Curing the Hepatitis C Treatment Gap

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Advocates for Basic Legal Equality, Inc.

INTRODUCTION

Highly effective direct-acting antivirals (DAAs) for the treatment of the Hepatitis C virus (HCV) are revolutionizing the prospect of ending the HCV epidemic. In fact, these DAAs have been shown to cure more than 90% of chronically infected individuals (over four major genotypes) and have been tolerated by recipients far better than previous treatment regimes.[1] This is great news for the more than 3.5 million individuals in the United States and more than 119,000 Ohioans currently infected with HCV.[2] These Ohioans are hopeful that the promise of these DAAs will allow them to continue being productive and contributing members of society and avoid future costly complications from HCV.

One of those Ohio residents hoping to gain access to the lifesaving treatment is Dwayne* (* denotes that a name has been changed to protect the privacy of the individual). Dwayne was diagnosed with chronic HCV in 1991 and is currently suffering through a multitude of symptoms, including chronic pain, weight loss, vitamin deficiency, skin problems, fatigue, and weakness. Despite his anguish and frequent visits to the emergency room, Dwayne is the guardian and sole caretaker of his grandchild. He is concerned that without access to curative DAAs, he will be unable to continue caring for his grandchild. Dwayne often feels hopeless when faced with the prospect that his grandchild will no longer be able to depend on him, and the thought that their family may be torn apart terrifies him. Although Dwayne was given a glimmer of hope that he would be able to continue being the caretaker and provider for his family when he was prescribed Harvoni, his hopes were soon dashed when his Medicaid Managed Care Provider (MCP) denied coverage.

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1 "Effectiveness, safety and clinical outcomes of direct-acting antiviral therapy in HCV genotype 1 infection: Results from a Spanish real-world cohort," Journal of Hepatology, Volume 66, Issue 6, Pages 1138-1148, June 2017, available at: **https://www.journal-of-hepatology.eu/article/S0168-8278(17)30063-6/pdf**.

2 "Statistics and Surveillance, Viral Hepatitis," Center for Disease Control, available at: **https://www.cdc.gov/hepatitis/statistics/index.htm**; "Estimation of State-Level Prevalence of Hepatitis C Virus Infection," U.S. States and District of Columbia, 2010, Clinical Infectious Disease, Volume 64, Issue 11, Pages 1573-1581, June 2017, available at: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5434341/**.

Similarly, John* was hoping to maintain his independence and continue providing for his family when he was prescribed a DAA by his physician. John was diagnosed with HCV in 2017 and is currently the sole caretaker for his 80-year-old father. He is concerned that he will no longer be able to care for his father if his condition continues to worsen. Not only do the symptoms of his HCV limit his physical ability to take care of his father, but the symptoms created difficulty in maintaining gainful employment. John currently works part-time, but still struggles with his schedule and travel to and from his employer due to the fatigue caused by his HCV. John has hope that one day with the curative effects of DAAs, he will be able to regain full-time employment, but his MCP also denied coverage.

Another Ohioan desperately in need of the curative promise of DAAs is Beth*. Beth was diagnosed with HCV in 2015 while working as a waitress to support herself and her family. Beth was the sole financial provider for her disabled ex-husband, disabled child, and two minor children. However, she had to discontinue working more than a year ago because of a foot deformity and issues with her hands that limit her mobility and dexterity. Although doctors have recommended surgeries to alleviate these ailments, Beth has been unable to find a surgeon to perform the procedure due to her HCV diagnosis. Because of her diagnosis, Beth and the rest of her family have become dependent upon her 21-year-old daughter's income. Beth was hopeful that she would be able to return to work when she received a prescription for a DAA. However, her plans of returning to the work force were halted when her MCP denied her coverage.

Dwayne, John, and Beth are just a few of the Ohioans prevented from working, caring for family, and maintaining their independence due to their progressing symptoms of HCV. Their experiences are not at all uncommon for individuals diagnosed with HCV and unable to obtain the life-altering DAAs due to the overly restrictive standards set by the Ohio Department of Medicaid and MCPs. However, after a review of the symptoms of HCV, how it progresses, and the societal and cost benefits of the DAAs, it becomes clear that these standards are unreasonable and that all individuals infected with HCV should have access to the promise of these revolutionary medications.

