



November 9, 2020

NC Medicaid
Department of Health and Human Services
2501 Mail Service Center
Raleigh, NC 27699-2501

Re: Prior Approval Criteria for Hepatitis C Virus Medications

To whom it may concern:

I am writing as a licensed pharmacist in North Carolina and as Policy Manager of the National Viral Hepatitis Roundtable (NVHR). NVHR is a national coalition of more than 500 members representing patients, providers, community-based organizations, advocates, and public health partners working together to eliminate viral hepatitis in the U.S.

While we applaud the efforts to increase access to treatment for NC Medicaid beneficiaries living with hepatitis C virus (HCV) by relaxing the prior approval criteria regarding substance use, we are concerned that the proposed criterion *"beneficiaries must agree to toxicology and/or alcohol screens as needed"* will result in an unnecessary barrier to care. Such criteria may dissuade patients from seeking care and interfere with clinicians' ability to provide the medical standard of care, thereby increasing patients' risk of death from liver disease. We request that any prior authorization criteria that do not align with the standard of care established by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) guidelines be removed.

Requirements that screening for substance or alcohol use be performed are not based on clinical evidence. According to IDSA/AASLD 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."* Concerns that persons who use drugs or alcohol may be nonadherent to HCV DAA therapy or risk reinfection have been countered by several peer-reviewed studies, cited in the AASLD/IDSA guidance. By creating additional barriers for patients with substance use disorders, we are forced to discriminate against patients due to comorbid medical diagnoses (a violation of disability rights) and forced to provide subpar care, a violation of the oath to *do no harm*.

We urge you to remove the requirement that *"beneficiaries must agree to toxicology and/or alcohol screens as needed"* and any requirement regarding substance use screening, in accordance with the AASLD/IDSA guidelines. We appreciate your actions to date and your attention to this matter. NVHR stands ready to improve health outcomes for North Carolinians living with HCV. Please do not hesitate to reach out if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Adrienne Simmons", written over a white background.

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP
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