

VTCAHT

Vermont Coalition for Access to HCV Treatment

October 16, 2017

Vermont Drug Utilization Review Board
Department of Vermont Health Access
312 Hurricane Lane Suite 201
Williston, Vermont 05495

cc: Al Gobeille, Secretary, Agency of Human Services
Cory Gustafson, Commissioner, Department of Vermont Health Access
Nancy Hogue, Pharmacy Director, Department of Vermont Health Access
Mary Kate Mohlman, Director of Health Care Reform
Scott Strenio, Medicaid Medical Director, Department of Vermont Health Access

Re: Removing Restrictions on Hepatitis C Virus Treatment for Medicaid Beneficiaries

To the members of the Vermont Drug Utilization Review Board:

We thank you for the improvements made to Vermont Medicaid's hepatitis C virus (HCV) treatment criteria after your December 2016 vote. This was an important step in the right direction and has allowed additional Vermonters to access lifesaving treatment. We are writing to continue to advocate for Vermont Medicaid beneficiaries with chronic HCV who, as a result of Vermont's remaining restrictive criteria, are unable to access medically necessary treatment. Treatment of all people with chronic HCV is the standard of care¹ and must be implemented immediately.

Despite the improvements made over the past year, the Vermont Medicaid HCV Prior Authorization Criteria² continue to unreasonably restrict access to curative treatments for HCV in violation of federal Medicaid law. These restrictions limit HCV treatment to beneficiaries who have liver fibrosis of at least Metavir stage F2 and have met or consulted with a liver or hepatitis specialist, preventing Vermonters from accessing medically necessary curative direct-acting antivirals (DAAs) that meet the standard of care for HCV.

To protect the health of Vermonters, maintain fiscal responsibility, and prevent unnecessary litigation, we ask the Drug Utilization Review Board (DURB) to take immediate steps to eliminate these unjust and unlawful restrictions. Curing HCV allows individuals to live healthier lives and prevents additional HCV infections from occurring in our communities.

Much of the pushback against appropriate HCV treatment has been related to the cost of DAAs. In August 2017 a new, less expensive, shorter-course DAA was approved by the U.S. Food and Drug Administration³. This drug, Mavyret, provides a curative option for many patients with an 8-week treatment course and a

¹ 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>.

² Department of Vermont Health Access. *Hepatitis C Treatment Prior Authorization Request Form*. Available at: <http://dvha.vermont.gov/for-providers/hepc-vt-1.15-02-01-2017.pdf>.

³ U.S. Food and Drug Administration. *FDA approves Mavyret for Hepatitis C*. Press Release August 3, 2017. Available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm570038.htm>.

maximum price tag of around \$20,000. This is less than a quarter of the list price of the DAAs that were previously available. We recently learned that Mavyret is highly likely to be available at a steeply discounted price to states with no fibrosis restrictions on HCV treatment. This type of discount is unlikely to remain available to Vermont if the state's treatment restrictions are removed via the courts or the legislature rather than by the DURB and the Department of Vermont Health Access (DVHA). We urge the DURB, DVHA, and the state to take advantage of this opportunity and give all Vermont Medicaid beneficiaries access to HCV treatment.

In our October 2016 letter we cited numerous federal lawsuits underway against state Medicaid and Corrections agencies related to treatment restrictions for HCV similar to Vermont's. In the past year, these have increased in number and geographic distribution and have continued to be successful. Just last month a judge in Colorado allowed a lawsuit⁴ to proceed alleging that Medicaid beneficiaries with fibrosis scores of F0 and F1 may not be denied treatment. The courts have determined in other lawsuits that criteria similar to Vermont's unlawfully fail to meet the medical standard of care. Settlements in some of these cases have included provisions such as requiring Medicaid agencies to actively reach out to *current and former* beneficiaries who were not provided curative treatment, and to provide that treatment without restriction regardless of the patient's current enrollment status in Medicaid. Many states⁵ including all of Vermont's neighbors (CT, MA, NH, and NY) and Maine currently offer treatment to Medicaid beneficiaries without a fibrosis score restriction. Vermont is lagging behind on this issue, allowing new harmful and costly HCV infections to occur and causing Vermonters unnecessary suffering.

As we described in our previous letter, treatment of HCV with curative DAAs is the only evidence-based intervention to prevent progression of liver disease. A large proportion of people living with chronic HCV who have mild or no fibrosis (F0-F2) will progress to cirrhosis without treatment. Determining a patient's fibrosis score often requires unnecessary invasive testing including liver biopsy, which some patients cannot tolerate. There is no effective way to predict who will develop advanced liver disease. Delaying treatment can harm patients and lead to unnecessary medical costs and preventable deaths. Chronic HCV is associated with numerous causes of death, including cancer and kidney disease. Delaying treatment until patients develop liver disease can result in painful and costly conditions, such as liver cancer and the need for a liver transplant. Research shows that DAAs cure nearly all patients followed for five years. Curing patients with HCV is associated with a more than 70% reduction in the risk of liver cancer and a 90% reduction in the risk of liver-related mortality and liver transplantation. National treatment guidelines⁶ published by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) (described in more detail in our October 2016 letter) recommend early treatment of HCV infection to improve survival rates.⁷ Rationing these treatments is harmful and illegal.

