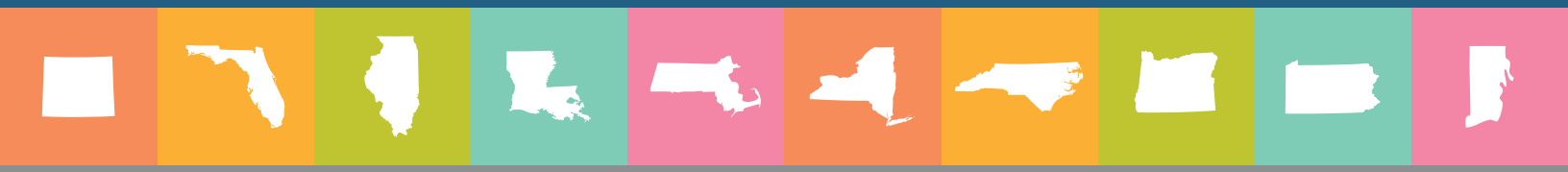
Examining Hepatitis C Virus Treatment Access: A Review of Select State Medicaid Fee-For-Service and Managed Care Programs

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS:



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

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

With special thanks to our Harvard Law School students,

James Fullmer, Kellen Wittkop, & Stephen Shaw,

for their help in researching and writing the state profiles in this report

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Introduction

The arrival of Sovaldi, a highly effective treatment for hepatitis C virus (HCV), is a truly exciting development for the millions of Americans who suffer from HCV. However, even in states that have committed themselves to improving the healthcare of their citizens by expanding Medicaid, barriers to treatment remain. Cost-conscious Medicaid programs, including Medicaid managed care organizations, have responded to the high cost of Sovaldi coverage through implementation of various restrictions on who, among individuals living with HCV, may actually receive the drug. These restrictions focus on four major factors:

+ Fibrosis criteria (how much liver damage or disease an individual must have);
+ Substance use (requiring periods of abstinence from substance use prior to and/or during treatment;
+ HIV co-infection criteria (such as requirements for an undetectable viral load); and
+ Prescriber limitations (only allowing reimbursement for treatment prescribed or performed by certain specialists).

These restrictions are not grounded in clinical evidence and instead appear to be driven exclusively by financial concerns in an effort to ration treatment to ensure cost containment. Such restrictions are also at odds with the treatment guidelines published jointly by the American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA). These guidelines state that "evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions."[1] The guidelines specify that individuals with fibrosis (Metavir F2 and above) are high priorities for treatment, along with individuals who are co-infected with HIV. The guidelines also note that treating active injection drug users and women of child-bearing age could yield significant transmission reduction benefits.

These brief profiles will give an overview of HCV in ten states, examine the accessibility of Sovaldi through Medicaid fee-for-service programs, and in five select states—Massachusetts, New York, Louisiana, Pennsylvania, and Oregon—also look at restrictions in Medicaid managed care plans that can differ from fee-for-service programs.

The Scope of the Epidemic

Nationally, it is estimated that there are between 3.2 and 5 million people currently living with HCV in the U.S.,[2] 75% of whom do not know they are infected.[3] Prevalence is generally concentrated among individuals in the baby-boomer generation (those born between 1945 and 1965).[4] As well, there is a large population of individuals who are co-infected with HIV; nationally it is estimated that 25% of individuals living with HIV are co-infected with HCV.[5]

While it is difficult to estimate the number of new infections each year, many states, including New York and Massachusetts, are also starting to see an increase in reported cases from young injection drug users (individuals ages 15-24), which is correlated with increases in opioid abuse among this age-group.[6]

About 15,000 individuals die every year in the U.S. from HCV-related causes, and starting in 2007, the number of HCV-related deaths exceeded that of HIV.[7]

Despite these statistics, there is very little federal funding for HCV. While each state has a designated Adult Viral Hepatitis Prevention Coordinator charged with integrating viral hepatitis services into public health programs, there are no federal dollars available for surveillance or program activities.

About the Profiles:

State-Specific Hepatitis C Virus (HCV) Data and Program Information

At the beginning of each state profile is state-specific HCV data on prevalence, yearly reported cases, and HCV-related deaths. Where available, we also include data on the number of individuals co-infected with HIV, and age categories for yearly reported cases. For instance, while the majority of reported cases are usually among baby boomers, states like Massachusetts and New York have also seen an increase in reported infections among 15- to 24-year-olds.

We use "yearly reported cases" rather than incidence. States vary with respect to how they report "acute infections." For example, while the CDC requires that a variety of criteria be met (including visible symptoms) in order for an infection to be considered "acute," Massachusetts considers all infections in the younger age cohort to be "acute."[8]

Because there are no federal dollars (beyond a few specific grants to particular states) for surveillance, the availability and detail of HCV data vary greatly among each state. Where possible, we supplement the data from state health departments with information from published estimates in journals and other compendia.

Similarly, where possible, we also include information about any state-specific programs (excluding community-based organizations) that provide access to HCV services such as testing, prevention, counseling, care, and/or treatment. In states where information on HCV programming was lacking from health department sites or where information appeared limited to general informational flyers, we indicate that information was "unavailable." As with surveillance, there are very few federal dollars available for any kind of HCV programing. While some states have been able to use their own funding to create programs or otherwise integrate services with existing HIV and sexually transmitted infection (STI) service infrastructures, other states have not. As a result, it is likely that many states where information was unavailable simply do not have any HCV-specific program resources.

Background on Medicaid Programs and Drug Formularies

States vary widely in how their Medicaid programs work, both in terms of eligibility and care delivery. In states that have chosen not to expand Medicaid, eligibility requirements remain extremely strict, with no means of eligibility for low-income adults, unless they meet categorical requirements such as being parents of children or being disabled. In states that have opted to expand their programs, most individuals with incomes up to 138% of federal poverty level (FPL) are now eligible.

In general, each state Medicaid program has a Pharmacy and Therapeutics Committee (or similar body) made up of providers, clinicians and other partners who meet on a regular basis to decide which drugs to include on their state formularies, and what prior authorization criteria or other requirements to impose. In general, these formulary requirements apply to Medicaid fee-for-service programs, which are applicable to more traditionally eligible Medicaid populations such as parents of children and individuals with disabilities.

While all states have some populations that remain in traditional fee-for-service programs, the majority of individuals in Medicaid now receive services through managed care organizations (MCOs). While we did not look at MCOs in every state, we did examine up to five managed care plans in five particular states: Massachusetts, New York, Louisiana, Pennsylvania, and Oregon. In some states, like Florida, MCOs follow the fee-for-service guidelines with respect to formularies and prior authorizations. In other states, like Massachusetts, managed care organizations set their own criteria, and there may be marked differences between Medicaid fee-for-service guidelines and MCOs within a state, or between two different Medicaid MCOs.

Access to Sovaldi in State Medicaid Fee-for-Service Programs

The high cost of Sovaldi has led almost every state Medicaid program to employ varying degrees of restrictive prior authorization criteria. For this project, we specifically examine restrictions with respect to:

+ Fibrosis criteria;
+ Requirements based on substance use;
+ HIV co-infection criteria; and
+ Prescriber limitations.

In each profile, language pursuant to each category is taken directly from the criteria and/or prior authorization form (in some cases with slight grammatical or formatting additions), to provide a sense of the different ways in which states describe their requirements. Links to each form and criteria are provided in the footnotes.

Among the states we examine, with the exception of Massachusetts and North Carolina, each fee-for-service program has specific criteria with respect to all factors except HIV co-infection (which varied more by state).

Fibrosis Criteria

Every state, except for Massachusetts and North Carolina, restricts treatment to individuals who have fibrosis equivalent to a Metavir score of F3 and above, while two states, Oregon and Illinois, restrict treatment to individuals at F4 (and in fact are two of only four states in the entire country to do so). Individuals at F4 are considered to have advanced liver disease, and/or cirrhosis, and may have already developed irreversible liver damage.

Requirements Based on Substance Use

Almost all states, with the exception of Massachusetts, have some form of criteria with respect to abstinence from substance abuse or use, ranging from 30 days (in Florida) to over a year (in Illinois and Louisiana). One state, North Carolina, does not have specific abstinence requirements, but does require a "commitment" to abstinence for individuals with a history of alcohol abuse (though not drug abuse). As with fibrosis criteria, Illinois continues to be an outlier, with a requirement not only that individuals not have evidence of diagnosis of drug and/or alcohol abuse within the past year, but also requiring that they not have been in treatment over the same timeframe. As well, Illinois delineates a long list of specific utilization data sources that will be examined with regard to a person's history (such as emergency room visits, for instance). Some states, like Colorado, require everyone to abstain from any drug or alcohol use or abuse for a specific period of time prior to treatment. Other states, like Rhode Island and Louisiana, only require a period of abstention for individuals with a history of abuse, and/or, only require that individuals abstain from drug or alcohol *abuse* (as opposed to any *use*). Two states, Florida and Rhode Island, make exceptions to their abstinence requirement for individuals who are enrolled in treatment programs.

