



June 7, 2024

B. Kaye Hayes, MPA
Deputy Assistant Secretary for Infectious Disease
U.S. Department of Health and Human Services
Tower Building
1101 Wootton Parkway
Rockville, MD 20852

RE: Public Comments on Potential Viral Hepatitis Quality Measures in Medicaid

Dear Ms. Hayes,

On behalf of the Hepatitis B Foundation, a national nonprofit organization dedicated to finding a cure and improving the quality of life for people affected by hepatitis B worldwide, Hep B United, our national coalition of nearly 60 local and national organizations across the United States, and the 21 undersigned organizations, we greatly appreciate the opportunity to provide public comment on potential viral hepatitis quality measures in Medicaid.

We commend the Department of Health and Human Services (HHS) for recognizing the importance of utilizing all available resources to eliminate viral hepatitis. Quality measures will play a critical role in the implementation of the Centers for Disease Control and Prevention's (CDC) recently updated adult hepatitis B screening recommendations and ensuring that people living with hepatitis B are linked to the care and treatment that they need.

We support the adoption of a hepatitis C screening and treatment initiation measure within state Medicaid programs and strongly encourage HHS to also propose feasible quality measures for hepatitis B screening, management, and treatment.

Multiple health centers and health systems across the country have proven that implementing measures for hepatitis B services is practical, feasible, and actionable with proper guidance. North East Medical Services, a federally qualified health center in California, and Cooperman Barnabas Medical Center, a large health system in New Jersey, are two examples of institutions that have successfully enacted widespread hepatitis B service measures to identify new cases of hepatitis B and link them to care. These groups demonstrate that commonly collected hepatitis B information can provide a sound basis for successful measures.

We would like to focus our attention on questions two and three from the request for public comment:

2. What other measures should HHS consider for testing and proposal to the Medicaid Adult Core Set (*i.e.*, hepatitis B screening, hepatitis B linkage to care, hepatitis C sustained virological response (SVR))? Please provide support for how that measure is clinically meaningful, feasible, and actionable for state Medicaid programs. What data source or data element can be utilized to calculate the measure?

We strongly suggest that HHS consider measures for hepatitis B screening, hepatitis B linkage to care, and hepatitis B treatment, for testing and proposal to the Medicaid Adult Core Set.

Below, we have included potential data elements that can be utilized to capture the suggested hepatitis B quality measures:

Hepatitis B Screening Measure

- One-time hepatitis B surface antigen (HBsAg) test for all adults aged 18 and over
- One-time triple panel (HBsAg, hepatitis B surface antibody (HBsAb), hepatitis B core antibody (HBcAb)) for all adults aged 18 and over

HBsAg has long been recognized as clinically meaningful as it detects the actual presence of the hepatitis B virus (HBV) and determines if a person has an active infection. This is often the first, if not the only test, that is run by providers to assess clinical steps and develop a plan of action.

HBsAb and HBcAb are also clinically significant. Along with HBsAg, HBsAb and HBcAb help assess a person's complete hepatitis B status, and can determine whether a person is currently infected, has recovered from a past infection and needs to be aware of the risk of reactivation, or needs vaccination. Together, these tests provide the most comprehensive picture of a person's hepatitis B status and allow for the provider to create the most accurate plan of action.

While a one-time hepatitis B triple panel test (HBsAg, HBsAb, and HBcAb) is recommended for all adults and essential to understanding a person's hepatitis B status, we understand that there are barriers to collecting all three tests. Therefore, we strongly encourage HHS to test a one-time HBsAg test and a one-time triple panel test to determine which one would be most feasible.

Hepatitis B Linkage to Care Measure

- HBV DNA test once a year for all HBsAg positive individuals

HBV DNA is routinely captured as part of follow-up tests for people living with hepatitis B and is one of the main determinants of treatment. Additionally, routine HBV DNA tests are essential to tracking a person's liver health, as HBV DNA can fluctuate over time. HBV DNA tests are

recommended by American Association for the Study of Liver Diseases ¹ (AASLD) and the World Health Organization ² (WHO) as a baseline for hepatitis B management and treatment decisions.

Hepatitis B Treatment Measure

- Antiviral prescription for all HBsAg positive individuals that have an ICD-code for HBV-related cirrhosis

A quality measure tracking antiviral prescriptions for those who have HBV-related cirrhosis is an effective measurement as it excludes people who *might* be considered for treatment at the discretion of their provider and focuses on those for whom treatment is recommended for based upon current treatment guidelines ¹.

3. Would it be feasible and clinically meaningful to implement a hepatitis B screening, hepatitis C screening and hepatitis C treatment initiation quality measure within state Medicaid programs? If you represent a state Medicaid program, what is the likely uptake of this measure?

We believe it would be feasible and clinically meaningful to implement quality measures focused on hepatitis B screening, linkage to care, and treatment. Data collection for our proposed hepatitis B quality measures could include several methods. Medicaid currently collects data for, and reimburses, multiple hepatitis B related data elements, including HBsAg and HBV DNA, and antiviral prescriptions.

With the release of the new CDC adult hepatitis B vaccine and screening recommendations ^{3,4}, we are also seeing more large health systems integrating hepatitis B services into their electronic health record (EHR) systems. This could be an avenue for multiple data sources, including EHR data and HIE data from hospitals and clinics, as large health systems link individuals to care and conduct subsequent testing.

¹ Terrault, Norah A. *,1; Lok, Anna S. F.2; McMahon, Brian J.3; Chang, Kyong-Mi4; Hwang, Jessica P.5; Jonas, Maureen M.6; Brown, Robert S. Jr7; Bzowej, Natalie H.8; Wong, John B.9. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Clinical Liver Disease* 12(1):p 33-34, July 2018. | DOI: 10.1002/cld.728

² Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.

³ Weng MK, Doshani M, Khan MA, et al. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:477–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7113a1>.

⁴ Conners EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023. *MMWR Recomm Rep* 2023;72(No. RR-1):1–25. DOI: <http://dx.doi.org/10.15585/mmwr.rr7201a1>

Additionally, major laboratories such as Quest and LabCorp now have an option for providers and public health workers to choose the hepatitis B triple panel test, making labs another ideal data source to support a hepatitis B screening quality measure.

Thank you again for this opportunity to provide input on potential viral hepatitis quality measures in Medicaid. Including hepatitis B in proposed Medicaid quality measures is critical to ensuring that we are capturing new infections, and that people living with chronic hepatitis B receive the care that they need. There is great momentum and effective tools to eliminate viral hepatitis in the U.S. and we look forward to working with federal and community partners to achieve national and global elimination goals. Please do not hesitate to contact Michaela Jackson, Program Director, Prevention Policy (michaela.jackson@hepb.org) with any questions or to request additional information.

Sincerely,

American Academy of HIV Medicine
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific American Medical Student Association (APAMSA)
Asian Pacific American Medical Student Association at UTMB Galveston
Association of Asian Pacific Community Health Organizations (AAPCHO)
Caring Ambassadors Program
Charles B. Wang Community Health Center, Inc.
Empire Liver Foundation
Global Liver Institute
Hep B United
Hep B United Philadelphia
Hep Free Hawai'i
Hepatitis B Foundation
HIV+Hepatitis Policy Institute
Leduc Medical Group
National Pharmaceutical Association (NPhA)
National Viral Hepatitis Roundtable (NVHR)
New Jersey Hepatitis Elimination Coalition
North East Medical Services
Student National Pharmaceutical Association (SNPhA)
The African Family Health Organization (AFAHO)
Wendy Lo Consulting, LLC