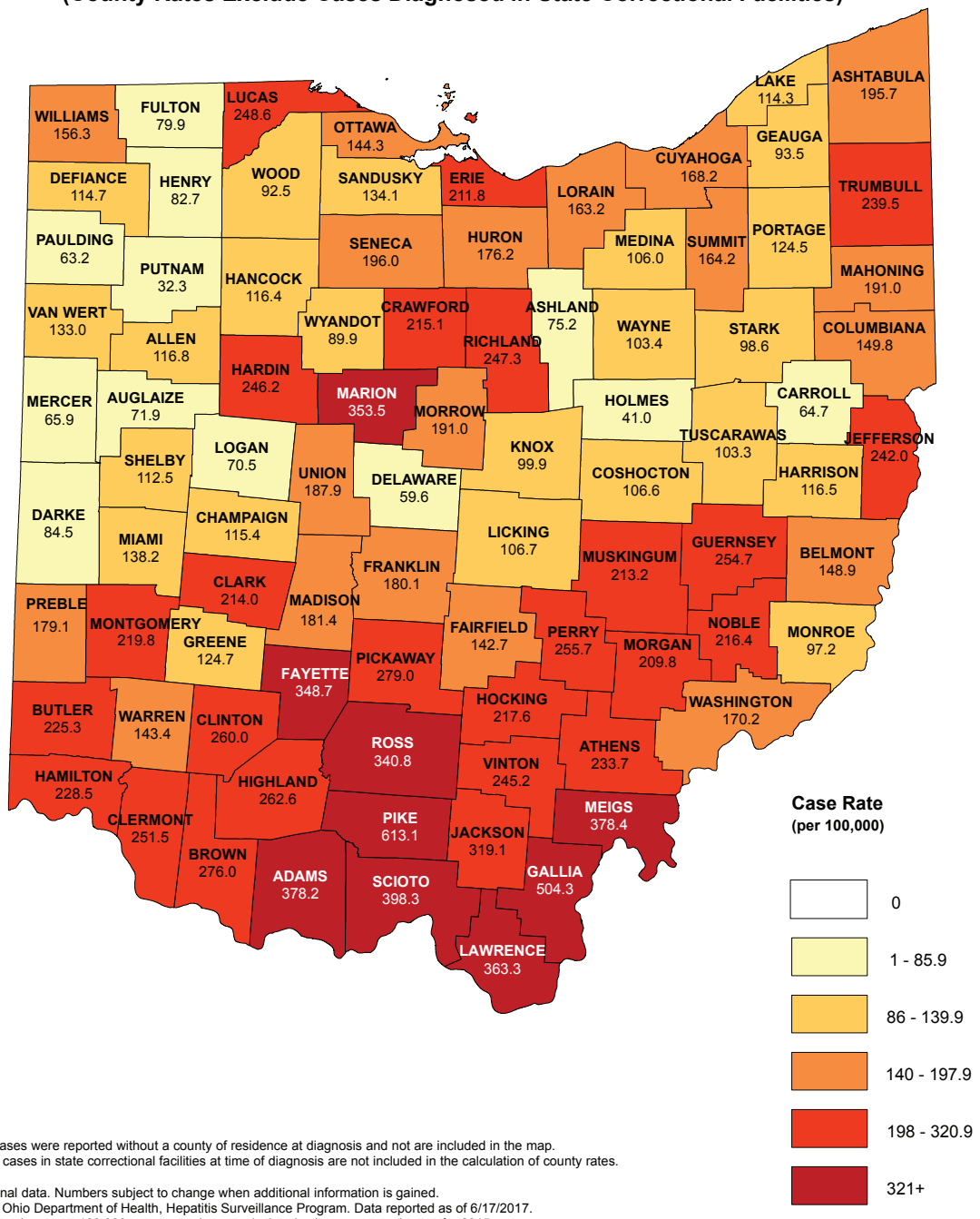
HEPATITIS C VIRUS

Despite the estimated 3.5 million infected individuals in the U.S., HCV has gained relatively little attention in recent years. Some estimate that this number may be even higher (up to 5.2 million), based on the knowledge that the Centers for Disease Control's (CDC) surveys did not include certain populations, including people who are incarcerated, nursing home residents, people who are homeless, hospitalized individuals, and persons on active military duty.[3]

As demonstrated in Map 1 on page 3, Ohioans like Dwayne, John, and Beth live in every county of the state. The rate of infection is particularly high in southern Ohio and in the more urban counties in the north.