In addition to strict abstinence requirements, some states also require drug and/or alcohol testing prior to and/or during treatment. It is unclear what consequences would ensue should an individual already in treatment receive a positive test result, even if that individual was otherwise actively adherent.

HIV Co-Infection Criteria

Only two states, New York and Florida, seem to have specific criteria for HIV co-infection, although many states ask about coinfection on their prior authorization forms. In New York, while those coinfected with HIV appear to be able to bypass fibrosis criteria requirements, they must have had an undetectable viral load for the past 6 months prior to treatment. Florida also has particular CD4 counts that must be met.

Prescriber Limitations

Almost every state has particular requirements for prescribers, with most requiring treatment be prescribed by, or in conjunction with, a hepatologist, infectious disease specialist, or gastroenterologist. A few states also make exceptions for, or have additional requirements related to, providers experienced in treating HCV.

Apart from these four criteria, some states have additional adherence requirements (such as signing a treatment plan), that we also include. In addition, it is worth noting that many states may have other forms of restrictive criteria that will need to be considered moving forward, such as criteria for interferon ineligibility and criteria for treatment continuation.

Finally, it is important to understand that these profiles represent a snapshot in time: states are continuously updating their criteria, and many states have implemented more restrictive requirements even within the past month.

Conclusion

After reviewing these states and their health plans, a few takeaways emerge. First, many of these requirements do not have a basis in clinical evidence, and steps must be taken to ensure that Medicaid pharmacy and therapeutic committees are educated about appropriate clinical criteria. Second, a number of plans use vague or confusing language in describing possible limitations on coverage, particularly in terms of substance abuse and medical compliance history. Clarity must be sought to ensure that these requirements are not being applied arbitrarily and unfairly to deny coverage. Third, many of the more explicit requirements in these areas, such as sobriety requirements, may be subject to legal challenge as pretexts for discrimination. Advocates and patients must be alert to the possibility of unfair discrimination and be prepared to report and challenge it. Fourth, without additional investments in HCV surveillance and programming, it will be impossible to estimate the true burden of the disease so that we can appropriately address its consequences.

It is also worth noting that these policies are likely to have a number of detrimental consequences, including, but not limited to, the following: First, these policies are likely to have the effect of discouraging testing, as individuals/providers who think they will not be able to obtain/offer treatment will have less motivation to obtain/provide screening. Without appropriate testing, Medicaid programs will not be able to identify those who actually do meet priority guidelines for immediate treatment. Failure to test also represents a missed opportunity to help mitigate deterioration in others who have not progressed as rapidly and to provide education around transmission risk. Second, these policies also have detrimental impact for women who may want to have children but are concerned about vertical transmission. Third, these requirements are a huge burden on providers who have to spend long periods of time filling out prior authorization forms rather than treating patients. Fourth, restricting access to treatment is a missed public health opportunity—we have the potential to eliminate the virus because we have a cure; yet the high cost of the medication and the resulting restrictive policies ensure that HCV will be around for a long time to come.

Finally, it is clear that collective and constructive action is needed among advocates, patients, providers, and state and federal governments to ensure access to education, testing, prevention, and treatment, and ultimately to address the high cost of HCV treatment.

EXAMINING HEPATITIS C VIRUS
TREATMENT ACCESS:
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Colorado

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Colorado

Hepatitis C Virus (HCV) in Colorado[9]

Prevalence

+ Estimates indicate that more than 70,000 Colorado residents have ever been infected with hepatitis C virus (HCV).

HIV Co-Infection

+ As of 2011, it was estimated that about 9.7% of individuals living with HIV in Colorado were co-infected with HCV.[10]

Yearly Reported Infections

+ In 2012, there were a total of 3,223 reported hepatitis C cases (acute, past, or present) in Colorado.

Age Breakdown

+ There were 874 cases reported among individuals ages 20-40; and 1,801 cases among individuals ages 40-60.

Deaths

+ Data unavailable

State HCV Programs in Colorado

The Colorado Viral Hepatitis Program oversees HCV testing of high-risk adults as well as education and outreach integrated with HIV and sexually transmitted infections (STIs), as well as viral hepatitis surveillance.[11]

Medicaid in Colorado

Eligibility

In addition to covering categorically needy populations, Colorado has also elected to expand Medicaid coverage. All eligible adults earning 138% of the federal poverty level (about $16,105/year) or under are eligible for Medicaid, regardless of whether they meet other categorical requirements, with slightly higher income limits for children and pregnant women.[12]

Care Delivery

Colorado Medicaid offers individuals the choice between enrolling in an Accountable Care Collaborative (a managed provider network), a managed care organization, or regular fee for service.[13] All managed care programs have to follow the Colorado fee-for-service policy.[14]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

The Drug Utilization Review (DUR) Board serves as an advisory body to the Colorado Medicaid program, and makes recommendations regarding issues of drug utilization, prior authorization for drugs with special prescribing guidelines, and/or non-preferred drugs, provider education interventions, and application of standards.[15] The DUR Board meets once quarterly. In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[16]

Fibrosis Criteria

+ Individuals must meet one of the following categories based on liver biopsy, symptoms, or other accepted test:
  - Serious extra-hepatic manifestations of HCV such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease;
  - Cirrhosis with evidence of hepatic dysfunction as defined by one of the following: Child-Turcotte Pugh (CTP) class A or B (score 5-9) ascites, hepatic encephalopathy, or variceal bleeding, and on the liver transplant list with a projected time to transplant of <1 year;
  - Listed on the liver transplant list with a projected time to transplant of <1 year (genotype: 1 naïve, 1 experienced, 2, 3, and 4);
  - Has hepatocellular carcinoma meeting MILAN criteria; or
  - Has a fibrosis score equivalent to Metavir 3-4.

Requirements Related to Substance Use

+ Individuals must be 6 months free of: alcohol and Schedule I controlled substances (including marijuana); and cocaine, opiate, benzodiazepine, and barbiturate misuse/abuse as documented by appropriate alcohol/drug screens.
+ Individuals must also be counseled about the importance of refraining from alcohol use and drug misuse/abuse.
+ Routine alcohol/drug screens must be conducted monthly for clients that have a history (within the past 2 years) of alcohol/drug abuse.

HIV Co-Infection Criteria

+ Colorado does not appear to have any specific criteria with respect to HIV co-infection, although the prior authorization form asks if the individual is co-infected with HIV/AIDS.[17]

Prescriber Limitations

+ Treatment must be prescribed by or in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist.

Additional Adherence Requirements

+ Colorado specifically requires that individuals be in compliance with approved regimens and adherent to the treatment regimen, and will prospectively evaluate medication adherence based on prescription fills. If an individual is non-adherent in filling their Sofosbuvir prescription (e.g., not filled within 7 days of the end of the previous fill), all treatment will be discontinued.

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS:

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Florida

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Florida

Hepatitis C Virus (HCV) in Florida[18]

Prevalence

+ As of 2009 (the most recent year for which data are available) about 300,000 Florida residents were estimated to be living with hepatitis C virus (HCV).[19]

HCV/HIV Co-Infection

+ Based on a data match between reported HIV and HCV cases, as of 2008, approximately 7,365 individuals were living with HIV and HCV co-infection.[20]

Yearly Reported Cases

+ From 2002-2006, a total of 98,049 cases of HCV were reported to the state.[21] Most cases were among individuals in the baby-boomer generation, with about 37% of reported cases during this period among individuals ages 40-49.[22]

Deaths

+ Unavailable

State HCV Programs in Florida

Florida offers many services relating to hepatitis C including: Hepatitis 101 Training (for nurses, counselors, and outreach workers); free testing and laboratory services in some specific counties; educational materials; and support groups.[23]

Medicaid in Florida

Eligibility

Florida has chosen to not expand Medicaid, which means that only low-income individuals who also meet categorical requirements (such as having a disability or being the parent of a child) are eligible.[24] In general, in order to qualify, parents of children must have an income of less than 19% of the federal poverty level (FPL) ($2,989/year for a family of two),[25] with higher income thresholds for pregnant women and children). Aged, blind, or disabled individuals must have incomes less than 88% FPL ($10,270/year for an individual).[26]

Care Delivery

Most Florida Medicaid recipients are enrolled in one of 14 managed care plans throughout the state.[27] Some limited categories of individuals still receive care through fee for service (such as individuals who are residents of a developmental disability center or enrolled in the developmental disabilities home and community-based services waiver).[28]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

The Florida Medicaid Pharmaceutical and Therapeutics Committee determines which drugs will be added or removed from the Medicaid preferred drugs list as well as prior authorization criteria for the fee-for-service program, and meets routinely throughout the year.[29] All Florida Medicaid managed care plans' formularies and prior authorization criteria must also follow the Florida Medicaid prior authorization criteria as determined by the Committee.[30]

Sovaldi is covered under the Florida Medicaid Preferred Drug Program, but it is not listed on the Preferred Drug List indicating that it is non-preferred drug.[31] As a non-preferred drug, Sovaldi requires certain prior authorization requirements be met for patients seeking treatment.[32] In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required):[33]

Fibrosis Criteria

+ Individuals must have evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following:
  - Liver biopsy confirming a Metavir score of F3 or F4; or
  - Transient elastography (FibroScan®) score greater than or equal to 9.5 kPa; or
  - FibroTest® score of greater than or equal to 0.58; or
  - APRI score greater than 1.5; or
  - Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); or
  - Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician.

