Expanding Access to Life-Saving Hepatitis C Treatment by Removing Discriminatory Sobriety Restrictions

By Sinead Hunt

Roosevelt @ Columbia University

THESIS

To expand access to direct-acting antivirals (DAAs) for people with hepatitis C who inject recreational drugs, the New York State Department of Health Drug Utilization Review Board should eliminate the state Medicaid pharmacy program's sobriety restrictions, thereby saving lives and reducing costs.

BACKGROUND & ANALYSIS

Hepatitis C Virus infection (HCV) is the most common chronic bloodborne infection in the US.[1,2] Left untreated, it can lead to cirrhosis, liver cancer, and death.[3] HCV disproportionately affects historically marginalized populations, including people who are homeless,[4] who are incarcerated,[5] or who inject drugs.[6] An estimated 70 percent of the more than 200,000 HCV-infected New Yorkers are people who inject drugs.[7,8]

Direct-acting antivirals (DAAs) are promising new drugs that target the specific proteins of the hepatitis C virus to disrupt its replication.[9] Because these medications boast cure rates of higher than 90 percent,[10] they have been hailed as a cure for hepatitis C.[11] Unfortunately, DAAs currently available to patients are prohibitively expensive—they can cost between $54,600–$94,500 per 8-to-12-week cycle.[12] Exorbitant DAA prices have caused many state Medicaid programs to limit the availability of these drugs through a variety of bureaucratic restrictions. Currently, New York State's Medicaid program impedes many New Yorkers from accessing these life-saving medications by employing sobriety restrictions.[13] The state's Medicaid Fee-For-Service (FFS) pharmacy program requires screening for substance and alcohol use to determine "treatment readiness,"[14,15] and five major Medicaid managed-care organizations likewise employ sobriety restrictions.[16] Proponents of these restrictions argue that users of recreational injection drugs should be excluded from antiviral therapy because they are unlikely to adhere to treatment.[17] In reality, mounting evidence demonstrates that sobriety is a poor indicator of psychosocial treatment readiness, and that when people who inject drugs are provided with adequate social support, they are just as likely to adhere to DAA treatment regimens as their abstinent counterparts.[18,19] According to official guidance provided by the Centers for Medicare & Medicaid Services,[20] by "imposing conditions for coverage that may unreasonably restrict access to these drugs," New York's use of sobriety restrictions violates the statutory requirements of section 1927 of the Social Security Act.[21] These sobriety restrictions serve to unreasonably curtail access to life-saving medication for people who inject drugs.

TALKING POINTS

- The sobriety restrictions included in the New York State Department of Health's Chronic Hepatitis C Infection Check List for Prior Authorization Requests unfairly preclude people who inject drugs—who comprise a majority of HCV patients—from accessing treatment.[22]
- Sobriety is a poor indicator of "treatment readiness"; people who inject drugs are just as likely to adhere to direct-acting antivirals (DAA) therapy when provided with appropriate social supports.[23]
- Though HCV DAAs may seem prohibitively expensive, they are, in fact, cost-saving when compared to the existing standard-of-care treatment (i.e., interferon therapy)[24,25] or the high costs associated with cirrhosis, liver failure, and other complications that develop from untreated HCV.[26]
- Removing sobriety restrictions would expand access to treatment for hundreds of thousands of New Yorkers and save money in the long run.

THE POLICY IDEA

To expand access to DAAs, the New York State Department of Health Medicaid Drug Utilization Review Board should abolish sobriety restrictions for the Medicaid FFS pharmacy program. In addition, it should collaborate with managed-care organizations to ensure that DAA prior authorization procedures are consistent across FFS and managed-care pharmacy benefits.

KEY FACTS

- 70 percent of New Yorkers living with HCV are people who inject drugs (PWID).[42]
- The five HCV DAAs currently available to patients are prohibitively expensive and can cost between $54,600–$94,500 per 8-to-12-week cycle.[43]
- 35 percent of Medicaid recipients with hepatitis C are routinely denied coverage for their prescription treatment.[44]

POLICY ANALYSIS

Thirteen states have already removed sobriety requirements from DAA prescribing guidelines, and several states, including New Mexico, Michigan, and Virginia, specify that a patient cannot be denied treatment for the sole reason of substance use.[27] New York should not only abolish all sobriety restrictions, but also make it explicitly clear that physicians cannot unreasonably exclude injection drug users from antiviral therapy.

