



June 9, 2023

Karen S. Lynch, President and Chief Executive Officer
Dr. Sree Chaguturu, Executive Vice President and Chief Medical Officer
T.J. Crawford, Vice President, Head of External Affairs
CVS Health®

Re: Removal of Vemlidy from CVS Health Formularies

Dear Ms. Lynch, Dr. Chaguturu, and Mr. Crawford,

Hep B United is a national coalition of over 50 organizations in 27 states and D.C. dedicated to reducing the health disparities associated with hepatitis B by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the United States. Recently, an alarming number of our community members have been notified by Aetna CVS Health and CVS Caremark that their insurance plan will no longer include Vemlidy (tenofovir alafenamide, TAF) as a covered medication for treating chronic hepatitis B. Hep B United and the undersigned 42 organizations strongly urge CVS Health to reconsider this decision. Every patient with hepatitis B should have access to medications and treatment services that enable them to actively manage and control their condition. Patients should not be abruptly forced to switch medications due to non-medical reasons, which disrupt the continuity of care.

Hepatitis B is the most common liver infection in the world. In the U.S., up to 2.4 million people are living with chronic hepatitis B infection. Chronic hepatitis B infection can lead to serious complications, including liver failure, liver cancer, scarring of the liver (cirrhosis) and premature death. Significant disparities are associated with hepatitis B. Asian American, Pacific Islander, and African communities are disproportionately affected by the virus, with these communities comprising up to 80% of all chronic hepatitis B infections in the U.S.

While there is currently no cure for hepatitis B, it is preventable by vaccination and treatable with antiviral medications that can suppress the virus and reduce the risk of liver damage and liver cancer. It is important to provide access to all effective FDA-approved medication options for hepatitis B, which are typically taken long-term and are critical for improving and prolonging the lives of people with chronic active hepatitis B infection. By removing Vemlidy from its formularies, Aetna CVS Health and CVS Caremark will effectively worsen the quality of life and future health outcomes of thousands of Americans who may need and/or rely on this drug to manage their hepatitis B and prevent cirrhosis and liver cancer.

Additionally, there are individuals for whom Vemlidy (tenofovir alafenamide, TAF) is the safest hepatitis B treatment option due to co-morbidities including kidney disease and osteoporosis. TAF is less likely to cause adverse bone mineral density and renal dysfunctions than tenofovir disoproxil fumarate (TDF).^{i,ii,iii,iv}

Furthermore, the timing of this formulary plan change, which comes in the middle of the year, leaves beneficiaries who were prescribed Vemlidy with no opportunity to choose a different insurance plan that covers their medication. Patients who are stable on their medication may now have to switch to a lower-cost and possibly less effective product for purely financial reasons. This practice is known as “non-medical switching,” when insurers or pharmacy benefit managers (PBMs) make changes to a formulary primarily due to financial negotiations with manufacturers in exchange for greater market share. Non-medical switching is associated with poor health outcomes. A study by the Alliance for Patient Access found that patients who had been switched off

their preferred medication experienced complications from the new medication; one in 10 reported being hospitalized for complications after the switch; and approximately 40% stopped taking their medication completely.^v Moreover, a 2017 study concluded that cost-motivated medication switches result in higher non-drug medical costs, such as doctor office visits, hospitalizations and ER visits.^{vi}

While we understand that CVS Health needs to control costs, it is imperative that formulary decisions be a collaborative effort between insurers, PBMs, clinicians and, most importantly, patients. We strongly believe that these decisions should not solely be based on cost-effectiveness and should be supported by verifiable, scientific evidence. We believe that all health insurance plans and PBMs have an obligation to consider the health risks of their decisions above any other reason. We also strongly oppose any formulary changes during the benefit year, when patients have little to no recourse in finding different coverage options.

We therefore urge CVS Health to reconsider its decision and immediately reinstate Vemlidy back on its formulary plan. We appreciate your attention and consideration. Please contact Michaela Jackson (michaela.jackson@hepb.org) or Rhea Racho (rhea.racho@hepb.org) with any questions or comments.

Sincerely,

Hep B United
Hepatitis B Foundation
ADAP Advocacy Association
ADILO
African Health Coalition
AIDS United
American Academy of HIV Medicine
American Liver Foundation
Any Positive Change Inc
Asian American Community Services
Asian Center - Southeast Michigan
Asian Liver Center at Stanford University
Asian Pacific Islander Coalition of Washington
Association of Asian Pacific Community Health Organizations (AAPCHO)
Bienestar Human Services
Caring Ambassadors Program, Inc.
Central Outreach Wellness Center
Charles B. Wang Community Health Center
CHIPO
Community Access National Network
Community Liver Alliance
Community Welfare Services of Metro Detroit
DAP Health
Global Liver Institute
GREAT LAKES PEACE CENTRE
Hawaii Health & Harm Reduction Center

Hepatitis C Mentor and Support Group-HCMSG
HIV+Hepatitis Policy Institute
Jeneso Development Initiative
Lifeline Health, Inc.
Midwest Asian Health Association
Mwatumwaya Rehabilitation Centre
NASTAD
National Viral Hepatitis Roundtable (NVHR)
NJ Viral Hepatitis Coalition
PlusInc
Robert G Gish Consultants LLC
San Francisco AIDS Foundation
San Jose Gastroenterology
SF Hep B Free - Bay Area
The African Family Health Organization (AFAHO)
The AIDS Institute
TruCare Internal Medicine & Infectious Diseases

ⁱ Seto WK et al. 2018. Improved Bone Safety of Tenofovir Alafenamide Compared to Tenofovir Disoproxil Fumarate Over 2 Years in Patients With Chronic HBV Infection. *Clin Gastroenterol Hepatol*. S1542-3565(18)30633-5.

ⁱⁱ Agarwal K et al. 2018. 96 weeks treatment of tenofovir alafenamide vs. tenofovir disoproxil fumarate for hepatitis B virus infection. *J Hepatol*. 68(4):672-681.

ⁱⁱⁱ Buti M et al. 2016. Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of patients with HBeAg-negative chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet Gastroenterol Hepatol*. 1(3):196-206.

^{iv} Chan HL et al. 2016. Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of HBeAg-positive chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet Gastroenterol Hepatol*. 1(3):185-195.

^v Alliance for Patient Access, Qualitative Impact of Non-Medical Switching Report, February 2019, http://allianceforpatientaccess.org/wp-content/uploads/2019/02/AfPA_Qualitative-Impact-of-Non-Medical-Switching_Report_Feb-2019.pdf

^{vi} Institute for Patient Access, Cost-Motivated Treatment Changes & Non-Medical Switching Commercial Health Plans Analysis, August 2017, https://instituteforpatientaccess.org/wp-content/uploads/2018/05/IfPA_Non-Medical-Switching-Commercial-Claims-Analysis_Aug-2017.pdf