Requirements Related to Substance Use

+ Individuals must have abstained from the use of illicit drugs and alcohol for a minimum of 1 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).
  - If the test results submitted are positive, the reviewer must review the patient's claims history or medical records to determine if the medications can be prescribed.
+ Alternatively, the individual must be receiving substance or alcohol abuse counseling services or seeing an addiction specialist as an adjunct to HCV treatment, and it must be documented in the medical records.

HIV Co-Infection Criteria

+ Individuals co-infected with HIV-1 must additionally meet the following criteria:
  - Documented HIV-1 diagnosis; AND
  - CD4 count greater than 500 cells/mm^3, if patient is not taking antiretroviral therapy; OR
  - CD4 count greater than 200 cells/mm^3, if patient is virologically suppressed (e.g., HIV RNA <200 copies/mL)

Prescriber Limitations

+ The requesting prescriber must be a hepatologist, gastroenterologist, infectious disease specialist, or transplant physician.

Additional Adherence Requirements

+ Florida also has additional "completion of therapy review criteria," which include:
  - No sign(s) of high-risk behavior (recurring alcoholism, IV drug use, etc.) or failure to complete HCV disease evaluation appointments and procedures should be evident in follow-up reviews.
+ In addition, continuation of treatment will only be authorized for members who are 100% compliant to the regimen as verified by the prescriber and member's medication fill history.

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Illinois

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Illinois

Hepatitis C Virus (HCV) in Illinois[34]

Prevalence

+ As of 2007 (the latest year for which data are available), between 99,863 and 150,903 individuals are living with hepatitis C virus (HCV) in Illinois.

HIV Co-Infection

+ Approximately one out of every three individuals living with HIV in Illinois is also infected with HCV.

Yearly Reported Cases

+ About 5,000 cases in individuals between the ages of 30 and 59 are reported each year.

Age Breakdown

+ Data unavailable

Deaths

+ Data unavailable

State HCV Programs in Illinois

Illinois integrates viral hepatitis risk reduction counseling and some testing services with its HIV and sexually transmitted infections (STI) programs.

Medicaid in Illinois

Eligibility

In addition to covering categorically needy populations, Illinois has also elected to expand Medicaid coverage. All eligible adults earning 138% of the federal poverty level (about $16,105/year) or under are eligible for Medicaid, regardless of whether they meet other categorical requirements.

Care Delivery[35]

Illinois is currently transitioning most of its Medicaid enrollees into managed care entities. Individuals newly eligible under Medicaid, as well as previously eligible families and children, will be enrolled into a Managed Care Organization (MCO), a Managed Care Community Network (MCCN) (a provider-organized entity, fully capitated), or an Accountable Care Entity (ACE) (similar to an MCCN, although not yet fully capitated), although managed care may not yet be mandatory or available in all counties. Seniors and/or disabled individuals may also be enrolled in Coordinated Care Entities (CCEs) (entities that are fee for service but with additional payments based on care coordination and meeting certain quality metrics).

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

The preferred drug list and prior authorization requirements for the fee-for-service program are created in consultation with the Illinois State Medical Society Committee on Drugs and Therapeutics (D and T Committee), which meets quarterly.[36] Individuals subject to fee-for-service requirements include those who are enrolled in either CCE or ACE programs. MCOs or MCCNs can set their own criteria with respect to prior authorization. As of October 2014, Sovaldi is covered as a non-preferred drug.[37] In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required)[38]:

Fibrosis Criteria

+ Individuals must have a Metavir score of ≥F4 or equivalent.

Requirements Related to Substance Use

+ Individuals must 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. Information pursuant to this requirement will be 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.
+ It is not clear from the criteria who (the state or the provider) is responsible for verifying the substance use requirements pursuant to the above medical records.
+ Individuals must also provide documentation of a negative standard urine drug screen report within 15 days prior to submission of the prior approval request.

HIV Co-Infection Criteria

+ Illinois does not appear to have any specific criteria with respect to HIV co-infection.

Prescriber Limitations

+ The prescriber can be any physician who holds a current unrestricted license to practice medicine and is currently enrolled as an Illinois Medicaid Provider.
+ If the prescriber is not a board-certified gastroenterologist, transplant hepatologist or infectious disease specialist, a one-time written consultation report from a board-certified gastroenterologist, transplant hepatologist or infectious disease specialist will be required within the past 3 months. This consulting specialist must have recommended Sovaldi therapy prior to approval. Requests will not be accepted from mid-level practitioners and pharmacies.

Additional Adherence Requirements

+ Non-compliance with the regimen or the individual's failure to obtain refills every 2 weeks will result in discontinuation of previous prior approval, and no further therapy with Sovaldi will be approved.
+ Provider must provide a copy of a signed patient commitment letter for Sovaldi treatment.[39]

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Louisiana

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Louisiana

Hepatitis C Virus (HCV) in Louisiana

Prevalence

+ Approximately 80,000 individuals in Louisiana are living with hepatitis C virus (HCV).[40]

HIV Co-Infection

+ Data unavailable

Yearly Reported Cases

+ Reported cases of HCV in Louisiana have been steadily increasing, with 5,000-6,000 cases reported in 2011.[41]

Age Breakdown

+ The highest number of reported cases is among individuals ages 45-54.[42]

Deaths

+ Approximately 120 Louisiana residents are expected to die each year from hepatitis C.[43]

State HCV Programs in Louisiana

The Louisiana State Legislature currently has a Louisiana Commission on HIV, AIDS, and Hepatitis C.[44] This commission is charged with serving as an advisor to the governor and as a coordinating body among government and non-governmental agencies, holding annual hearings, researching and reviewing state policies, guidelines and procedures related to the prevention, care, and treatment of HIV, AIDS, and HCV, and as appropriate, making recommendations for improvement.

Medicaid in Louisiana

Eligibility

Louisiana has chosen to not expand Medicaid, which means that only low-income individuals who also meet traditional categorical requirements (such as being the parent of a child or being disabled) are eligible.[45] In general, in order to qualify, parents of children must have an income of less than 15% of the federal poverty level (FPL) ($2,360/year for a family of two), with higher income thresholds for pregnant women and children).[46] Aged, blind, or disabled individuals must have incomes less than 74% FPL ($8,266/year for an individual).[47]

Care Delivery

In Louisiana Medicaid (as well as LaCHIP), almost all recipients receive care through the Bayou Health program, and are required to enroll in one of five managed care plans.[48] Only a small number of individuals remain in fee for service or are otherwise excluded from Bayou Health/managed care, including for instance, individuals who are residents of a nursing facility, development center, or group home, and children with disabilities.[49]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

The Louisiana Medicaid Pharmaceutical & Therapeutics Committee is comprised of 21 members, approved by the Governor, and meets each spring and fall to discuss drugs which will be added to/removed from the Pharmacy Benefits Management (PBM) Program, as well as other pharmacy-related issues such as prior authorization criteria for various drugs.[50]

Under the PBM Program, Sovaldi is considered a covered drug.[51] As a non-preferred drug, Sovaldi requires certain prior authorization requirements to be met for patients seeking treatment.[52] In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[53]

Fibrosis Criteria

To be considered, an individual must:

- Have a diagnosis of
  - Genotype 2 or 3 with a documented history of relapse or nonresponse to standard therapy (peginterferon alfa and ribavirin); or
  - Hepatocellular carcinoma meeting MILAN criteria (defined as the presence of a tumor 5 cm or less in diameter in patients with a single hepatocellular carcinoma and no more than three tumor nodules, each 3 cm or less in diameter in patients with multiple tumors and no extra-hepatic manifestations of the cancer or evidence of vascular invasion of the tumor) and is currently awaiting liver transplantation.
- For genotypes 2 and 3, the individual must have a liver biopsy showing advanced fibroris or cirrhosis (Ishak stage ≥4 or Metavir score ≥3); and
- The indiviudal must have compensated liver disease (Child-Turcotte-Pugh CTP), Score 6, Class A;
- It is not clear whether individuals with genotype 1 may also be eligible for Sovaldi if the above criteria are met.