Some argue that, because people who inject drugs are unlikely to adhere to treatment, providing them with DAAs is an inefficient use of public funds. However, there is a growing body of evidence that people who inject drugs are just as likely to adhere to treatment when they are provided with appropriate social supports.[28] Moreover, because people who inject drugs constitute 70 percent of HCV-infected Medicaid recipients,[29,30,31] the use of sobriety restrictions impedes the majority of hepatitis C patients from getting the lifesaving treatment that they need. Without access to appropriate treatment, these individuals may develop serious health complications that will require even greater healthcare expenditures (i.e., liver transplantation).[32]

Seventy-six percent of state Medicaid hepatitis C patients receive treatment through managed-care organizations, not the Medicaid FFS pharmacy program.[33] Therefore, any proposed effort to amend Medicaid prescribing guidelines for DAAs must be enforced among managed-care organizations. Prior attempts by activist groups to reform restrictive DAA prescribing guidelines demonstrate that if standardized DAA authorization criteria are not enforced across FFS and managed-care organizations, such reforms are, at best, symbolic.[34] Transparency and enforcement across managed-care organizations will ensure DAA coverage parity across both FFS and managed-care programs.[35]

Expanding access to antiviral therapy would actually reduce healthcare expenditures by averting HCV-induced liver disease. Liver cirrhosis accounts for more than two-thirds of the $4.3 billion to $8.3 billion spent annually caring for people with hepatitis C.[36] Thus, by decreasing the incidence of severe liver disease, DAAs actually reduce the lifetime treatment costs associated with hepatitis C. The societal value of antiviral therapy—$197,574 per person[37]—far exceeds its sticker price.

NEXT STEPS

Implementing this proposal would require approval from the New York State Department of Health Medicaid Drug Utilization Review Board, which is charged with establishing clinical standards for the State's Medicaid pharmacy program.[38] One potential ally in this process is Voices Of Community Activists & Leaders (VOCAL-NY), a statewide grassroots organization that advocates for low-income people affected by blood-borne illnesses, including hepatitis C.[39] Because VOCAL-NY has experience effectively advocating for the board to reform its DAA prescribing guidelines, it would be an invaluable partner throughout this process.[40] I will organize VOCAL-NY members and students to testify before the Drug Utilization Review Board during the 90-minute public comment period at the beginning of its next meeting. Through personal testimony and rigorously established objective evidence, I aim to engender a dialogue about this issue among members of the board. I will also collaborate with VOCAL-NY to launch a social media campaign highlighting the lived experiences of HCV-infected New Yorkers personally affected by discriminatory sobriety restrictions. This social media campaign will serve to illustrate the substantive impact that authorization requirements have on the lives of New Yorkers.

In addition, ensuring DAA coverage parity across FFS and managed-care providers would require the cooperation of the state Department of Health Office of Insurance Program's Hepatitis C Workgroup, which was first convened in 2014 to "develop standardized [DAA authorization] criteria to be used across FFS and managed care."[41]

ENDNOTES

1. Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The Prevalence of Hepatitis C Virus Infection in the United States, 1999 through 2002. *Ann Intern Med* (2006) May 16;144(10):705-14.

2. Chen SL, Morgan TR. The Natural History of Hepatitis C Virus (HCV) Infection. *Int J Med Sci* (2006) 3(2):47-52.

3. "Hepatitis C." HHS.gov. April 10, 2018. Accessed November 03, 2018. https://www.hhs.gov/opa/reproductive-health/fact-sheets/sexually-transmitted-diseases/hepatitis-c/index.html.

4. Nyamathi, Adeline M., Elizabeth L. Dixon, Wendie Robbins, Cynthia Smith, Dorothy Wiley, Barbara Leake, Douglas Longshore, and Lillian Gelberg. "Risk Factors for Hepatitis C Virus Infection among Homeless Adults." *Journal of General Internal Medicine* 17, no. 2 (2002): 134-43. doi:10.1046/j.1525-1497.2002.10415.x.

5. Hammett, Theodore M., Mary Patricia Harmon, and William Rhodes. "The Burden of Infectious Disease Among Inmates of and Releasees From US Correctional Facilities, 1997." *American Journal of Public Health* 92, no. 11 (2002): 1789-794. doi:10.2105/ajph.92.11.1789.

6. Hagan H, Pouget ER, Des Jarlais DC. "A Systematic Review and Meta-Analysis of Interventions to Prevent Hepatitis C Virus Infection in People who Inject Drugs." *J Infect Dis* (2011) Jul 1;204(1):74-83. https://www.ncbi.nlm.nih.gov/pubmed/21628661.

7. Hart-Malloy, R, Carrascal, A, DiRienzo, AG, Flanigan, C, et al. (August 2013). "Estimating HCV Prevalence at the State Level: A Call to Increase and Strengthen Current Surveillance Systems." American Journal of Public Health, Vol. 103, No. 8. (2013): 1402-1405. doi: 10.2105/AJPH.2013.301231.

