NVHR
National Viral Hepatitis Roundtable

May 20, 2022

Re: Hepatitis C Prior Authorization Criteria

Dear West Virginia Drug Utilization Review (DUR) Board,

The National Viral Hepatitis Roundtable (NVHR) appreciates the opportunity to submit comments on the prior authorization criteria for hepatitis C virus (HCV) treatment for West Virginia Medicaid beneficiaries. NVHR is a coalition of patients, health care providers, community-based organizations, and public health partners fighting for an equitable world free of viral hepatitis. In partnership with Harvard Law School's Center for Health Law and Policy Innovation (CHLPI), NVHR tracks HCV treatment access across the country through our Hepatitis C: State of Medicaid Access project (stateofhepc.org). Most recently we issued a progress report examining state-level trends in aligning treatment access through state Medicaid programs with evidence-based treatment guidelines.

As of January 2022, West Virginia was one of only eight states whose Medicaid program requires that patients abstain from drugs and alcohol for at least three months to receive HCV treatment. Additionally, West Virginia was one of only 14 states that requires that prescriptions be written by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician. We remain concerned that, in a state with high rates of hepatitis C infection, treatment is limited by these requirements.

We encourage the DUR Board to remove all sobriety restrictions. According to AASLD/IDSA guidance, *"Active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment."* Concerns that people who use drugs or alcohol may be nonadherent to DAA therapy or risk reinfection have been countered by several peer-reviewed studies, cited in the AASLD/IDSA guidance. The FDA-approved labeling for Epclusa and Mavyret also note their favorable safety and efficacy profiles among people who inject drugs. Moreover, requiring that patients demonstrate sobriety unfairly places additional burden on, and limits access to treatment for, persons with a comorbid medical condition, a violation of the Americans with Disabilities Act. CHLPI recently filed a complaint with the U.S. Department of Justice against Alabama's Medicaid program for illegally denying HCV treatment to people with substance use disorder by imposing the same abstinence requirement as is required by West Virginia Medicaid.

Some states have replaced their period of abstinence requirements with a requirement that clinicians screen and counsel patients on substance use. According to AASLD/IDSA guidance, *"There are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy."* Although well-intended, in practice, the inclusion of any criteria that references substance use, such as an attestation that a patient is enrolled in a substance use treatment program, invites the opportunity for discrimination against people who use substances due to non-evidenced based assumptions about non-adherence. While NVHR shares the goal of improving comprehensive care for people with substance use disorders, our position is that such screening and counseling requirements nevertheless pose undue barriers to accessing appropriate HCV treatment and their inclusion in Medicaid prior authorization criteria for HCV DAAs have not been demonstrated to increase quality nor comprehensiveness of care nor improve patient outcomes. As such, West Virginia should remove all substance use-related criteria for both initial treatment and retreatment.

We encourage the DUR Board to remove all prescriber restrictions. As with sobriety restrictions, state Medicaid programs have trended towards reconsidering and removing these requirements, recognizing that a broader range of health care providers has sufficient capability of managing HCV treatment and will be necessary to achieve population health goals of viral hepatitis elimination, particularly in areas experiencing shortages in

specialists. While West Virginia has systems in place to expand the number of midlevel practitioners and primary care physicians engaged in the treatment of HCV infection in accordance with AASLD/IDSA guidance, challenges remain. Specialist involvement results in delayed treatment initiation and poses additional burdens for rural communities who have limited transportation, particularly in a state that has a limited number of specialists. Specialist consultation for each prescription should not be a prior authorization requirement or a provider training program requirement. Rather training programs should support providers to independently prescribe HCV therapy by offering access to specialists when it is necessary to do so, such as in the infrequent case of decompensated cirrhosis. In nearly all states who have implemented provider training programs, the specialist consultation requirement has been removed safely and effectively. Thus, the removal of the requirement to involve a specialist in prescribing would maintain a support system while better utilizing scarce healthcare resources.

Fortunately, prescribing HCV treatment for non-cirrhotic and compensated cirrhotic patients has been made easy with the adoption of the AASLD/IDSA *Simplified Treatment Algorithm*. This systematic process walks prescribers step-by-step through evidence-based eligibility criteria, pretreatment assessments, and recommended regimens. The simplicity of the guidelines and pan-genotypic nature of preferred agents makes prior authorizations administratively burdensome and obsolete. A study in Rhode Island found that the complete prior authorization process from prescription to DAA acquisition took 45-120 minutes per patient, longer with a protracted denial and appeals process.[1] Pharmacists who are dispensing HCV treatment are trained and pharmacy software are designed to assess clinical appropriateness and drug interactions for all medications. Given the favorable safety profile of HCV treatment, having pharmacists manually review HCV prior authorizations is a costly, redundant, and inefficient process. Ultimately, prior authorizations place an undue administrative burden on prescribers, which takes away time and resources from other life-saving care and increases patients' risk of hepatocellular carcinoma, liver failure, and death.

Given that unsafe injection drug use drives most new HCV infections, scaling up HCV treatment among persons who use drugs represents an opportunity to positively impact HCV incidence. We look forward to the prospect of West Virginia making significant progress towards viral hepatitis elimination goals by removing all sobriety and prescriber restrictions and will monitor developments with great interest.

Sincerely,

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[1] Duryea P, Habchi J, Sprecht-Walsh S, Thomas AM, Bratberg J, et.al. A Modifiable Barrier to Hepatitis C Virus Elimination in Rhode Island: The Prior Authorization Process for Direct-Acting Antiviral Agents. R I Med J. 2020;103(5):41-44. http://rimed.org/rimedicaljournal/2020/06/2020-06-41-hcv-duryea.pdf.