Requirements Related to Substance Use

- As part of the prior authorization request, the provider must submit confirmation that the individual has not been actively participating in substance abuse and/or alcohol abuse within the past year (must be attested by the prescriber and substantiated by the results of a negative urine drug screen and blood alcohol level 30 days prior to treatment start and at the start of treatment); and
- In the presence of prior substance abuse and/or alcohol abuse, a urine drug screen and blood alcohol level are required on a random basis at some point during each 30-day HCV treatment interval while on sofosbuvir (the results of these screenings/levels must remain negative during sofosbuvir treatment).

Prescriber Limitations

- Sovaldi must be prescribed/requested by a physician with a specialty/subspecialty of gastroenterology, hepatology, or infectious disease.

HIV Co-Infection Criteria

- Louisiana does not appear to have any specific criteria with respect to HIV co-infection, although the prior authorization form asks whether the individual is co-infected.

Additional Adherence Requirements

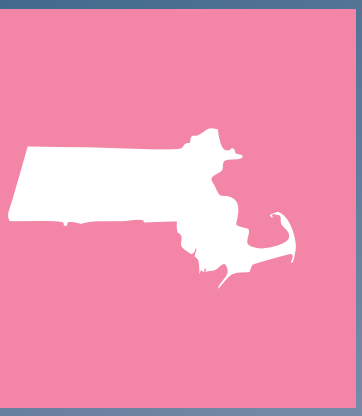
- Individuals are required to sign a completed "Hepatitis C Therapy Agreement" with the original prior authorization request, which among other requirements, provides that individuals must agree to take all medication doses; missing doses may result in Medicaid no longer paying for treatment, and indicates that Louisiana Medicaid may only pay for one treatment per lifetime.

Managed Care

Two of the managed care plans, United Healthcare Community Plan and Community Health Solutions, do not include pharmacy benefits as part of managed care, and individuals receive pharmacy benefits through the fee-for-service program.[54] Out of the other three managed care plans Amerigroup, AmeriHealth Caritas (formerly LaCare), and Louisiana Healthcare Connections, only AmeriHealth Caritas appears to offer access to Sovaldi (though it is listed as not covered, there are specific prior authorization criteria and forms available).[55] AmeriHealth's criteria are generally less restrictive, requiring only a Metavir score ≥2 compared to 3, and requiring only 6 months abstinence from substance use as opposed to a year. As well, individuals co-infected with HIV are required to provide information on HIV serology. (See page 21 for more information).

Louisiana Medicaid Fee for Service Compared to AmeriHealth Caritas (Medicaid Managed Care Organization): Prior Authorization Requirements for Sovaldi

	Fee for Service[56]	AmeriHealth Caritas[57]
Fibrosis Criteria	The individual must have a diagnosis of • Genotype 2 or 3 with a documented history of relapse or no response to standard therapy (peginterferon alfa and ribavirin); OR • Hepatocellular carcinoma meeting MILAN criteria (defined as the presence of a tumor 5 cm or less in diameter in patients with a single hepatocellular carcinoma and no more than three tumor nodules, each 3 cm or less in diameter in patients with multiple tumors and no extrahepatic manifestations of the cancer or evidence of vascular invasion of the tumor); AND is currently awaiting liver transplantation; AND For genotypes 2 and 3, the individual must have a liver biopsy showing advanced fibroris or cirrhosis (Ishak stage ≥4 or Metavir score ≥3; AND The individual must have compensated liver disease (Child-Turcotte-Pugh CTP), Score 6, Class A.	The individual must have had a liver biopsy showing advanced to severe fibrosis, or a FibroScan® (elastometry (TE), or an acoustic radiation force impulse (ARFI) imaging test. The individual must have either Ishak stage >3 or Metavir Score >2 or FibroScan score >12.5 or ARFI score >1.75.
Requirements Relating to Substance Use	Requires confirmation that the individual has not been actively participating in substance abuse and/or alcohol abuse within the past year; Abstinence must be attested by the prescriber and substantiated by the results of a negative urine drug screen and blood alcohol level 30 days prior to treatment start and at the start of treatment; AND In the presence of prior substance abuse and/or alcohol abuse, a urine drug screen and blood alcohol level are required on a random basis at some point during each 30-day HCV treatment interval while on sofosbuvir.	In the presence of previous substance abuse (including alcohol and prescription drugs): no alcohol or illicit drug use within 6 months of treatment onset. Abstinence must be attested by the physician and documented by a negative urine drug screen and drug and alcohol level test within 30 days prior to the start of treatment.
HIV Co-Infection Criteria	Prior authorization form asks whether individual is co-infected.	HIV serology (CD4 + T cell count and HIV RNA are required for patients co-infected with HIV. In patients with lower CD4 counts (e.g. < 200 cells/mm^3) it may be preferable to delay HCV therapy until CD4 counts increase).
Prescriber Limitations	Specialist only – Hep, GI, or ID	Specialist only – Hep, GI, or ID
Additional Adherence Requirements	Patient must sign HCV Treatment Agreement; missing doses may cause Medicaid to stop paying for treatment; one treatment per lifetime.	Demonstrated non-compliance with the treatment regimen, defined as two consecutive missed doses or more than four missed doses in a 4-week period, renders the treatment ineffective and may result in denial of additional authorizations.



EXAMINING HEPATITIS C VIRUS
TREATMENT ACCESS:
A REVIEW OF SELECT STATE MEDICAID FEE-FOR-SERVICE AND MANAGED CARE PROGRAMS

Massachusetts

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

Massachusetts

Hepatitis C Virus (HCV) in Massachusetts

Prevalence

+ It is estimated that 197,000 people in Massachusetts are living with hepatitis C virus (HCV).[58]

HIV Co-Infection

+ 4,396 individuals with HIV have been identified as being co-infected with HCV as of 2010—14% of the total population of HIV positive individuals.[59]

Yearly Reported Cases

+ Approximately 7,963 cases were reported in 2013.[60]

Age Breakdown

+ The incidence of HCV among individuals between the ages of 15 and 25 has increased over the past decade, more than doubling while the incidence of HCV in those over 30 decreased over the same time period.[61] Between 2002 and 2009, injection drug users between the ages of 15 and 24 saw diagnoses increase by 74%.[62]

Deaths

+ In 2011, 407 people in Massachusetts died as a result of HCV, either as the main or a contributing cause of their death.[63]
+ This was a slight decrease from 2010, when 442 people in Massachusetts died as a result of HCV.[64]

State HCV Programs in Massachusetts

Massachusetts provides funding for medical case management of individuals infected with HCV.[65] This takes place through five facilities at seven locations throughout the state, with services including phone check-in, social services coordination, adherence support, meals, transportation, peer support, and housing assistance.[66] Other services for prevention, testing, and referral are integrated with services for HIV/AIDS and sexually transmitted infections (STI) at locations throughout the state.[67]

Medicaid in Massachusetts

Eligibility

Eligibility for MassHealth, Massachusetts's Medicaid program, is open to a number of different populations, and is relatively generous compared to other states.[68] In addition to covering categorically needy populations, Massachusetts was one of the first states to expand its Medicaid program, beginning in 2006. Currently, all eligible adults earning 138% of the federal poverty level (FPL) (about $16,105/year for an individual) or under are eligible for Medicaid, regardless of whether they meet other categorical requirements, with higher income limits for children and pregnant women.[69] Those living with HIV are eligible up to 200% of the FPL (about $23,340/year for an individual), while certain adult workers with insurance are eligible for MassHealth premium assistance up to 300% of the FPL (about $43,740/year for an individual).[70]

Care Delivery

Most individuals in MassHealth are required to enroll in a managed care organization (MCO) rather than traditional fee-for-service MassHealth.[71] Those exempt from this requirement include:

+ People with Medicare or other health insurance;
+ Those over age 65;
+ Institutionalized individuals; and
+ Children in the foster care system.[72]

Five MCOs provide services to eligible MassHealth recipients in all categories: Boston Medical Center HealthNet Plan (HealthNet), Fallon Community Health Plan (FCHP), Health New England (HNE), Neighborhood Health Plan (NHP), and Tufts Health Plan Network Health (Network Health).[73] A sixth, CeltiCare, began in 2014 to cover MassHealth CarePlus recipients specifically.[74]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

Drug coverage decisions for MassHealth are made by the Drug Utilization Review (DUR) Board.[75] This board consists of physicians and pharmacists and meets on a quarterly basis. MassHealth requires prior authorization to cover most hepatitis antiviral drugs, including Sovaldi, but there do not appear to be any explicit restrictions based on a patient's history of substance use or fibrosis status, although the prior authorization form asks specifically about fibrosis stage and substance use; the effect that the answers to these questions have on eligibility is not clear.[76]

Fibrosis Criteria

+ Massachusetts does not appear to have fibrosis criteria; although the prior authorization form asks whether an individual's liver fibrosis stage falls within one of two ranges: F1-F2 or F3-F4.