3 "HCV Epidemiology in the United States," Hepatitis C Online, May 24, 2018, available at: https://www.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all.

Map 1—HCV Case Rate by County[4]



1) 661 cases were reported without a county of residence at diagnosis and not are included in the map.
2,276 cases in state correctional facilities at time of diagnosis are not included in the calculation of county rates.

Provisional data. Numbers subject to change when additional information is gained.
Source: Ohio Department of Health, Hepatitis Surveillance Program. Data reported as of 6/17/2017.
Rates are shown per 100,000 persons and were calculated using census estimates for 2015.

4 "Hepatitis Surveillance Data and Statistics," Ohio Department of Health, June 17, 2017, available at: https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/bid/survhep/Data-and-Statistics/2016-HCV-Rate-Map--072417.pdf?la=en.

According to the CDC, what is commonly known as HCV is a contagious liver disease that results from an infection.[5] In fact, hepatitis means "inflammation of the liver." HCV is spread primarily by blood-to-blood contact, through poorly sterilized medical equipment, needlestick injuries in healthcare, transfusions, intravenous drug use, sexual contact, and being born to a mother infected with HCV, to name a few causes.

HCV can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness that attacks the liver. Symptoms may include, but are not limited to:[6]

- Fever
- Fatigue
- Loss of appetite
- Nausea
- Vomiting
- Abdominal pain
- Dark urine
- Clay-colored bowel movements
- Joint pain
- Jaundice (yellow color in the skin or eyes)

During the initial infection, individuals often have mild or no symptoms, so many who are infected are unaware of how or when they were infected. An estimated 50% of persons infected with HCV are unaware of their HCV infection status.[7] In fact, due to the lack of awareness of infected individuals, the CDC has stated that "Hepatitis C is an unrecognized health crisis in the United States," calling it a "silent epidemic."[8] Over many years, HCV often leads to liver damage and occasionally cirrhosis, so the infection is sometimes discovered decades later during routine medical tests.

The majority, more than 75%, of American adults with HCV are baby boomers (persons born between 1945 and 1965).[9] Many baby boomers do not know how or when they contracted HCV. The CDC has conceded that the reason baby boomers have higher rates of HCV is not completely understood.[10] Because HCV is primarily spread through contact with blood from person with the disease, experts believe baby boomers could have contracted the disease from medical equipment or procedures before universal precautions and infection control procedures were adopted. Others may have contracted the disease from contaminated blood and blood products before widespread screening virtually eliminated the virus from the blood supply by 1992. Regardless of how any person contracted HCV, no one deserves to be denied curative treatment for the disease.

As baby boomers continue to age, the likelihood that they will develop serious, life-threatening, and costly complications from the disease will continue to increase, unless those infections are diagnosed and treated.

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5 "Hepatitis C FAQs for the Public," Center for Disease Control, April 23, 2018, available at: **https://www.cdc.gov/hepatitis/hcv/cfaq.htm**.

6 "Hepatitis C FAQs for the Public," Center for Disease Control, April 23, 2018, available at: **https://www.cdc.gov/hepatitis/hcv/cfaq.htm**.

7 "HCV Epidemiology in the United States," Hepatitis C Online, May 24, 2018, available at: **https://www.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all**.

8 "Hepatitis C: Proposed Expansion of Testing Recommendations, 2012," CDC Fact Sheet, Center for Disease Control, May 2012, available at: **https://www.cdc.gov/nchhstp/newsroom/docs/hcv-testingfactsheetnœmbargo508.pdf**.

9 "Hepatitis C: Proposed Expansion of Testing Recommendations, 2012," CDC Fact Sheet, Center for Disease Control, May 2012, available at: **https://www.cdc.gov/nchhstp/newsroom/docs/hcv-testingfactsheetnœmbargo508.pdf**.

