three states (Maryland, Rhode Island, and Vermont) have approved health homes

for individuals with opioid dependency, and the Centers for Medicare and Medicaid Services recently issued a detailed brief on considerations for states in designing health homes for this population.<sup>29</sup>

## **E. ASSESS THE CAPACITY OF MASSACHUSETTS PROVIDERS TO DELIVER CONCURRENT ADDICTION AND HCV TREATMENT**

Assessing the capacity of the wide range of Massachusetts substance use treatment programs and HCV treatment programs to meet the needs of dually- (or multiply-) diagnosed individuals is important in attaining effective treatment for this population. Studies have found that successful models of HCV treatment for PWID all include a multidisciplinary approach encompassing clinicians, drug/alcohol support services, psychiatric services, social workers, and support services (including peer support).<sup>30</sup> Co-locating HCV prevention and treatment services with addiction treatment facilities can increase uptake of HCV treatment. The MDPH Bureaus of Infectious Disease (BID) and Substance Abuse Services (BSAS) should assess the extent to which Massachusetts has treatment settings adapted to the needs of PWID, and the prevalence of provider- and setting-level barriers mentioned above.

## **F. INCREASE HCV EDUCATION FOR BOTH CONSUMERS AND PROVIDERS**

Lack of knowledge about HCV is cited as a barrier to prevention, screening, and treatment on the part of both consumers and substance use treatment providers. This may particularly be an issue for young people who misuse opioids, who may not understand their risk for contracting HCV. More educational materials and programs on HCV could help to address this knowledge gap. One example of this is the Governor's Opioid Working Group calling for more prevention education for youth – this education should include information about HCV prevention and treatment.

## **H. INTEGRATE HCV INFORMATION THROUGHOUT SUBSTANCE USE, MENTAL HEALTH, AND CORRECTIONS PROGRAMS**

BSAS, DMH, and the Department of Corrections (DOC) all fund and operate programs that reach people living with and at risk for HCV. Incorporating information about HCV prevention, screening, and treatment into this wide range of programs can help increase awareness among both consumers and providers, and ultimately support BID's efforts to promote greater screening and linkage to HCV treatment.

## ENDNOTES

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- <sup>25</sup> Office of the Governor, “Governor Baker Releases Opioid Working Group Recommendations,” June 22, 2015, <http://www.mass.gov/governor/press-office/press-releases/fy2015/governor-releases-opioid-working-group-recommendations.html>. See also, Freyer, F., “Opioid task force says more beds, treatment options needed,” *THE BOSTON GLOBE*, June 22, 2015, <https://www.bostonglobe.com/metro/2015/06/22/baker-release-findings-state-opioid-crisis/yP4me9jqa4fJJSabUDiNuJ/story.html>.
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