Requirements Related to Substance Use

+ Massachusetts does not appear to have requirements related to substance use, although the prior authorization form requires providers to state whether individuals currently have a substance use disorder, and if so, whether they are currently enrolled in a support program.

HIV Co-Infection Criteria

+ Massachusetts does not appear to have any particular criteria for HIV co-infection.

Prescriber Limitations

+ Massachusetts does not appear to have any prescriber limitations.

Additional Adherence Requirements

+ Massachusetts does not appear to have any additional adherence requirements.

Managed Care

Each of the MassHealth MCOs covers Sovaldi through its formulary, with each requiring prior authorization. The four plans whose criteria are available for viewing have similar requirements, each of which are much stricter than the MassHealth fee-for-service requirements.[77] Each requires that a prescription be written by a gastroenterologist, hepatologist, or infectious disease specialist. All except Network Health require fibrosis at a Metavir level of F3 or F4 (or alternative measures of equivalent liver damage), although HealthNet permits authorization if, alternatively, the patient is co-infected with HIV.[78] Network Health only requires fibrosis in patients with HCV genotype 1.[79] Each has some type of substance use requirement requiring abstinence for 6 months, with Health New England having the strictest requirements, but only for "known abusers:" 6 months sobriety, referral to addiction specialist, ongoing participation in formal treatment, and having an adequate support network.[80] (See page 26 for more information).

MassHealth Managed Care Organizations: Prior Authorization Requirements for Sovaldi

	Boston Med. Ctr. Health Net Plan[81]	Neighborhood Health Plan[82]	Tufts Health Plan Network Health[83]	Health New England[84]
Fibrosis Criteria	Presence of cirrhosis or fibrosis stage 3 or above; OR HIV co-infection; OR urgency due to extra-hepatic complications or need for hepatotoxic treatment/ immunosuppression	Metavir stage F3-4 or FibroScan > 11 kPa; OR two blood tests (e.g., FibroTest >0.75; APRI >2.0); OR severe extra-hepatic symptoms	For genotypes 2, 3, 4: chronic liver disease (any stage of fibrosis) OR serologic evidence of persistent infection For genotype 1: Stage 3 or 4 fibrosis (shown by any of: Metavir F3 or F4; FibroScan ≥9.5 kPa; FibroSURE ≥0.58; APRI ≥1.5; evidence of cirrhosis)	Current (within 6 weeks) HCV RNA test; liver disease indicated by one of: Metavir F4 (F2 for genotype 2 and 3), Ishak 5 or 6 (4-6 for genotype 2 or 3), FibroScan >12.5; ARFI >1.75; serum markers of fibrosis
Requirements Related to Substance Use	Member has not abused illicit substances, narcotics, or alcohol for at least 6 months	For members with past or current issues with alcohol abuse or substance use: abstinence from injection drug use and/ or excessive alcohol use for 6 months and participation in supportive care	No illicit substance or alcohol abuse within past 6 months; or receiving counseling services/seeing addiction specialist	Individuals who are known abusers of alcohol (AUDIT C Score >8) or illicit substances must have: been referred to an addiction specialist; abstinence of alcohol abuse or illicit substances for at least 6 months; ongoing participation in a formal treatment program; and presence of adequate psychosocial supports as determined by social service and psychiatry consultants
HIV Co-Infection Criteria	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
Prescriber Limitations	Prescribed by or in collaboration with gastroenterologist, hepatologist, or ID specialist	Prescribed by or in consultation with a GI specialist, hepatologist, or ID specialist	Prescribed by gastroenterologist, hepatologist, or ID specialist	Prescribed by gastroenterologist, hepatologist, or ID specialist
Additional Adherence Requirements	No history of nonadherence; no history of treatment failure with prior HCV treatment due to 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

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS:

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New York

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

New York

Hepatitis C Virus (HCV) in New York

Prevalence

+ Between 2001 and 2009, 175,785 cases of chronic hepatitis C (HCV) were reported in New York State.[85]

HIV Co-Infection

+ It is estimated that as of 2000 there were 23,900 persons co-infected with HCV and HIV.[86]

Yearly Reported Cases

+ In 2013, there were 12,344 cases of HCV reported in the state.[87]

Age Breakdown

+ Between 2001 and 2009, 66% of all cases affected people between the ages of 40 and 60.[88] During this time, a shift in age distribution occurred, as cases in those aged between 25 and 35 years increased relative to other age groups.[89]

Deaths

+ Within New York City, between 2000 and 2011, 13,307 HCV mono-infected individuals and 5,475 HCV/HIV co-infected individuals died.[90] 64.1% of the mono-infected deaths and 94% of the co-infected deaths were categorized as premature—compared to 25.3% of deaths in non-infected individuals.[91]
+ The death rate from HCV in New York City was approximately 8.0 per 100,000 in 2011,[92] giving an estimated death toll in the city for the year of between 650 and 700 people.

State HCV Programs in New York

New York has made several moves to combat HCV. Beginning in 2014, hospitals and other health service providers are required by law to offer HCV testing to all patients born between 1945 and 1965.[93] The New York City Department of Health and Mental Hygiene recently created a program called "Check Hep C," which seeks to detect HCV in individuals who may not know they are infected and link such individuals to care and treatment services.[94] The program operates at 12 community sites and tested 4,500 people in its first year of operation. The state Department of Health also operates the Hepatitis C Continuity Program, which assists prison inmates in ensuring continuation of HCV care after their release.[95]

Medicaid in New York

Eligibility

New York is a Medicaid expansion state.[96] Adults with incomes at or below 138% of the Federal Poverty Level (FPL) (about $16,105/year) are eligible, with slightly higher income levels for pregnant women and children.[97] As of September 2014, there were 6,107,337 eligible beneficiaries for Medicaid in New York.[98] Approximately 1.5% of beneficiaries—a total of 94,138—had a known diagnosis of HCV.[99] Of those, 24.3% (14,070) were co-infected with HIV.[100]

Care Delivery

In New York, as in most states, the majority of individuals are required to enroll in Medicaid managed care organizations (MCOs).[101] Most Medicaid-eligible New Yorkers must enroll in an MCO rather than fee-for-service Medicaid. Some groups may choose between fee for service and an MCO, including people in long-term residential programs and Native Americans.[102] Other groups may only enroll in fee for service. These include people in nursing homes at the time of their enrollment, spend-down cases, and those with other full-benefits health insurance.[103]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

For individuals enrolled in fee for service, New York's Drug Utilization Review Board (DURB) sets the standards for covered drugs, including drug formulary and any associated prior authorization requirements.[104] The board meets "as often as necessary" to carry out its responsibilities,[105] which in both 2013 and 2014 has meant once every quarter.[106] In September 2014, the state Department of Health proposed new guidelines for restricting access to Sovaldi for Medicaid beneficiaries.[107] A recent edition of the New York State Medicaid Update implements some of these recommendations, and indicates that other recommendations made by the DURB at the September meeting will be implemented at a future date."[108] According to the notice, in order to receive approval for Sovaldi, the following criteria must currently be met (note that additional criteria in other categories may also be required).[109]

Fibrosis Criteria:

+ Individuals will be required to have one of the following:
  - › Evidence of stage 3 or stage 4 hepatic fibrosis including one of the following:
    - Liver biopsy confirming a Metavir score of F3 or F4; or
    - Transient elastography (FibroScan®) score greater than or equal to 9.5 kPa
    - OR FibroSURE® score of greater than or equal to 0.58; or
    - APRI score greater than 1.5; or
    - Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension); or
  - › Evidence of extra-hepatic manifestation of hepatitis C, such as type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis), or kidney disease (e.g., proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis). Documentation of the presence of extra-hepatic manifestations based on lab results or imaging results (e.g., CBC, erythrocyte sedimentation rate (ESR)/ C-reactive protein (CRP), urinalysis, BUN/ creatinine and angiography) must be submitted; or
  - › Liver transplant; or
  - › HIV-1 co-infection; or
  - › HBV co-infection; or
  - › Other coexistent liver disease (e.g. nonalcoholic steatohepatitis); or
  - › Type 2 diabetes mellitus (insulin resistant); or
  - › Porphyria cutanea tarda; or
  - › Debilitating fatigue impacting quality of life (e.g. secondary to extra-hepatic manifestations and/or liver disease).

Restrictions Related to Substance Use

+ One of the clinical criteria listed is patient readiness and adherence, which requires evaluation by using scales or assessment tools readily available to healthcare practitioners at: http://www.integration.samhsa.gov/clinical-practice/screening-tools or https://prepc.org/ to determine a patient's readiness to initiate HCV treatment (specifically drug and alcohol abuse potential).[110]

HIV Co-Infection Criteria

+ It appears that individuals co-infected with HIV can bypass requirements related to fibrosis criteria per the clinical criteria.
+ The PA form also asks whether co-infected individuals have had an undetectable viral load for 6 months.[111]

Prescriber Limitations

+ Medications must be prescribed by a hepatologist, gastroenterologist, infectious disease specialist, transplant physician, or a healthcare practitioner experienced and trained in treatment of hepatitis C; or a healthcare practitioner under the direct supervision of a listed specialist.
  - › Clinical experience is defined as the management at least 20 patients with HCV infection and treatment of 10 HCV patients in the last 12 months and at least 10 HCV-related CME credits in the last 12 months; or
  - › Management and treatment of HCV infection in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria.

