NVHR
National Viral Hepatitis Roundtable

January 26, 2022

Re: Proposed clinical prior authorization criteria for hepatitis C direct-acting antivirals (DAAs)

The National Viral Hepatitis Roundtable (NVHR) appreciates the opportunity to submit comments on the proposed clinical criteria for the treatment of hepatitis C virus (HCV) for Iowa 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, NVHR tracks and documents 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, Iowa was one of only eight states whose Medicaid program requires a period of abstinence as part of HCV DAA prior authorization criteria. We commend the DUR for moving to remove this detrimental barrier to appropriate, evidence-based care, but we have concerns about the proposed approach and share the following recommendations:

Remove criteria related to substance use disorder
Medicaid programs in 13 states, along with the District of Columbia, include prior authorization criteria similar to those under consideration which mandate some form of substance use screening or counseling. Although well-intended, in practice, the inclusion of this criteria 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, Iowa should remove substance use-related criteria for both initial treatment and retreatment.

Remove criteria related to adherence
Furthermore, adherence criteria, including the use of psychosocial readiness tools, have not been associated with improved adherence or patient outcomes.[1] While *some* adherence is required for cure, real-world investigations support that even with imperfect adherence, individuals can achieve high rates of sustained virologic response.[2,3] The assessment of readiness and adherence once again creates the possibility for discrimination; poorly validated adherence assessments disproportionately affect marginalized communities such as people who use drugs, despite evidence that these communities successfully complete HCV treatment. While we support voluntary self-assessment of adherence as a

[1] Bosch-Capblanch X, Abba K, Prictor M, Garner P. Contracts between patients and healthcare practitioners for improving patients' adherence to treatment, prevention and health promotion activities. Cochrane Database Syst Rev. 2007;(2):CD004808. doi(2):CD004808. doi: 10.1002/14651858.CD004808.pub3 [doi]
[2] Rosenthal ES, Silk R, Mathur P, et al. Concurrent initiation of hepatitis C and opioid use disorder treatment in people who inject drugs. *Clin Infect Dis*. 2020;71(7):1715-1722. doi: 10.1093/cid/ciaa105 [doi].
[3] Norton BL, Akiyama MJ, Agyemang L, Heo M, Pericot-Valverde I, Litwin AH. Low adherence achieves high HCV cure rates among people who inject drugs treated with direct-acting antiviral agents. *Open Forum Infect Dis*. 2020;7(10):ofaa377. doi: 10.1093/ofid/ofaa377 [doi].

tool to identify and address barriers, adherence should not be reflected in the prior authorization process. As such, Iowa should remove criteria related to adherence and readiness.

Remove prescriber restrictions

While not on the agenda for discussion at the February meeting, we would also encourage the DUR at a future meeting to review and revise HCV DAA prior authorization requirements stipulating that HCV treatment be provided by designated specialists. 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. Fortunately, prescribing HCV treatment for non-cirrhotic and compensated cirrhotic patients has been made easy with the adoption of the American Association for the Study of Liver Disease and the Infectious Disease Society of America (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.[4] **Ultimately NVHR encourages Iowa to follow in the footsteps of the 11 state Medicaid programs who have removed prior authorizations for most patients.**

Lastly, we encourage consideration on the part of the state Medicaid program in rapid and thorough dissemination to providers and patients of any changes in HCV prior authorization that result from this meeting. As part of our work, NVHR recently released a brief toolkit [link to PDF] on Best Practices for Sharing Policy Updates Affecting the Viral Hepatitis Community which may be of interest for efforts to disseminate information to health care providers and Medicaid beneficiaries about the changes in Medicaid access to antiviral agents for HCV treatment. NVHR stands ready to make ourselves available if we can be of any assistance around disseminating updates or other implementation considerations.

We look forward to the prospect of Iowa making significant progress towards viral hepatitis elimination goals through this policy change and will monitor developments with great interest.

Sincerely,

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[4] 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.