NVHR
National Viral Hepatitis Roundtable

November 18, 2022

Re: Hepatitis C Prior Authorization Criteria

Dear Executive Director Snyder,

This letter is submitted on behalf of the National Viral Hepatitis Roundtable (NVHR) regarding the prior authorization criteria for hepatitis C virus (HCV) treatment for Mississippi 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 national report examining state-level trends in aligning treatment access through state Medicaid programs with evidence-based treatment guidelines.

As of November 2022, Mississippi is one of only five states whose Medicaid program requires that patients abstain from drugs and alcohol for at least six months to receive HCV treatment. Additionally, Mississippi is one of only seven states that require 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 urge Mississippi Medicaid to remove all substance use 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 Mississippi Medicaid. Alabama Medicaid recently announced the removal of all substance use restrictions.

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, Mississippi Medicaid should remove all substance use-related criteria for both initial treatment and retreatment.

We urge Mississippi Medicaid 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. Blanket requirements for 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. Fortunately, managing HCV treatment for non-cirrhotic and compensated cirrhotic patients has been streamlined 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 these 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]

Given the favorable safety profile of HCV treatment, cumbersome prior authorization 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 liver disease, liver cancer, and death. It is estimated that the annual per-patient HCV-related medical costs for non-cirrhotic disease, compensated cirrhosis, and end-stage liver disease is $6,043, $8,957, and $47,711, respectively.[2] A study by Roebuck et al. estimated the impact of DAA treatment on healthcare costs in Medicaid specifically, finding that a course of DAA treatment, on a per-person basis, can be expected to be fully offset by healthcare cost savings after 16 months, on average.[3] Thus, timely HCV treatment saves lives and tax dollars.

We look forward to the prospect of Mississippi making significant progress towards viral hepatitis elimination goals by removing all sobriety and prescriber restrictions and will monitor developments with great interest.

Sincerely,

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP
Director of Programs, National Viral Hepatitis Roundtable

CC Bureau of Pharmacy DOMPharmacyOffice@medicaid.ms.gov

[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.

[2] Cline M, Schweitzer K, Silseth S, Wang M. Projected U.S. national Hepatitis C treatment costs and estimated reduction to medical costs. Milliman (September 2021): https://www.milliman.com/-/media/milliman/pdfs/2021-articles/9-22-21-hcv-treatment-and-medical-cost-whitepaper.ashx.

[3] Roebuck MC, Liberman JN. Assessing the burden of illness in chronic hepatitis C and impact of direct-acting antiviral use on healthcare costs in Medicaid. Am J Manag Care. 2019;25:S131-S139.