Additional Adherence Requirements

+ In addition, the PA form asks whether the patient demonstrated treatment readiness, including the ability to adhere to the prescribed treatment regimen.[112]

Medicaid Managed Care

Medicaid MCOs in New York do not have to cover the exact same drugs as the fee-for-service program.[113] As a result, seven out of 17 MCOs do not appear to cover Sovaldi on their formularies.[114] As well, each MCO has its own medical review board (or equivalent) that sets criteria with respect to medical necessity and prior authorization requirements, and as a result, prior authorization criteria for plans that do cover Sovaldi vary greatly. The most generous plans have requirements that parallel the proposed fee-for-service regulations, while some plans have extremely restrictive substance abuse requirements or limited qualifying conditions. (See page 31 for more information).

New York Medicaid Fee for Service and Select Medicaid Managed Care Organizations: Prior Authorization Requirements for Sovaldi

	Fee for Service (proposed)[115]	Excellus[116]	United Healthcare[117]	WellCare[118]	MetroPlus[119]	HealthNow NY[120]
Region(s) served	All	Central, Northeast, Western	Central, Hudson Valley, Long Island, NYC	Hudson Valley, NYC, Northeast	NYC	Western
Fibrosis Requirements	Any of: Stage 3 or 4 fibrosis, HBV co-infection, co-existent liver disease, Type 2 diabetes mellitus, HIV co-infection, porphyria cutanea tarda, prior liver transplant, debilitating fatigue; certain extra-hepatic manifestations	Any of: Stage 3 or 4 fibrosis, HBV co-infection, co-existent liver disease, Type 2 diabetes mellitus, HIV co-infection, porphyria cutanea tarda, prior liver transplant, debilitating fatigue; certain extra-hepatic manifestations	Any of: Stage 3 or 4 fibrosis, prior liver transplant, certain serious extra-hepatic manifestations, HIV co-infection	Stage 3 or 4 fibrosis	Stage 3 or 4 fibrosis OR hepatic carcinoma(s) awaiting liver transplant	Any of: Stage 3 or 4 fibrosis, prior liver transplant, certain extra-hepatic manifestations
Requirements Related to Substance Use	Evaluation by using scales or assessment tools readily available to healthcare practitioners at: http://www.integration.samhsa.gov/clinical-practice/screening-tools or https://prepc.org/ to determine a patient's readiness to initiate treatment (specifically drug and alcohol abuse potential)	Individuals with a history of substance abuse disorder (IV drug user or chronic alcoholic) must be abstinent for 3 months	For individuals with a known prior history of illicit drug abuse or alcohol abuse, abstinence for previous 6 months and negative urine sample within 30 days prior	All individuals should be evaluated for current alcohol and other substance use, and must be drug and/or alcohol free prior to treatment and not have ongoing alcohol or illicit drug use (as evidenced by documentation in the medical record); if history of abuse: individual must: (1) be actively participating in a substance or alcohol abuse program (including relapse prevention); and provide ongoing documentation of attendance and, (2) pass a urine drug screening and/or blood alcohol level, 30 days prior to treatment, and random screening throughout treatment (positive results may cause disqualification) and (3) prior to authorization, attend 90 meetings in 90 days through a program such as Narcotics Anonymous or Alcoholics Anonymous; Suboxone or Methadone may be required as part of treatment plan.	No history of alcohol or drug abuse within the past 6 months	None listed
HIV Co-Infection Criteria	Appears to require no detectable viral load for previous 6 months	No detectable viral load for previous 6 months	None listed	None listed (not a qualifying condition)	None listed (not a qualifying condition)	None listed (not a qualifying condition)
Prescriber Limitations	By: gastroenterologist, hepatologist, infectious disease specialist, transplant physician; OR by PCP with HCV training; OR in conjunction with one of above specialists	By: gastroenterologist, hepatologist, infectious disease specialist, HIV/HCV specialist; OR by PCP with HCV training; OR in conjunction with one of above specialists	By: gastroenterologist, hepatologist, or infectious disease specialist	By or in consultation with gastroenterologist, hepatologist, or infectious disease specialist	By: gastroenterologist, hepatologist, oncologist, or infectious disease specialist	By: gastroenterologist, hepatologist, infectious disease specialist, or "pertinent specialist"
Additional Adherence Requirements	"Patient has demonstrated treatment readiness and ability to adhere to drug regimen"	"Must demonstrate treatment readiness and ability to adhere to drug regimen."	None listed	None listed	None listed	None listed

EXAMINING HEPATITIS C VIRUS
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North Carolina

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North Carolina

Hepatitis C Virus (HCV) in North Carolina

Prevalence

+ There are an estimated 150,000 individuals living with hepatitis C virus (HCV) in North Carolina, of whom over 100,000 are chronically infected.[121]

HIV Co-Infection

+ Data unavailable

Yearly Reported Cases[122]

+ Data unavailable

Age Breakdown

+ Data unavailable

Deaths

+ Data unavailable

State HCV Programs in North Carolina

North Carolina offers HCV testing, counseling, linkage to care, and referral services at sites throughout the state as part of integrated services for HIV and sexually transmitted infections (STI).[123] North Carolina also participates in the *One and Only Campaign*, a program led by the CDC to raise awareness among patients and doctors about safe injection practices.[124]

Medicaid in North Carolina

Eligibility

North Carolina has chosen to not expand Medicaid, which means that only low-income individuals who also meet categorical requirements (such as being the parent of a child or being disabled) are eligible. In general, in order to qualify, parents of children must have an income of less than about 44% of the federal poverty level (FPL) ($6,828/year for a family of two),[125] with higher income thresholds for pregnant women and children. Aged, blind, or disabled individuals must have incomes less than about 100% FPL ($11,676/year for an individual).[126]

Care Delivery

Most North Carolina Medicaid enrollees are required to participate in a primary care case management program, Carolina ACCESS (CA), and/or Community Care of North Carolina (CCNC) (an enhanced case management program).[127] Within this system, medical providers are paid a fee for service and primary care providers participating in a network are provided a management fee, as is the network in which the provider is enrolled.[128] Some Medicaid enrollees may request an exemption from participating in CCNC/CA.[129]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

The North Carolina Medicaid Preferred Drug List Review Panel meets periodically throughout the year to discuss recommended policies and procedures related to the Medicaid preferred drug list.[130] In general, these criteria are followed for all North Carolina Medicaid enrollees (whether enrolled in CA or CCNC or otherwise). While Sovaldi is not currently listed as either preferred or non-preferred, there are particular prior authorization criteria that apply.[131] In particular, in order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[132]

Fibrosis Criteria

+ North Carolina does not appear to have any specific criteria with respect to fibrosis.

Requirements Related to Substance Use

+ For individuals with a history of alcohol abuse, a commitment to abstinence is required, and for individuals with a recent history of alcohol abuse (within the past year), enrollment in counseling or an active support group is also required.
+ It is not clear what a "commitment to abstinence" means, although individuals must agree to toxicology and/or alcohol screens as needed.

HIV Co-Infection Criteria

+ North Carolina does not appear to have any specific criteria with respect to HIV co-infection.

Prescriber Limitations

+ North Carolina does not appear to have any specific prescriber limitations.

Additional Adherence Requirements

+ North Carolina does not appear to have any additional adherence requirements.

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Oregon

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Oregon

Hepatitis C Virus (HCV) in Oregon[133]

Prevalence

+ As of September 2014, 47,435 persons in Oregon have been reported as having hepatitis C virus (HCV) infections. Because it is estimated that half of all HCV infections go unreported, the actual number of Oregonians living with HCV could be closer to 95,000.

HIV Co-Infection

+ Approximately 15% of individuals living with HIV in Oregon have ever been co-infected with HCV.[134]

Yearly Reported Cases

+ An average of 5,151 reports of chronic infection were reported every year from 2009 to 2013.

Age Breakdown

+ Nearly two-thirds of newly reported chronic HCV infections over the past 5 years have affected individuals born between 1945 and 1965.[135] However, the largest increase in infection rates over that time period occurred in those under the age of 30, who saw infection rates increase while the population as a whole saw infection rates decrease.

Deaths

+ Approximately 400 people have died every year from HCV in the past 5 years in Oregon.[136]

State HCV Programs in Oregon[137]

The Oregon state public health authority provides viral hepatitis workshops to increase awareness, screening, prevention, and care. Funds from the Centers for Disease Control and Prevention (CDC) also support projects to improve screening and linkage to care.

