



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

## New York



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## 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.<sup>1</sup>

### *HIV Co-Infection*

+ It is estimated that as of 2000 there were 23,900 persons co-infected with HCV and HIV.<sup>2</sup>

### *Yearly Reported Cases*

+ In 2013, there were 12,344 cases of HCV reported in the state.<sup>3</sup>

### *Age Breakdown*

+ Between 2001 and 2009, 66% of all cases affected people between the ages of 40 and 60.<sup>4</sup> 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.<sup>5</sup>

### *Deaths*

+ Within New York City, between 2000 and 2011, 13,307 HCV mono-infected individuals and 5,475 HCV/HIV co-infected individuals died.<sup>6</sup> 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.<sup>7</sup>

+ The death rate from HCV in New York City was approximately 8.0 per 100,000 in 2011,<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup>

## Medicaid in New York

### *Eligibility*

New York is a Medicaid expansion state.<sup>12</sup> 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.<sup>13</sup> As of September 2014, there were 6,107,337 eligible beneficiaries for Medicaid in New York.<sup>14</sup> Approximately 1.5% of beneficiaries—a total of 94,138—had a known diagnosis of HCV.<sup>15</sup> Of those, 24.3% (14,070) were co-infected with HIV.<sup>16</sup>

## Care Delivery

In New York, as in most states, the majority of individuals are required to enroll in Medicaid managed care organizations (MCOs).<sup>17</sup> 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.<sup>18</sup> 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.<sup>19</sup>

## 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.<sup>20</sup> The board meets "as often as necessary" to carry out its responsibilities,<sup>21</sup> which in both 2013 and 2014 has meant once every quarter.<sup>22</sup> In September 2014, the state Department of Health proposed new guidelines for restricting access to Sovaldi for Medicaid beneficiaries.<sup>23</sup> 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."<sup>24</sup> 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).<sup>25</sup>

### 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<sup>®</sup>) score greater than or equal to 9.5 kPa
    - OR FibroSURE<sup>®</sup> 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).<sup>26</sup>

### ***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.<sup>27</sup>

### ***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.<sup>28</sup>

## **Medicaid Managed Care**

Medicaid MCOs in New York do not have to cover the exact same drugs as the fee-for-service program.<sup>29</sup> As a result, seven out of 17 MCOs do not appear to cover Sovaldi on their formularies.<sup>30</sup> 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 5 for more information).

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

		Fee for Service (proposed) <sup>31</sup>		Excellus <sup>32</sup>		United Healthcare <sup>33</sup>		WellCare <sup>34</sup>		MetroPlus <sup>35</sup>		HealthNow NY <sup>36</sup>	
Region(s) served	All	Central, Northeast, Western	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, HBV co-infection, co-existent liver disease, Type 2 diabetes mellitus, HIV co-infection	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 carcinomata(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: <a href="http://www.integration.sam.hsa.gov/clinical-practice/screening-tools">http://www.integration.sam.hsa.gov/clinical-practice/screening-tools</a> or <a href="https://prepc.org/">https://prepc.org/</a> 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	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)	None listed (not a qualifying condition)						
Prescriber Limitations	By: gastroenterologist, hepatologist, infectious disease specialist; 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	None listed						

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