In addition to the fibrosis restriction, Vermont's criteria deny patients access to curative HCV treatment if the prescribing physician has not consulted with a "gastroenterologist, hepatologist, infectious disease specialist or other Hepatitis specialist," documenting the recommended regimen. Such a consultation likely requires the beneficiary to meet with a specialist before the primary care physician can prescribe the HCV cure. Since

⁴ "Plaintiffs allege that DAA treatment is medically necessary for every Medicaid enrollee infected with HCV, even those with MFSs of F0 or F1; that Plaintiffs are eligible Medicaid enrollees infected with HCV; that HCPF has denied Plaintiffs coverage of DAA treatment; and that HCPF has provided coverage of DAA treatment for similarly situated enrollees, i.e. enrollees with MFSs of F2 or above. These allegations are sufficient to allege Plaintiffs' second claim that HCPF violated § 1396a(a)(10)(B) and § 440.240. Accordingly, the Court denies Defendant's Motion [#22] with respect to Plaintiffs' second claim." *Ryan v. Birch*, 2017 WL 3896440, at *4 (D. Colo. Sept. 5, 2017).

⁵ Data from the National Viral Hepatitis Roundtable, report to be published in October 2017.

⁶ 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>.

⁷ National Viral Hepatitis Roundtable. *The Medical Case for Curing All Hepatitis C Patients*. Available at http://nvhr.org/sites/default/files/.users/u27/NVHR%20Cure%20Fact%20Sheet_One%20Pager.pdf.

primary care physicians can diagnose chronic HCV and specialists are difficult for Medicaid beneficiaries to access in Vermont, this requirement is an unreasonable barrier to accessing medically necessary treatment.⁸ For those who can access a specialist, this requirement results in unnecessary additional costs to Medicaid.

Earlier this month an article⁹ was published in the *Annals of Internal Medicine* describing best practices for HCV treatment as implemented by the Department of Veterans' Affairs (VA). The VA offers and actively pursues treatment for all veterans with chronic HCV and has made significant progress toward eradicating HCV among veterans since the introduction of curative DAAs in 2014. The authors state that “[t]he VA has emphasized the expansion of HCV care beyond specialty providers. A substantial portion of HCV treatment has shifted from liver and infectious disease specialty clinics to primary care and community clinics. At more than half of VA facilities, treatment is delivered by clinical pharmacy specialists, nurse practitioners, and physician assistants, who have been recognized as delivering the same quality of care and providing more timely access to HCV treatment.” Because DAAs require only a short course of treatment and involve few serious adverse side effects, the AASLD and IDSA guidelines also recommend relying on and expanding the role of primary care physicians in managing and treating HCV.

We ask you to look to these best practices as well as to the AASLD and IDSA guidelines when determining Vermont's HCV policies.

Removing Vermont Medicaid's restrictions on curative HCV treatments is not only legally required, it is 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 Vermont has put in place. DAAs are the most effective and curative treatment available, and do not require patients to endure complex or debilitating side effects. Providing full access to these lifesaving HCV treatments is also cost-effective in the long-term, as DAAs prevent future costly medical conditions as well as new infections. This is especially relevant given the recent approval of a lower cost treatment option.

We ask the DURB to rescind these unjust criteria, which prevent Vermonters from receiving medically necessary treatment. Removing the criteria will prevent needless suffering among beneficiaries and additional expense to taxpayers in the form of increased long-term health care costs and potential litigation.

If you have any questions or concerns please contact Julia Shaw at jshaw@vtlegalaid.org or (802) 383-2211.

Sincerely,

The Vermont Coalition for Access to HCV Treatment

s\ Julia Shaw, Policy Analyst, Office of the Health Care Advocate, Vermont Legal Aid

s\ Jay Diaz, Staff Attorney, ACLU of Vermont

s\ Peter Jacobsen, Executive Director, Vermont CARES

s\ Seth Lipschutz, Supervising Attorney, Prisoners' Rights Office

s\ Karen Peterson, Executive Director, AIDS Project of Southern Vermont

s\ Laura Byrne, Executive Director, HIV/HCV Resource Center

⁸ The AASLD/IDSA guidelines specifically deem the lack of access to specialists “a primary barrier to hepatitis C care.”

⁹ Belperio PS, Chartier M, Ross DB, Alaigh P, Shulkin D. *Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs*. *Ann Intern Med*. 2017 Oct 3;167(7):499-504. doi: 10.7326/M17-1073. Epub 2017 Sep 26. Available at <https://www.ncbi.nlm.nih.gov/pubmed/28973196>.