Medicaid in Oregon

Eligibility

In addition to covering categorically needy populations, Oregon has also elected to expand Medicaid coverage.[138] All eligible adults earning 138% of the federal poverty level (about $16,105/year) or under are eligible for Medicaid, regardless of whether they meet other categorical requirements, with slightly higher income limits for infants and pregnant women.[139] Approximately 5,600 Oregon Health Plan (OHP) patients have been diagnosed with HCV, and it is estimated that an additional 13,000 have the disease but have not been diagnosed.[140]

Care Delivery

Sixteen coordinated care organizations (CCOs) provide care for most OHP members.[141] These CCOs are geographically based and many areas are only served by one CCO.[142] OHP members in areas with multiple CCOs may choose which CCO to enroll in.[143] Dual-eligibles (members who are eligible both for Medicare and Medicaid) may choose not to enroll in a CCO and remain in fee-for-service OHP.[144]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

Drug coverage for OHP is determined by the Pharmacy and Therapeutics Committee, which consists of 11 members and meets every other month.[145] Although Sovaldi is listed as a preferred drug, Oregon requires that certain prior authorization requirements be met for patients seeking treatment.[146] In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[147]

Fibrosis Criteria

Oregon's fee-for-service prior authorization criteria are organized based on a series of questions with respect to fibrosis and/or other serious conditions that indicate the following:

+ Individuals must:
  - Have a biopsy or other non-invasive technology (FibroScan®), including serum tests (FibroSURE®, FibroTest®) to indicate severe fibrosis (stage 4); or
  - Have radiologic, laboratory, or clinical evidence of cirrhosis without ongoing progressive decompensation (MELD score between 8 and 11), and an expected survival from non-HCV associated morbidity greater than 5 years.
+ If those criteria are not present, the form asks whether individuals have one of the following extra-hepatic manifestations of HCV and have formal documentation from a relevant specialist that their condition is HCV related, and an expected survival from non-HCV associated morbidity greater than 5 years:
  - Vasculitis
  - Glomerulonephritis
  - Cryoglobulinemia
  - Lymphoma
+ If those criteria are not present, the form asks whether the individual has HIV co-infection with cirrhosis (stage 4 disease), and an expected survival from non-HCV associated morbidity greater than 5 years; and if so, whether the individual is under the care of an HIV specialist.
+ The final question asks whether the individual has HCV in the transplant setting, including the following scenarios:
  - Individual is listed for a transplant and it is essential to prevent recurrent HCV infection post-transplant
  - Post-transplant patients with stage 4 fibrosis
  - Post-transplant patients with fibrosing cholestatic hepatitis due to HCV infection
+ In each of these cases, expected survival from non-HCV associated morbidity should be greater than 5 years.

Substance Use Requirements

+ Individuals must have been abstinent from IV drugs, illicit drugs and marijuana use, and alcohol abuse for a period greater than 6 months.

HIV Co-Infection Criteria

+ There do not appear to be any specific criteria with respect to HIV, except that if criteria are not met with respect to fibrosis, the prior authorization form asks whether an individual is co-infected with cirrhosis (stage 4 disease); and if so, requires that they be in the care of an HIV specialist.
+ It is not clear whether co-infected individuals who meet other fibrosis requirements (i.e., evidence of the specific extra-hepatic manifestations of HCV as described) pursuant to the first few questions of the form must also meet this requirement related to cirrhosis and HIV specialty care.

Prescriber Limitations

+ Treatment must be prescribed by, or in consultation with, a hepatologist or gastroenterologist with experience in HCV.

Additional Adherence Requirements

+ Oregon does not appear to have any additional requirements related to adherence.

Coordinated Care Organizations

All CCOs must provide at least the same quality of benefits as fee-for-service OHP, but are permitted to create their own formularies and prior authorization requirements pursuant to certain guidelines.[148] Among the five plans we examined, Yamhill, Columbia Pacific, and Cascade Health Alliance generally followed the same criteria as the fee-for-service plan, except that all three allowed an exception to the abstinence requirement if the individual was enrolled in treatment, and all three require consultation specifically with a hepatologist. Trillium Community Health Plan also had similar guidelines as the fee-for-service program, except that it allows for treatment of individuals with fibrosis stage F3 and F4. Finally, the Family Care Program did not appear to have any specific prior authorization requirements. (See page 39 for more information).

Oregon Medicaid Fee for Service and Select Medicaid Managed Care Organizations: Prior Authorization Requirements for Sovaldi

	Oregon Health Plan Fee for Service[149]	Trillium Community Health Plan[150]	Family Care[151]	CareOregon CCOs (includes Yamhill Community Care Organization, Columbia Pacific CCO, Jackson Care Connect, and Health Share of Oregon)[152]
Fibrosis Requirements	Fibrosis stage F4 or certain extra-hepatic manifestations or transplant patient with danger of relapse post-transplant	Fibrosis stage F3 or F4	Chronic HCV infection confirmed by presence of HCV RNA	Individual must meet one of the following clinical scenarios and be expected to live at least 5 years from non-HCV associated morbidities: • Specific (identified in the form) extra-hepatic manifestations of hepatitis C infection • Cirrhotic (stage 4) patients without ongoing progressive decompensation • HCV in the transplant setting • HCV/HIV co-infection with cirrhosis (stage 4 infection)
Requirements Related to Substance Use	Abstinence for 6 months from alcohol abuse, marijuana use, and IV drug use	Abstinence for 6 months from IV drug use and alcohol abuse	None listed	Individual must be abstinent from drug and alcohol abuse (> 1 per day for women or >2 per day for men) for at least 6 months or enrolled in a substance abuse recovery program
HIV Co-infection Criteria	Form inquires whether individual is co-infected with cirrhosis and if so, under supervision of HIV specialist	None listed	None listed	Form asks about HCV/HIV co-infection with cirrhosis (stage 4 infection)
Prescriber Limitations	Must be prescribed by or in consultation with hepatologist or gastroenterologist with experience in HCV	Therapy initiated by gastroenterologist, infectious disease specialist, or physician who specializes in hepatitis	No requirements listed	Treatment must be performed by, under the supervision of, or with consultation of a board-certified, licensed hepatologist
Additional Adherence Requirements	None listed	No documented non-compliance with prior meds or medical treatment; must commit to scheduled follow-up and monitoring	None listed	Prior authorization form asks if there are any signs the member lacks the necessary behavioral/social support to be successful on treatment, such as evidence of significant non-compliance with office visits or medication adherence; if yes, plan must consult with prescriber on concerns if treatment should continue.

EXAMINING HEPATITIS C VIRUS TREATMENT ACCESS:
A REVIEW OF SELECT STATE MEDICAID FEE-FOR-SERVICE AND MANAGED CARE PROGRAMS

Pennsylvania

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

Pennsylvania

Hepatitis C Virus (HCV) in Pennsylvania

Prevalence

+ Although state-wide data were unavailable, there are approximately 47,207 individuals living with hepatitis C virus (HCV) in Philadelphia alone.[153]

HIV Co-Infection

+ Data unavailable

Yearly Reported Cases

+ In 2012, 9,747 cases of HCV were reported to The Centers for Disease Control and Prevention (CDC) from Pennsylvania.[154]

Age Breakdown

+ The number of newly reported HCV infections among individuals ages 15 to 34 nearly doubled from 2003 to 2010, from 1,384 to 2,393.[155]

Deaths

+ Data unavailable

State HCV Programs in Pennsylvania[156]

The CDC provides financial support to a local health department to integrate viral hepatitis prevention activities into existing public health programs. In addition, the CDC provides support to a project to improve viral hepatitis screening and linkage to care, and an education and training provider in Pennsylvania.

Medicaid in Pennsylvania

Eligibility

In Pennsylvania, only low-income individuals who also meet traditional categorical requirements (such as being the parent of a child or being disabled) are eligible. In general, in order to qualify, parents of children must have an income of less than 33% of the federal poverty level (FPL) ($5,191/year for a family of two), with higher income thresholds for pregnant women and children.[157] Aged, blind, or disabled individuals must have incomes less than about 74% of FPL ($8,917/year for an individual).[158]

However, Pennsylvania has recently decided to expand its Medicaid coverage beginning January 1, 2015, through implementation of a Private Coverage Option (PCO). The expansion program, known as *Healthy Pennsylvania,* will be available to all adults who were not eligible for Pennsylvania's existing Medicaid plan and who make less than 138% FPL (about $16,105 per year for an individual).[159] Those eligible for the PCO will be offered the choice of at least two commercial health plans offered in their area.[160]

Care Delivery

Currently, most enrollees in Pennsylvania are in mandatory managed care organizations through the Health Choices program. However, there are some counties where Health Choices is not available, and individuals only have access to fee-for-service coverage.[161]

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

Pennsylvania's Pharmacy and Therapeutics Committee sets the standards for Medicaid's prescription drug formulary, including prior authorization criteria, and meets a few times per year. Sovaldi is listed as a preferred drug, but requires prior authorization.[162] In general, in order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[163]

Fibrosis Criteria

+ Individuals must have a Metavir fibrosis score of F3 or F4 documented by either a non-invasive test like a blood test depicting liver fibrosis or an invasive test like a liver biopsy.

