



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

Louisiana



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Hepatitis C Virus (HCV) in Louisiana

Prevalence

+ Approximately 80,000 individuals in Louisiana are living with hepatitis C virus (HCV).¹

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 2011.²

Age Breakdown

+ The highest number of reported cases is among individuals ages 45-54.³

Deaths

+ Approximately 120 Louisiana residents are expected to die each year from hepatitis C.⁴

State HCV Programs in Louisiana

The Louisiana State Legislature currently has a Louisiana Commission on HIV, AIDS, and Hepatitis C.⁵ 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.⁶ 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.⁷ Aged, blind, or disabled individuals must have incomes less than 74% FPL (\$8,266/year for an individual).⁸

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.⁹ 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.¹⁰

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.¹¹

Under the PBM Program, Sovaldi is considered a covered drug.¹² As a non-preferred drug, Sovaldi requires certain prior authorization requirements to be met for patients seeking treatment.¹³ In order to receive approval for Sovaldi, the following criteria must be met (note that additional criteria in other categories may also be required).¹⁴

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 fibrosis 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;
- + 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.¹⁵ 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).¹⁶ 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 5 for more information).

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

Fee for Service¹⁷

AmeriHealth Caritas¹⁸

Fibrosis Criteria	<p>The individual must have a diagnosis of</p> <ul style="list-style-type: none"> 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 <p>For genotypes 2 and 3, the individual must have a liver biopsy showing advanced fibrosis or cirrhosis (Ishak stage ≥ 4 or Metavir score ≥ 3; AND</p> <p>The individual must have compensated liver disease (Child-Turcotte-Pugh CTP), Score 6, Class A.</p>	<p>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.</p> <p>The individual must have either Ishak stage > 3 or Metavir Score > 2 or FibroScan score > 12.5 or ARFI score > 1.75.</p>
Requirements Relating to Substance Use	<p>Requires confirmation that the individual has not been actively participating in substance abuse and/or alcohol abuse within the past year;</p> <p>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</p> <p>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.</p>	<p>In the presence of previous substance abuse (including alcohol and prescription drugs); no alcohol or illicit drug use within 6 months of treatment onset.</p> <p>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.</p>
HIV Co-Infection Criteria	<p>Prior authorization form asks whether individual is co-infected.</p>	<p>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/mm³) it may be preferable to delay HCV therapy until CD4 counts increase).</p>
Prescriber Limitations	<p>Specialist only – Hep, GI, or ID</p>	<p>Specialist only – Hep, GI, or ID</p>
Additional Adherence Requirements	<p>Patient must sign HCV Treatment Agreement; missing doses may cause Medicaid to stop paying for treatment; one treatment per lifetime.</p>	<p>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.</p>

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