Hep B United™
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October 20, 2022

Savitha R. Vivian, PharmD
SVP, Clinical and Formulary Services
Optum

Re: Removal of Vemlidy from Optum's Formulary

Dear Dr. Vivian,

We are disappointed in Optum's response to our previous letter regarding the removal of Vemlidy as a covered medication for treating chronic hepatitis B from Optum's formulary. We strongly disagree with this decision and once again urge Optum to reconsider and immediately reinstate Vemlidy back on its formulary plan. In response to your letter, on behalf of the undersigned 52 organizations, we have compiled additional data and comments below for your consideration.

Data Supports Vemlidy's Clinical Efficacy and Better Safety Related to Renal or Bone Issues

As stated in our previous letter, 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]

There are large controlled clinical studies that showed similar antiviral efficacy[2,3,4] and significantly better renal and bone safety for Vemlidy compared to tenofovir.[5,6] In phase III clinical trials, patients receiving TAF had smaller mean losses in bone mineral density in hip and spine compared with patients receiving TDF.[7] HBeAg+ patients receiving TAF had a lower mean increase in creatinine compared with those receiving TDF. This was a critical study, one that was taken seriously by FDA, in support of Vemlidy's FDA product label.[7] Other studies have shown that when patients were switched from TDF to TAF, renal and bone disease induced by TDF improved.[8] Though these assessments are not long-term, clinical trial results that show drug toxicities for specific organ systems are typically assumed to be associated with chronic toxicities, for drugs that require chronic dosing (such as those for long-term hepatitis B treatment).

Additionally, while overall, clinical studies have shown equivalent efficacy between TAF and TDF in meeting clinical endpoints for control of chronic hepatitis B infection, one large study did see a higher proportion of patients treated with TAF who achieved normalization of ALT at 96 weeks (80.9% versus 71.1%), and this difference was statistically significant.[9]

Hepatitis B Treatment is a Long-Term, Lifelong Commitment

Every patient with chronic hepatitis B (CHB) should have access to medications and treatment services that enable them to actively manage and control their condition. With no cure for hepatitis B, it is critical for patients to have access to all effective FDA-approved medication options, which are typically taken long-term and are

critical to suppressing the virus, reduce the risk of liver damage and liver cancer, and thereby improve and prolong the lives of people with chronic active hepatitis B infection.

Your statement that "patients who have started treatment on Vemlidy will be able to complete course of therapy" is not definitive and fails to provide long-term assurance to people living with CHB, given that currently available treatments typically require a lifelong course of therapy once initiated. If an individual begins taking medication for hepatitis B, they will likely never be advised to stop treatment – not until a future cure for hepatitis B becomes available, which would allow for a finite course of treatment. People living with CHB should not have to face a lifelong uncertainty that their health insurance plan could change again at any time and no longer cover the cost of their prescribed, life-saving medication. **At the very least, if Optum continues to exclude Vemlidy as an option for new prescriptions, we ask that all patients who have already started Vemlidy retain full coverage for as long as their clinician prescribes Vemlidy as the best option for their hepatitis B treatment. We also urge Optum to clearly communicate this "grandfathering" to ALL people who have already started on Vemlidy.**

Formulary Restrictions Negatively Impact Patient Outcomes

In addition to the poor health outcomes associated with "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 – referenced in our previous letter, other types of formulary restrictions including step therapy and prior authorization similarly create unnecessary barriers and disrupt the continuity of care, leading to negative effects on patient health:

- A 2018 analysis highlighted that step therapy goes against the findings of precision medicine, which states that medical plans work best when they account for a patient's unique need and do not treat patients through a "one-size fits all" approach.[10]
- A 2017 literature review found that of all of the outcome types (164 outcomes across the patient, health care resource utilization, and economic outcome categories), the majority were negatively associated with formulary restrictions (medication adherence [70.6%], clinical outcome [91.7%], patient-reported outcomes [treatment satisfaction, 100%], health care resource utilization [outpatient visits, 82.4%, and hospitalization, 64.7%], and economic outcomes [medical costs, 66.6%]).[11]
- Another literature review concluded "there is a strong evidence base demonstrating a negative correlation between formulary restrictions on medication adherence outcomes," with 68.3% of negative outcomes being associated with medication adherence.[12]

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. 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
AIDS Alabama

AIDS United
American Liver Foundation
Any Positive Change Inc
Asian American Community Services
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific Health Foundation
BYE CIS
Caring Ambassadors Program
Charles B. Wang Community Health Center
City of York- Bureau of Health
Clary Strategies
Community Health Action of Staten Island
Community Liver Alliance
Community Welfare Services of Metro Detroit
Downtown Renal Medicine, PC
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
Hepatitis B Initiative of Washington, D.C.
HepTREC at Prevention Point Philadelphia
HIV + Hepatitis Policy Institute
Knight Technology Group
Korean Community Services of Metropolitan New York, Inc. (KCS)
La Maestra Community Health Centers
Merakey
Mercy Housing and Human Development
Midwest Asian Health Association
NASTAD
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable (NVHR)
North East Medical Services
Rise Against Hepatitis Global initiative
Robert G Gish Consultants LLC
SF Hep B Free - Bay Area
Taiwan Hepatitis Information & Care Association (THICA)
The AIDS Institute
The Hepatitis C Mentor and Support Group-HCMSG
The National Organisation for People Living with Hepatitis B
Treatment Action Group
Vietnamese American Cancer Foundation (VACF)
Virginia Hepatitis Coalition
VTC APAMSA

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