Requirements Related to Substance Use

+ Individuals must have a documented history of a pattern of abstinence from alcohol and drugs for at least 6 months prior to treatment.
+ It is not clear what is needed to demonstrate a "documented history of a pattern of abstinence," but individuals with a history of substance dependence must also have a lab test (such as blood alcohol level (BAL) and urine drug screen (UDS) that support abstinence, and be compliant with treatment if currently being treated for substance dependence.

HIV Co-Infection Criteria

+ Pennsylvania does not appear to have specific criteria with respect to treatment of individuals who are co-infected with HIV.

Prescriber Limitations

+ The medication must be prescribed by an infectious disease, gastroenterology, hepatology, or transplant specialist.

Additional Adherence Criteria

+ Pennsylvania does not appear to have additional adherence criteria.

Note that Pennsylvania's criteria also specifies that if a prior authorization request is made for an individual who does not meet the clinical review guidelines, treatment may still be approved if, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

Managed Care

In Pennsylvania, Medicaid managed care plans generally set their own formularies and prior authorization criteria. Of the four plans examined, all had criteria very similar to that of the fee-for-service program. The only exception was the Gateway Health Plan, which requires a period of 12 months of abstinence as compared to 6 months in the other plans (all other criteria were similar). Three plans, Geisinger Family Health Plan, Keystone Health, and Amerihealth Northeast, did not appear to cover Sovaldi at all.[164] (See page 43 for more information).

Pennsylvania Medicaid Fee for Service and Select Medicaid Managed Care Organizations: Prior Authorization Requirements for Sovaldi

	Medicaid Fee for Service	UPMC Health Plan[165] (PA form only; no specific criteria available)	United Healthcare Community & State[166]	Aetna Better Health[167]	Gateway Health[168] (non-formulary)
Fibrosis Criteria	Has Metavir score of F3 or F4, documented by a recent noninvasive test such as a blood test showing liver fibrosis or an invasive test like a liver biopsy	Form asks if patient has advanced fibrosis or decompensated cirrhosis, but criteria for evaluation are not clear	Evidence of stage 3 or 4 fibrosis, including one of: liver biopsy confirming Metavir F3 or F4, FibroScan ≥9.5, FibroTest ≥ 0.58, APRI >1.5, radiology consistent with cirrhosis, prescribing physician attestation of clinical findings consistent with cirrhosis	Documentation of Metavir F3 or F4 or Metavir ≥2 with serious extra-hepatic manifestations of HCV	Documented liver biopsy or liver fibrosis panel results showing Metavir F3 or F4 or otherwise demonstrating advanced liver fibrosis
Requirements Related to Substance Use	Individual must have a documented history of a pattern of abstinence from alcohol and drugs for at least 6 months prior to treatment If there is a history of substance abuse, must provide lab testing to support abstinence and be compliant with substance dependence treatment, if any	If the individual has a history of substance use, must provide documentation that: (1) the member has not abused drugs in the past three months; (2) of a recent (within three months) urine drug screen, including testing for licit and illicit substances with the potential for abuse; and (3) that the member has been screened for alcohol abuse	If there is a known history of illicit drug or alcohol abuse, must have abstained from abuse for past 6 months AND submit negative urine drug screen collected within 30 days of onset of treatment	Requires documentation to support abstinence from alcohol or illicit drugs for at least 6 months as well as compliance with dependency treatment	No diagnosis of alcohol or substance abuse, or documented history of abstinence for at least 12 months prior to treatment, including adherence to any prescribed substance abuse treatment and pertinent lab testing
HIV Co-Infection Criteria	No severe renal impairment or end stage renal disease	N/A	It appears that individuals who are co-infected with HIV do not otherwise have to meet fibrosis criteria	N/A	Plan states that individuals with HIV who meet applicable criteria are eligible
Prescriber Limitations	Must be prescribed by a GI, ID, hepatologist, or transplant specialist	Prior Authorization form does not specify	Must be prescribed by a GI, ID, or hepatologist	Must be prescribed by, or in consultation with, a GI, ID, hepatologist, transplant specialist, or HIV specialist	Must be prescribed by a GI, ID, hepatologist, or transplant specialist
Additional Adherence Requirements	Fee for service: N/A	N/A	N/A	Documentation of treatment compliance and adherence counseling	Individual must commit in writing to a treatment agreement

EXAMINING HEPATITIS C VIRUS
TREATMENT ACCESS:
A REVIEW OF SELECT STATE MEDICAID FEE-FOR-SERVICE AND MANAGED CARE PROGRAMS

Rhode Island

PREPARED BY THE CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

Rhode Island

Hepatitis C Virus (HCV) in Rhode Island

Prevalence

+ It is estimated that there are between 16,603 and 22,660 individuals living with hepatitis C virus (HCV) in Rhode Island, of whom 12,286 to 16,768 are chronically infected.[169]

HCV/HIV Co-Infection

+ Unavailable

Yearly Reported Cases

+ Reported cases of HCV have significantly increased in recent years, rising from 182 reports in 1992 to 1,962 reports in 2006.[170]

Age Breakdown

+ Most reported cases have been among individuals in the baby-boomer generation.[171]

Deaths

+ Unavailable

State HCV Programs in Rhode Island

Rhode Island provides several HCV services through its Integrated HIV/Viral Hepatitis Counseling, Testing, and Referral System (CTR).[172] CTR works with three funded agencies to provide HCV screening throughout the state.[173] Additionally, the Office of HIV/AIDS & Viral Hepatitis in Rhode Island runs a program called Education, Needle Exchange, Counseling, Outreach, and Referral (ENCORE) to provide an anonymous and confidential needle exchange program that also offers education, counseling, outreach, and referrals for HCV.[174]

Medicaid in Rhode Island

Eligibility

In addition to covering categorically needy populations, Rhode Island has also elected to expand Medicaid coverage. All eligible adults earning 138% of the federal poverty level (about $16,105/year) or under are eligible for Medicaid, regardless of whether they meet other categorical requirements. All individuals who are newly eligible for Medicaid pursuant to the expansion are enrolled in the Rhody Health Partners program.[175] Rhode Island also offers two supplemental Medicaid programs for families with slightly higher income limits: RIte Care, which covers uninsured families, children, and pregnant women, and RIte Share, which covers some portion of health insurance premiums and copays to help families get insurance through their employer.[176]

Care Delivery

Most individuals in Rhode Island Medicaid receive care through one of two managed care plans, Neighborhood Health Plan of Rhode Island or United Health of New England.[177] Some individuals (those who are blind or disabled, and/or other categorically needy populations) may also choose to enroll in the Connect Care Choice primary care case management program and/or fee for service.

Medicaid Coverage of Sofosbuvir (Sovaldi)

Fee for Service

Rhode Island Medicaid's fee for service program follows the criteria for prior authorization of Sovaldi set by the Rhode Island Medicaid Pharmacy and Therapeutics Committee, which meets four times a year to develop formulary and associated prior authorization criteria.[178] Currently, sofosbuvir (Sovaldi) is considered non-preferred.[179] In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).[180]

Fibrosis Criteria

+ Individuals must be diagnosed with stage 3 or 4 hepatic function and/or stage 3 or 4 cirrhosis using at least one of the following methods:
  - AST to Platelet Ratio Index (APRI) greater than or equal to 1.0; or
  - Liver biopsy indicating Metavir score 3 or 4; or
  - FibroScan® score greater than or equal to 9.5kPa; or
  - FibroTest® score greater than or equal to 0.58; or
  - Imaging study consistent with cirrhosis.

Requirements Related to Substance Use

+ Individuals with current or past significant alcohol or intravenous drug use disorder must be abstinent for 6 months prior to treatment; OR
+ Actively participating in a substance abuse treatment program.

Prescriber Limitations

+ The requesting provider must be a gastroenterologist, hepatologist, or infectious disease practitioner;
+ Other physicians may, however, request to be an approved prescriber upon submission of a written request supporting this capability.

HIV Co-Infection Criteria

+ Rhode Island does not appear to have specific criteria with respect to treatment of individuals who are co-infected with HIV.

Additional Adherence Requirements

+ Rhode Island also requires that individuals sign a "patient contract," which among other requirements, provides that failure to complete all required office visits and/or laboratory testing will result in discontinuing the individual's supply of prescription medication.[181] The contract does not need to be submitted with the prior authorization request, but must be kept on file by the provider.

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