



July 7, 2022

Sir Andrew Witty
Chief Executive Officer
UnitedHealth Group

Re: Removal of Vemlidy from Optum's Formulary

Dear Sir Witty,

As Optum is instituting changes to its formulary plan, Hep B United and the undersigned 36 organizations strongly urge you to reconsider the decision to remove Vemlidy as a covered medication for treating chronic hepatitis B. 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 formulary plan, Optum 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). This is true not only for patients at risk of these complications, but the overall hepatitis B patient population as demonstrated in clinical studies comparing TAF and TDF.^{1,2,3,4}

¹ 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.

² 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.

³ 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.

⁴ 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.

The timing of Optum’s 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.⁵ 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.⁶

Hep B United is a national coalition of over 50 organizations in 24 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. While we understand that Optum needs to help control healthcare 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 a strong 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 Optum to reconsider its decision and immediately reinstate Vemlidy back on its formulary plan. We appreciate your attention and consideration. Please contact Rhea Racho (rhea.racho@hepb.org) with any questions or comments.

Sincerely,

Hep B United
Hepatitis B Foundation
Association of Asian Pacific Community Health Organizations (AAPCHO)
African Services
American Liver Foundation
Any Positive Change Inc
Asian American Community Services
Asian Center - Southeast Michigan
BYE CIS
Caring Ambassadors Program
City of York- Bureau of Health
Community Health Action of Staten Island
Community Liver Alliance
Downtown Renal Medicine, PC

⁵ 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

⁶ 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

GREAT LAKES PEACE CENTRE
Greater Philadelphia Health Action
Hep B Free Los Angeles
Hep B United Philadelphia
Hep Free Hawai'i
Hepatitis B Advocacy Initiative
HepTREC at Prevention Point Philadelphia
HIV + Hepatitis Policy Institute
Knight Technology Group
Korean Community Services of Metropolitan New York, Inc. (KCS)
Merakey
Mercy Housing and Human Development
NASTAD
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable (NVHR)
Rise Against Hepatitis Global initiative
SF Hep B Free - Bay Area
Taiwan Hepatitis Information & Care Association (THICA)
The AIDS Institute
The Hepatitis C Mentor and Support Group-HCMMSG
The National Organisation for People Living with Hepatitis B
Treatment Action Group
VTC APAMSA

cc:

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Cory B. Alexander
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