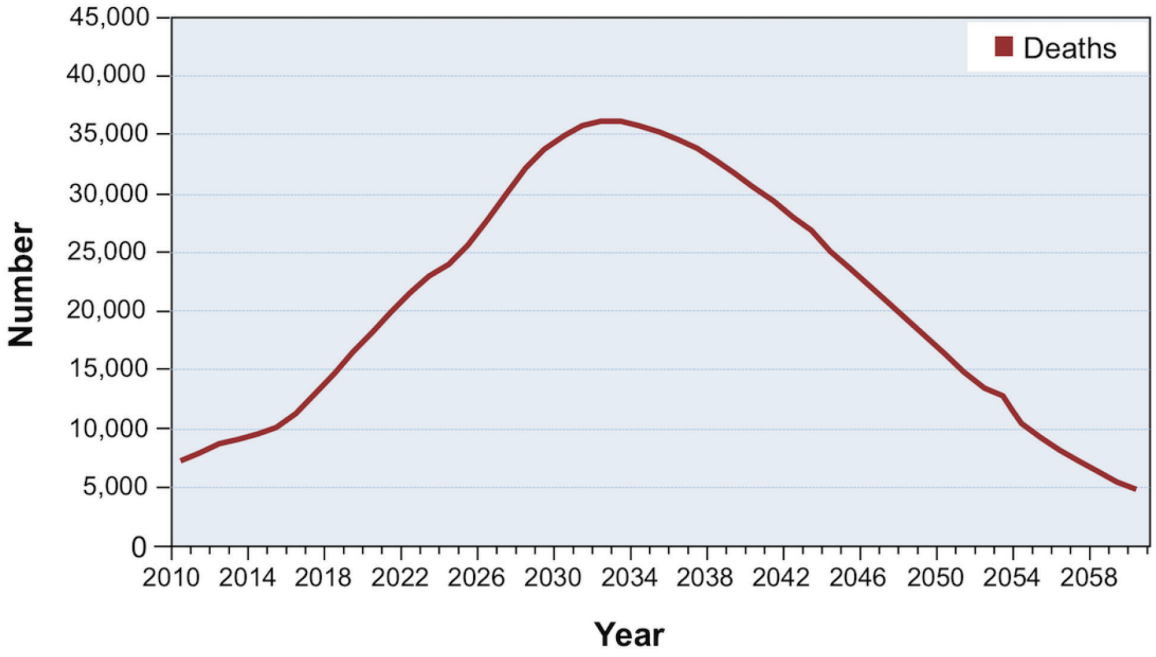
10 "Hepatitis C: Why People Born from 1945-1965 Should Get Tested," Know More Hepatitis, Center for Disease Control, 2016, available at: **https://www.cdc.gov/knowmorehepatitis/media/pdfs/factsheet-boomers.pdf**.

HCV is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or even death. It is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the U.S.[11] Out of every 100-people infected with HCV, about 75-85 will develop chronic HCV infection, and of those:[12]

- 60-70 will go on to develop chronic liver disease
- 5-20 will go on to develop cirrhosis over a period of 20-30 years
- 1-5 will die from cirrhosis or liver cancer

Persons infected with HCV have a 15-year shorter life expectancy than those who are not infected with HCV.[13] In fact, according to the CDC, HCV kills more Americans than all the other 60 infectious diseases combined.[14] Table 1 shows forecasted annual deaths associated with chronic HCV, which will likely peak in 2030 to 2035. This table corresponds to the high number of baby boomers currently infected, who are aging and experiencing more severe symptoms of HCV.

Table 1—Forecasted Annual Deaths Associated with Chronic Hepatitis C Infection[15]



11 "Hepatitis C FAQs for the Public," Center for Disease Control, April 23, 2018, available at: **https://www.cdc.gov/hepatitis/hcv/cfaq.htm**.

12 "Hepatitis C FAQs for the Public," Center for Disease Control, April 23, 2018, available at: **https://www.cdc.gov/hepatitis/hcv/cfaq.htm**.

13 "Two U.S. Studies Show that Hepatitis C has a Major Impact on Life Expectancy," InfoHep, May 27, 2014, available at: **http://www.infohep.org/Two-US-studies-show-that-hepatitis-C-has-a-major-impact-on-life-expectancy/page/2842841/**.

14 "Hepatitis C Mortality," National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Center for Disease Control, May 4, 2016, available at: **https://www.cdc.gov/nchhstp/newsroom/2016/hcv-mortality.html**.

15 "HCV Epidemiology in the United States," Hepatitis C Online, May 24, 2018, available at: **https://www.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all**.