8. Zibell, J, Hagan, H. "Hepatitis C Prevention Opportunities Among People Who Inject Drugs: *Confronting the Growing Epidemic*." Webinar, HHS Office of HIV/AIDS and Infectious Disease Policy. https://www.hhs.gov/sites/default/files/hcv-in-pwid-webinar.pdf.

9. Jakobsen, Janus Christian, Emil Eik Nielsen, Ronald L. Koretz, and Christian Gluud. "Do Direct Acting Antivirals Cure Chronic Hepatitis C?" The BMJ. May 10, 2018. Accessed November 03, 2018. https://www.bmj.com/content/361/bmj.k1382.

10. Brown, Robert S., and Eugene Schiff. "The Possible Association Between DAA Treatment for HCV Infection and HCC Recurrence." *Gastroenterology & Hepatology* 12, no. 12 (December 2016): 776-79. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5193084/.

11. Jakobsen, et al. "Do Direct Acting Antivirals Cure Chronic Hepatitis C?"

12. National Alliance of State and Territorial AIDs Directors (NASTAD). "Science over Stigma: The Public Health Case Against HCV Treatment Sobriety Restrictions." August, 2017. Accessed November 04, 2018. https://www.nastad.org/sites/default/files/nondiscrimination-in-hcv-tx-provision_final_tem.pdf.

13. New York State Department of Health. "Chronic Hepatitis C (CHC) Infection Check List for Prior Authorization Requests." 07/2018. Accessed November 03, 2018. https://newyork.fhsc.com/downloads/providers/NYRx_PDP_CHC_checklist.pdf.

14. Toohey, Monica. "Prior Authorization of Hepatitis C Medications in NYS Medicaid Fee for Service (FFS) and Medicaid Managed Care." PowerPoint, NYS Department of Health Office of Insurance Programs, February 08, 2018.

15. Center for Health Law and Policy Innovation at Harvard Law School. "Hepatitis C: State of Medicaid Access Report Card, New York." 2017. Accessed November 03, 2018. https://stateofhepc.org/wp-content/themes/infinite-2/reports/HCV_Report_NewYork.pdf.

16. National Alliance of State and Territorial AIDs Directors (NASTAD). "Science over Stigma: The Public Health Case Against HCV Treatment Sobriety Restrictions." August, 2017. Accessed November 04, 2018. https://www.nastad.org/sites/default/files/nondiscrimination-in-hcv-tx-provision_final_tem.pdf.

17. Medical Xpress, *New research supports the removal of drug use as a restriction to hepatitis C treatment*, August 9, 2016 http://medicalxpress.com/news/2016-08-drug-restriction-hepatitis-treatment.html.

18. Dore, Gregory J., Frederick Altice, Alain H. Litwin, Olav Dalgard, Edward J. Gane, Oren Shibolet, Anne Luetkemeyer, Ronald Nahass, Cheng-Yuan Peng, Brian Conway, Jason Grebely, Anita Y.m. Howe, Isaias N. Gendrano, Erluo Chen, Hsueh-Cheng Huang, Frank J. Dutko, David C. Nickle, Bach-Yen Nguyen, Janice Wahl, Eliav Barr, Michael N. Robertson, and Heather L. Platt. "Elbasvir–Grazoprevir to Treat Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy." Annals of Internal Medicine165, no. 9 (2016): 625. doi:10.7326/m16-0816.

19. Grebely, Jason, Elizabeth Knight, Krista A. Genoway, Mark Viljoen, Milan Khara, Doug Elliott, Lesley Gallagher, Michelle Storms, Jesse D. Raffa, Stanley Devlaming, Fiona Duncan, and Brian Conway. "Optimizing Assessment and Treatment for Hepatitis C Virus Infection in Illicit Drug Users: A Novel Model Incorporating Multidisciplinary Care and Peer Support." *European Journal of Gastroenterology & Hepatology* 22, no. 3 (2010): 270-77. doi:10.1097/meg.0b013e32832a8c4c.

20. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Assuring Medicaid Beneficiaries Access to Treatment Drugs*, by Alissa Mooney DeBoy, Release No. 172 (Baltimore, Maryland, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

21. U.S. Congress. *United States Code: Social Security Act, 42 U.S.C. §§ 301-Suppl. 4 1934*. 1934. Periodical. https://www.loc.gov/item/uscode1934-005042007/.

22. New York State Department of Health. "Chronic Hepatitis C Infection Check List for Prior Authorization Requests." 07, 2018. Accessed November 5, 2018. https://newyork.fhsc.com/downloads/providers/NYRx_PDP_CHC_checklist.pdf.

