

May 28, 2015

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: A Formal Request for a National Coverage Determination for Screening for Hepatitis B Virus Infection Among High Risk Individuals

Dear Ms. Jensen:

The undersigned organizations are writing with a formal request for a Medicare National Coverage Determination (NCD) for Screening for Hepatitis B Virus (HBV) Infection.

Specifically, we ask that the Centers for Medicare & Medicaid Services (CMS) provide hepatitis B screening coverage for Medicare beneficiaries who are at high risk for HBV infection as defined by the United States Preventive Services Task Force (USPTF), including those born in countries and regions with a high prevalence of HBV infection ($\geq 2\%$); people born in the United States who were not vaccinated as infants and whose parents were born in a region with a very high prevalence of hepatitis B infection ($\geq 8\%$), such as sub-Saharan Africa, and southeast and central Asia; HIV-positive individuals; injection drug users; men who have sex with men and household partners and sexual partners of people who are HBV infected.

An estimated 700,000 to 2.2 million people in the United States have chronic HBV infection, according to sources cited in the USPSTF's recommendation statement. Alarming, an estimated 67% are unaware of their chronic HBV infection, placing them at significant risk for advanced liver disease, liver cancer, and/or in need of a liver transplant. HBV is the leading cause of primary liver cancer (hepatocellular carcinoma, HCC), and remains the only cancer that continues to rise in both incidence and mortality among men and women in the U.S. Both chronic HBV and HCC disproportionately affect Asians and Pacific Islanders (API), who make up 50% of the HBV infection burden in the U.S., and have liver cancer rates that are up to 13 times higher than Caucasian populations in the U.S. In fact, HCC has recently become the #1 cause of cancer death in Vietnamese men in the U.S.

There are significant barriers to HBV screening in the U.S., including the silent nature of the disease and the lack of HBV screening currently being conducted at the primary care level. Increasing HBV screening is critical to saving lives, as those who are diagnosed can take advantage of lifestyle changes and FDA approved medications that can help prevent end-stage liver disease and liver cancer. In addition, many new treatments are now in development promising a bright future for preventing morbidity and mortality among infected individuals.

Under the authority granted by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS has the authority to cover preventive services that have received an "A" or

“B” grade from the USPSTF after a service undergoes an NCD. In May, 2014, the USPSTF updated its HBV screening recommendations and issued a “B” grade for testing those at risk for HBV infection.

The revised USPSTF hepatitis B screening recommendations are a significant advance in efforts to identify those with chronic HBV and link them to care. However, Medicare coverage currently doesn’t include HBV screening for any population. This lack of coverage does not reflect current science or recommendations from the nation’s leading medical and public health experts. We urge CMS to initiate an NCD consideration of hepatitis B screening under the “Preventive and Screening Services” category in light of the new evidence-based recommendations.

Adoption of USPSTF’s revised grade for HBV testing would allow Medicare to play a crucial role in helping to identify those who are unaware they are HBV positive. Of the identified and reported cases of HBV in the U.S. between 2007 and 2012, 15.6% were over the age of 65 and part of the Medicare covered population. Seniors who are Medicare beneficiaries and are unaware of their HBV infection are likely to have been living with the disease for a very long time and it is vital to ensure they are linked to care and treatment before they develop advanced liver disease or liver cancer. Additionally, those with end stage renal disease are at higher risk for HBV infection and are less likely to respond to the HBV vaccine, and would benefit greatly from screening and subsequent linkage to care.

By including the USPSTF hepatitis B screening recommendations under Medicare Preventive Services, CMS would align its policy not only with the science, the Centers for Disease Control and Prevention (CDC) and the USPSTF, but also with the goals of the federal government’s Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis, and would lead to improved health outcomes for Medicare beneficiaries, many of whom face significant disparities in health care.

We greatly appreciate your consideration of this request. If you have any questions, or need additional information, please contact Chari Cohen at (215) 489-4900 or chari.cohen@hepb.org or Ryan Clary at (415) 235-8593 or rclary@nvhr.org.

Sincerely:

Association of Asian Pacific Community Health Organizations (AAPCHO)
Hep B United
Hepatitis B Foundation
National Task Force on Hepatitis B: Focus on Asian and Pacific Islander Americans
National Viral Hepatitis Roundtable

Co-signed:

30 for 30 Campaign
ADAP Advocacy Association (aaa+)
Africans for Improved Access

African Services Committee
AIDS United
American Association for the Study of Liver Diseases
American Liver Foundation
Asian American Health Coalition (HOPE Clinic)
Asian American Research Center on Health (ARCH)
Asian Health Center – St. Barnabas Medical Center
Asian Health Coalition
Asian Pacific Community in Action
Asian Pacific Liver Center
Asian Pacific Health Foundation
Asian Services in Action (ASIA)
Association of Asian Pacific Community Health Organizations (AAPCHO)
California Center for Rural Policy, Humboldt State University
California Hepatitis Alliance
Caring Ambassadors Program
Charles B. Wang Community Health Center
Chinese American Medical Society – Greater Boston Chapter
CHIPO: The Coalition Against Hepatitis for People of African Origin
CHOW Project
Cincinnati Exchange Project
CISC
Community Access National Network (CANN)
Dallas – Ft. Worth Hepatitis B Free Project
Filipino American Community Health Initiative of Chicago (FACHIC)
Frederick County Hepatitis Clinic, Inc.
Global Liver Institute
Harm Reduction Coalition
Hep B Free Las Vegas
Hep B Free Los Angeles
Hep B Project
Hep B United Philadelphia
Hep B United Twin Cities
Hep C Alliance
Hep C Connection
Hepatitis B Coalition of Washington
Hepatitis B Initiative of Washington, DC
Hepatitis C Association
Hepatitis C Support Project
Hepatitis Education Project
Hepatitis Foundation International, Inc.
HIV Medicine Association
International Community Health Center (IHC)
Lao Assistance Center of MN
Laotian American National Alliance, Inc. (LANA)
Life Beyond Hepatitis C. com

MESA Public Health Associates
Midwest Asian Health Association
Multicultural AIDS Coalition
National Alliance for Medication Assisted Recovery
National Alliance of State and Territorial AIDS Directors (NASTAD)
National Asian American Pacific Islander Mental Health Association
National Asian Pacific American Families Against Substance Abuse
National Association of County and City Health Officials (NACCHO)
National Center for Transgender Equality
New Jersey Hepatitis B Coalition
North East Medical Services
NYC Hepatitis B Coalition
NYU Center of the Study of Asian American Health
Ohio Asian American Health Coalition
Project Inform
Project Prevention
Southern Arizona AIDS Foundation
Tacoma-Pierce County Health Department
The AIDS Institute
The Hepatitis C Mentor and Support Group (HCMSG)
TheSTDProject.com
Treatment Action Group
Trust for America's Health
Vietnamese American Medical Association (VAMA)
Vietnamese Community Health Promotion Project
Vietnamese Social Services of Minnesota
Working Partnerships USA