In addition to baby boomers, certain populations are more likely to have HCV. For example, African Americans have substantially higher rates of chronic HCV and HCV-related deaths compared to other ethnic groups.[16] Within the African American community, chronic liver disease and cirrhosis, often HCV-related, were among the leading causes of death in those 45-64 years of age.[17] In addition, estimates for the prevalence of HCV among people with a serious mental illness are high compared with the general population.[18] Although people with serious mental illness are at a higher risk for several blood-borne viral infections, studies have found it is unlikely to be the sole risk factor but rather could be associated with low economic status or other factors.[19]

Unfortunately, because of the stigma associated with HCV, it is also a health crisis that is not always given attention. Many people currently infected with HCV are reluctant to come forward because of this stigma, including the misunderstanding of how the virus can be spread. Again, HCV can be spread by blood-to-blood contact, which includes many more possibilities than intravenous drug use. However, it is not spread so easily that individuals should fear coming into contact with an infected individual. In fact, the CDC's recommendations for the prevention and control of HCV do not suggest that individuals be excluded from work, school, play, childcare, or other settings because there is no evidence that people can become infected from food handlers, teachers, or other service providers without blood-to-blood contact.[20]

TREATMENT AVAILABLE

Although HCV was first identified by doctors in 1989, there were only two drugs approved by the Food and Drug Administration (FDA) for treatment until a few years ago.[21] Thus, the standard treatment for HCV has long been a synthetic, injectable version of Interferon, one of the immune system's most powerful proteins, plus the antiviral drug Ribavirin. Ribavirin, alone, cannot treat HCV and Interferon has significant side effects, including flu-like symptoms, fatigue, depression, and anemia. These side effects are often so severe that they become intolerable. In addition, HCV often becomes resistant to medication, allowing the disease to worsen. In fact, HCV treatments were historically used sparingly because of toxic effects and modest efficacy.[22]

16 "Hepatitis C Disproportionately Affects the African American Community," CDC, February 1, 2017, available at: **https://www.cdc.gov/hepatitis/blackhistmnth-hepc.htm**.

17 "Hepatitis C Disproportionately Affects the African American Community," CDC, February 1, 2017, available at: **https://www.cdc.gov/hepatitis/blackhistmnth-hepc.htm**.

18 "Hepatitis C in Psychiatry Inpatients: Testing Rates, Prevalence and Risk Behaviours," Australasian Psychiatry, August 1, 2007, available at: **http://journals.sagepub.com/doi/abs/10.1080/10398560701358113**.

19 "Prevalence of HIV, hepatitis B, and hepatitis C in people with several mental illness, a systemic review and meta-analysis, Lancet Psychiatry, Volume 3, Issue 1, pages 40-48, January 2016, available at: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703902/**.

20 "Hepatitis C FAQs for the Public, Center for Disease Control," April 23, 2018, available at: **https://www.cdc.gov/hepatitis/hcv/cfaq.htm**.

21 "Advances in Medication to Treat Hepatitis C," American Liver Foundation, October 2016, available at: **http://hepc.liverfoundation.org/treatment/the-basics-about-hepatitis-c-treatment/advances-in-medications/**.

22 "HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C," AASLD/IDSA, available at: **http://hcvguidelines.org/**.

For the large percentage of HCV-infected individuals who develop chronic liver disease and cirrhosis because of this ineffective treatment, a liver transplant may be required. However, in most cases, a liver transplant alone does not cure HCV.[23] Rather, the infection is likely to return, requiring additional treatment with antiviral medications to prevent damage to the transplanted liver.

Recent advancements have made treatment regimens shorter in duration, less difficult to tolerate, and more effective and will reduce the need for liver transplantation. In September 2014, the FDA approved Solvadi, a DAA and the first combination pill to treat HCV.[24] Solvadi allowed infected individuals to be treated with only one pill, eliminating the need for weekly injections with devastating side effects.

Following the approval of Solvadi, several other DAAs were approved, including Harvoni in October 2014, Viekira Pak in December 2014, Technivie in July 2015, Daklinza in July 2015, Zepatier in January 2016, and Epclusa in June 2016.[25] Again, these DAAs are more than 90% effective (across four genotypes) at curing HCV.[26] Although the initial retail costs of these powerful DAAs ranged from $83,000 to $153,000 per treatment course,[27] as new DAAs are becoming available, costs are starting to decline. As of November 2016, costs for a treatment course ranged from $54,600 to $94,500.[28]

BARRIERS

Individuals infected with HCV face many barriers in attempting to access the life-altering DAA treatment. Individuals infected may lack access to health care and treating physicians may lack familiarity with this new curative treatment. However, the high cost of DAAs and resulting restrictive polices set by insurance companies likely create the most substantial barrier to curing the 3.5 million infected Americans. Currently, patient access to HCV treatment requires health care practitioners and staff to expertly navigate a complex and time-consuming authorization process. Thus, despite studies by the CDC that demonstrate that treating all HCV-infected persons is a cost-effective solution that prevents future infections and promotes long-term health savings,[29] patient access to DAAs still remains very low.