23. Dore, et al. "Elbasvir–Grazoprevir to Treat Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy."

24. Chhatwal, Jagpreet, Tianhua He, Chin Hur, and Maria A. Lopez-Olivo. "Direct-Acting Antiviral Agents for Patients With Hepatitis C Virus Genotype 1 Infection Are Cost-Saving." *Clinical Gastroenterology and Hepatology* 15, no. 6 (2017). doi:10.1016/j.cgh.2016.09.015.

25. Rosenthal, Elana S., and Camilla S. Graham. "Price and Affordability of Direct-acting Antiviral Regimens for Hepatitis C Virus in the United States." *Infectious Agents and Cancer* 11, no. 1 (2016). doi:10.1186/s13027-016-0071-z.

26. Beckman, Adam. "Follow California's Lead: Treat Inmates With Hepatitis C, " Health Affairs Blog, July 24, 2018. doi: 10.1377/hblog20180724.396136.

27. Center for Health Law and Policy Innovation at Harvard Law School. "Hepatitis C: The State of Medicaid Access, 2017 National Summary Report." October 23, 2017. Accessed October 6, 2018. https://stateofhepc.org/wp-content/uploads/2017/10/State-of-HepC_2017_FINAL.pdf.

28. Medical Xpress, *New research supports the removal of drug use as a restriction to hepatitis C treatment*, August 9, 2016 http://medicalxpress.com/news/2016-08-drug-restriction-hepatitis-treatment.html.

29. Hart-Malloy, et al. "Estimating HCV Prevalence at the State Level: A Call to Increase and Strengthen Current Surveillance Systems."

30. Dore, et al. "Elbasvir–Grazoprevir to Treat Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy."

31. Grebely, et al. "Optimizing Assessment and Treatment for Hepatitis C Virus Infection in Illicit Drug Users: A Novel Model Incorporating Multidisciplinary Care and Peer Support."

32. Beckman, "Follow California's Lead: Treat Inmates With Hepatitis C."

33. Kaiser Family Foundation. "Total Medicaid Managed Care Enrollment, 2016." July 01, 2016. Accessed November 5, 2018. https://www.kff.org/medicaid/state-indicator/total-medicaid-mc-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

34. Goldberg, Dan, and Kassie Parisi. "State Removes Bars for Hepatitis C Patients Needing Expensive Cures." Politico PRO. April 27, 2016. Accessed November 06, 2018. https://www.politico.com/states/new-york/albany/story/2016/04/state-removes-bars-for-hepatitis-c-patients-needing-expensive-cures-100835.

35. Center for Health Law and Policy Innovation at Harvard Law School. "Hepatitis C: State of Medicaid Access Report Card, New York." 2017. Accessed November 03, 2018. https://stateofhepc.org/wp-content/themes/infinite-2/reports/HCV_Report_NewYork.pdf.

36. Ryan, Benjamin. "Considering Its Exorbitant Price, Is Hepatitis C Treatment a Good Value?" Hep. June 21, 2017. Accessed November 25, 2018. https://www.hepmag.com/article/considering-exorbitant-price-hepatitis-c-treatment-good-value.

37. Ibid.

38. "Drug Utilization Review (DUR)." New York State Department of Health (DOH). Accessed November 17, 2018. https://www.health.ny.gov/health_care/medicaid/program/dur/.

39. Brunsdon, Nigel. "VOCAL-NY." Accessed November 17, 2018. http://www.vocal-ny.org/.

40. Goldberg, "State Removes Bars for Hepatitis C Patients Needing Expensive Cures."

41. Toohey, "Prior Authorization of Hepatitis C Medications in NYS Medicaid Fee for Service (FFS) and Medicaid Managed Care."

42. Zibell, "Hepatitis C Prevention Opportunities Among People Who Inject Drugs: *Confronting the Growing Epidemic*." Webinar, HHS Office of HIV/AIDS and Infectious Disease Policy. https://www.hhs.gov/sites/default/files/hcv-in-pwid-webinar.pdf

43. National Alliance of State and Territorial AIDs Directors (NASTAD). "Science over Stigma: The Public Health Case Against HCV Treatment Sobriety Restrictions." August, 2017. Accessed November 04, 2018. https://www.nastad.org/sites/default/files/nondiscrimination-in-hcv-tx-provision_final_tem.pdf.

44. Cone, Allen. "One-third of Hepatitis C Prescriptions Rejected by Insurers, Study Says." UPI. June 07, 2018. Accessed November 17, 2018. https://www.upi.com/One-third-of-hepatitis-C-prescriptions-rejected-by-insurers-study-says/6121528372701/.