23 "Diagnosis: Hepatitis C," Mayo Clinic, March 6, 2018, available at: **https://www.mayoclinic.org/diseases-conditions/hepatitis-c/diagnosis-treatment/drc-20354284**.

24 "Advances in Medication to Treat Hepatitis C," American Liver Foundation, October 2016, available at: **http://hepc.liverfoundation.org/treatment/the-basics-about-hepatitis-c-treatment/advances-in-medications/**.

25 "Advances in Medication to Treat Hepatitis C," American Liver Foundation, October 2016, available at: **http://hepc.liverfoundation.org/treatment/the-basics-about-hepatitis-c-treatment/advances-in-medications/**.

26 "Effectiveness, safety and clinical outcomes of direct-acting antiviral therapy in HCV genotype 1 infection: Results from a Spanish real-world cohort," Journal of Hepatology, Volume 66, Issue 6, Pages 1138-1148, June 2017, available at: **https://www.journal-of-hepatology.eu/article/S0168-8278(17)30063-6/pdf**.

27 "Barriers to Treatment Access for Chronic Hepatitis C Virus Infection: A Case Series," Topics in Antiviral Medicine, Volume 25, Issue 3, Pages 110-113, July 2017, available at: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5678961/**.

28 "State Medicaid Programs Continue to Restrict Access to Hepatitis C Drugs," STAT News, November 14, 2016, available at: **https://www.statnews.com/pharmalot/2016/11/14/medicaid-hepatitis-gilead/**.

29 "The Cost-effectiveness, Health Benefits, and Financial Costs of New Antiviral Treatments for Hepatitis C Virus," Clinical Infectious Diseases, Volume 15, Issue 2, Pages 157-168, July 2015, available at: **https://www.ncbi.nlm.nih.gov/pubmed/25778747**.

OHIO DEPARTMENT OF MEDICAID'S CURRENT RESTRICTIONS

The prevalence rate of HCV is 7.5 times higher for Medicaid recipients than individuals with a commercial medical insurance plan.[30] Indeed, 41,913 Ohio Medicaid recipients have been identified as HCV infected. Thus, the policies of Medicaid and the Managed Care Providers (MCPs) it contracts with—Buckeye Community Health Plan, Molina Healthcare of Ohio, United Healthcare Community Plan, CareSource, and Paramount Advantage—have a great impact on Ohio's HCV-infected population and their access to treatment.

Although the restrictions vary slightly, individuals with Fee for Service (FFS) Medicaid or one of the MCPs must satisfy four criteria to gain access to DAAs, detailed in Table 1 below. These restrictions earned Ohio a "D" grade by the National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation at Harvard Law School.[31]

Table 2—Restrictions to Accessing DAAs

Liver Damage Restrictions	**FFS, CareSource, Paramount**—moderate liver damage (F2 or greater) **Molina and United**—severe liver damage (F3 or greater) **Buckeye**—unclear
Sobriety Restrictions	**FFS, Buckeye, Molina, and Paramount**—6 months sobriety from alcohol and substance use prior to requesting prior authorization **CareSource**—three months consecutive abstinence documented by negative urine and drug alcohol screens **United**—negative drug screen within the last 30 days
Psychiatric Restrictions	**All**—patients with mental conditions must have psychiatric status documented as stable for six months in medical record and mental health professional must be consulted to assess readiness
Prescriber Restrictions	**FFS, Paramount, United**—specialist must prescribe **Buckeye**—must be prescribed by or in consultation with specialists **CareSource**—specialist or nurse practitioner working with specialist must prescribe **Molina**—unclear

30 "The Burden of Hepatitis C Virus Disease in Commercial and Managed Medicaid Populations," Milliman, Primrose Healthcare, LLC, July 8, 2015, available at: **http://www.milliman.com/uploadedFiles/insight/2015/milliman-hcv-burden.pdf**.

31 "Hepatitis C: State of Medicaid Access Report Card: Ohio," National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation at Harvard Law School, 2017, available at: **https://stateofhepc.org/wp-content/themes/infinite-2/reports/HCV_Report_Ohio.pdf**.

Of these restrictions, liver damage or fibrosis restrictions are the most concerning. These restrictions require patients to wait until HCV damages their liver to a certain level, as measured by the METAVIR fibrosis scale. A METAVIR score of F0 indicates no fibrosis, whereas F4 indicates damage to the liver that is so severe as to be considered cirrhosis. By requiring patients to demonstrate a minimum level of liver damage before they qualify for treatment with DAAs, Medicaid programs are forcing individuals to wait until their health declines, which can result in inability to work and care for others, to access curative treatment for HCV.

FIBROSIS RESTRICTIONS CONTRAVENE FEDERAL LAW

The Ohio Department of Medicaid's (ODM) fibrosis restrictions are not only concerning, but they contravene federal law. The Medicaid Act requires participating state programs (including Ohio) to make medical assistance available to qualified individuals for certain services, including prescription drugs.[32] It is unlawful to withhold prescription drugs that cure a disease from Medicaid beneficiaries based on the cost of those drugs.

RECOMMENDATIONS

Based on the overwhelming evidence of the value of providing curative treatment of HCV, advocates and supporters have already been calling for increased transparency and the removal of restrictive criteria for prior authorization of DAAs. Again, the requirement of beneficiaries to have a fibrosis score of 2 or more prevents Ohio Medicaid beneficiaries from receiving curative HCV treatment, unless they have significant liver damage. These restrictions plainly contravene guidelines[33] published by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), which are widely accepted as the standard of care. These guidelines advise that all patients with chronic HCV be provided the HCV cure regardless of their fibrosis score, unless they have short life expectancies that cannot be remediated with treatment. ODM's restrictive criteria also contradict the Center for Medicaid Services (CMS) guidance,[34] which explicitly states that fibrosis score "limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections."

Other states are moving toward removing or lessening these criteria already. In 2014, FFS programs in four states required a score of F4, but in 2017 that number was 0.[35] In fact, 18 states' FFS programs place no

32 See 42 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(a)(12); 42 U.S.C. § 1396a(a)(54).

33 The American Association for the Study of Liver Diseases and The Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C: When and in Whom to Initiate HCV Therapy. Available at: **http://www.hcvguidelines.org**.

34 Centers for Medicare & Medicaid Services. Medicaid Drug Rebate Program Notice Release No. 172 for State Technical Contacts. Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs. November 5, 2015. Available at: **https://www.medicaid.gov/medicaid/prescription-drugs/hcv/index.html**.

35 Hepatitis C: State of Medicaid Access Report Card: 2017 National Summary Report, National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation at Harvard Law School, October 23, 2017, available at: **https://www.chlpi.org/wp-content/uploads/2013/12/State-of-HepC_2017_FINAL.pdf**.

restriction on liver damage and eight states managed care plans place no restriction on liver damage.[36]

Second, the criteria deny the HCV cure to beneficiaries who have used alcohol, marijuana, or other illicit substances in any amount at any time in the six months prior to the Medicaid authorization request. This requirement is not medically justified. There is simply no evidence that drug and alcohol use decrease the efficacy of DAA treatment of HCV. Furthermore, as described in the AASLD/IDSA guidelines, injection drug users have demonstrated adherence to DAA treatment regimens at rates comparable to individuals who do not use injection drugs. Injection drug users also have comparably low rates of reinfection. The AASLD/IDSA guidelines recommend treating individuals who use injection drugs to prevent new HCV infections. These criteria create barriers to treatment, add unnecessary cost and effort, and may result in additional infections. They should be abandoned. In fact, other states are also already moving in this direction with half of states (25) having no restrictions or only requiring screening and counseling.[37]

Third, the criteria deny Ohio Medicaid beneficiaries who have not demonstrated a stable psychiatric condition for the past six months. This is an arbitrary requirement that is discriminatory to beneficiaries who suffer from mental illnesses and may be in violation of federal anti-discrimination law.

Fourth, the criteria deny curative HCV treatment to those who have not been prescribed the medication by a physician specializing in hepatology, gastrœnterology, or infectious disease. Since primary care physicians can diagnose chronic HCV and specialists can be difficult to find and get an appointment with, this requirement is an unreasonable barrier to accessing medically necessary treatment. Because DAAs require only a short course of treatment and involve few serious adverse side effects, the AASLD/IDSA guidelines recommend relying on and expanding the role of primary care physicians in managing and treating HCV.

NEXT STEPS

There are tens of thousands of people just like Dwayne, John, and Beth suffering from HCV in Ohio. DAAs are the most effective and curative treatment available and would not require them to endure complex or debilitating side effects. And future infections could be prevented. According to a study from the University of Pittsburgh Graduate School of Public Health reveals that HCV could become a "rare disease" by 2036 if individuals are screened and have access to curative treatments is increased.[38] Providing full access to these lifesaving HCV treatments is cost-effective in the long-term, as they prevent future costly medical conditions as well as the spread of new infections.

36 "Hepatitis C: State of Medicaid Access Report Card: 2017 National Summary Report," National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation at Harvard Law School, October 23, 2017, available at: **https://www.chlpi.org/wp-content/uploads/2013/12/State-of-HepC_2017_FINAL.pdf**.

37 "Hepatitis C: State of Medicaid Access Report Card: 2017 National Summary Report," National Viral Hepatitis Roundtable and the Center for Health Law and Policy Innovation at Harvard Law School, October 23, 2017, available at: **https://www.chlpi.org/wp-content/uploads/2013/12/State-of-HepC_2017_FINAL.pdf**.

38 "Screen and Drug Therapy Predicted to Make Hepatitis C a Rare Disease, "The University of Pittsburg Medical Center, August 4, 2014, available at **http://www.upmc.com/media/newsreleases/2014/pages/gsph-study-hepatitis-c-guidelines.aspx**.

Removing the above described restrictions on curative HCV treatments is not only compliant with federal law; it is also the logical and moral thing to do. There is no question among the medical community that such treatments are medically necessary, and there are no reasonable justifications for the restrictions ODM has put in place.

Since the advent of lifesaving HCV treatments, advocates in various state have used litigation to remove restrictive state Medicaid criteria and to ensure treatment by state correctional systems. To date, federal class action lawsuits have commenced in Washington, Colorado, Indiana, Pennsylvania, Massachusetts, Minnesota, and Tennessee challenging similar access criteria. In Washington, a federal court required that the state's Medicaid agency provide medications for beneficiaries with chronic HCV, without regard to fibrosis score.[39]

In other states, advocacy efforts have resulted in positive changes to the Medicaid prior authorization rules. In Vermont, the Drug Review and Utilization Board (DURB) voted in November to lift the liver damage requirements for their state Medicaid recipients, following advocacy from Vermont Legal Aid and others.[40] As these states show, the tide is turning in favor of state Medicaid agencies providing payment for DAAs without restrictions.

Advocates for Basic Legal Equality, Inc. (ABLE) has engaged in efforts to remove ODM's restrictive criteria, with some success. But, ABLE maintains that all Ohio Medicaid recipients should be able to receive lifesaving DAAs without restrictions. ABLE has advocated to the Ohio Department of Medicaid and the Drug Review and Utilization Board that fibrosis score is an impermissible restriction on access to this treatment. Removing restrictive criteria for prior authorization of DAAs would enable the thousands of Ohioans in need of medical care, including ABLE's clients, to receive necessary medical treatment and prevent needless suffering. It would also avoid additional expense to taxpayers in the form of increased long-term health care costs and potential litigation.

Individuals and organizations interested in updates on our work should contact ABLE through Facebook message or via email at **kford@ablelaw.org**. ABLE also encourages individuals and organizations to write to ODM's director, Barbara Sears, to voice opposition to ODM's restrictive Hepatitis C medication policies. Letters should be sent to:

Barbara Sears, Director
Ohio Department of Medicaid
50 West Town Street, Suite 400
Columbus, Ohio 43215

39 See Order Granting Plaintiffs' Motion for Preliminary Injunction, B.E. v. Teeter, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016).

40 See Medicaid review board lifts liver damage restriction on life-saving cures for Vermonters with Hepatitis C, VT Digger, November 1, 2017, available at: **https://vtdigger.org/2017/11/01/medicaid-review-board-lifts-liver-damage-restriction-life-saving-cures-vermonters-hepatitis-c/**.