HIV+HEP
POLICY INSTITUTE

April 24, 2024

Maryland Prescription Drug Affordability Stakeholder Council
18900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Stakeholder Council members,

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Given the important nature of prescription drugs to the life-saving treatment of HIV and hepatitis B, and now, the cure of hepatitis C and the prevention of HIV, affordable access to prescription medications is extremely critical to the patients we serve.

While we support the Maryland Prescription Drug Affordability Board (PDAB) goal of addressing affordability of treatments, we believe the current approach of the Board to set upper payment limits (UPLs) on the proposed drugs for review will neither benefit patient health outcomes nor result in reduced out-of-pocket costs for patients.

As the Board considers the affordability of an initial list of eight prescription drugs, including a treatment for HIV, we urge the Board and Stakeholder Council to consider the unique needs of the patient populations impacted by each treatment and the specific public health implications of interruptions to treatment.

Unique Perspectives of People Living With HIV

As of 2022, over 31,000 Marylanders were living with HIV and 61 percent of those diagnosed were virally suppressed, meaning they cannot transmit the virus.[1] At both the individual and broader community levels, achieving viral suppression is critical to end the epidemic and address the impacts of HIV as a public health issue in Maryland and beyond. The U.S. Department of Health and Human Services (HHS) initiative, *Ending the HIV Epidemic in the U.S.,* launched in 2019 to reduce HIV infections nationwide starting with 57 priority jurisdictions, with three of those Phase 1 jurisdictions in Maryland (Prince George's County, Baltimore City, and Montgomery County).[2] These jurisdictions account for more than two-thirds of all diagnosed

[1] Maryland HIV County Overview Dashboard
[2] Ending the HIV Epidemic: A Plan for America

cases of HIV in the state. Along with diagnoses being concentrated by location, Black communities are disproportionately impacted–with Black patients accounting for over 70 percent of both new diagnoses and deaths due to HIV in the state.[3]

Drug pricing policy must also respect patient choice and providers' clinical judgment. Patients work closely with their health care providers to identify the best course of treatment for them. Each individual living with HIV has unique needs based on a wide variety of circumstances. Treatments outside of those recommended by their provider may not be as effective or result in side effects that negatively impact their health outcomes. For some patients, it may take years of trial and error to find a medication that works for them and their lifestyle. Interruptions to treatment for any reason–such as being unable to access a medicine due to cost or if a provider can no longer afford to stock and store the treatment–can have serious negative implications for those living with HIV. Even a brief delay in treatment can trigger viral resistance, which renders that medication, and the entire class of medications like it, an ineffective option for that patient.

Despite the significant potential consequences of setting UPLs on medicines to treat HIV and other complex conditions, the Maryland PDAB has yet to release its UPL action plan–a roadmap for the Board's decisions to set prices for the prescription drugs selected for review. To date, patients, providers, and caregivers have not been given the opportunity to review or provide input on the action plan–leaving them in the dark about how a UPL may impact access to care.

Existing Assistance Programs Help Link People Living With HIV to Treatment & Care

The inclusion of a treatment for HIV on the list of drugs selected for affordability review by the Maryland PDAB fails to recognize the role of existing state, federal, and industry assistance programs in increasing access to treatments for patients. Patients within the Board's scope–those on Medicaid and state-purchased plans–typically pay between zero and three dollars out-of-pocket for their treatments.

In 2020, the Maryland Insurance Administration (MIA) capped copay costs for drugs prescribed to treat HIV and AIDS for all insurance plans regulated by the agency.[4] Additional patient assistance programs, such as those administered by biopharmaceutical manufacturers and the AIDS Drug Assistance Program (ADAP), provide financial support around the costs of HIV treatment to those who qualify.[5] According to IQVIA, in 2022 manufacturer copay assistance brought down patient costs by nearly $19 billion and accounted for 23 percent of their out-of-pocket costs.[6] According to a study done by the Partnership to Fight Chronic Disease (PFCD) and Avalere, most payers do not anticipate that UPL-related savings will be passed on to patients in

[3] Maryland HIV County Overview Dashboard
[4] Maryland Attorney General: Patient Copayment and Coinsurance Costs Are Capped at $150 a Month for Specialty Drugs and Drugs that Treat Diabetes, HIV, or AIDS
[5] AIDS Drug Assistance Program: Maryland
[6] IQVIA Institute: The Use of Medicines in the U.S. 2022

the form of lower premiums, deductibles, or cost savings.[7] Setting a UPL on these treatments without considering unique patient experiences or demonstrating lower patient out-of-pocket costs as a result will only threaten to put treatments out of reach.

Price Setting is Complex and Is Not a Function of State Government

At the federal level, the government is facing litigation and implementation challenges as it attempts to set prices for some drugs in the Medicare program. While we acknowledge that processes surrounding drug pricing are highly opaque, we do know that it is based on multiple complicated factors. In the search for a successful launch of a new drug, pharmaceutical manufacturers are engaged in hundreds of research and development projects at one time. Years of research and billions of dollars are invested into the development of that one new drug, while at the same time hundreds of molecules and their combinations that do not result in a viable product are studied. While there is a lot of attention on the high list price of the drugs that do come to market, the cost of all the failures, and all other functions of a pharmaceutical company, must be embedded into a treatment's list price.

Additionally, drug companies rely on the profits of today to invest in the successes and failures of tomorrow. Companies engaged in R&D of HIV medicines are working on longer-acting treatment and prevention drugs, vaccines, and even a cure for the virus. Many companies are working on a cure for hepatitis B while so many others are working on better cancer treatments, and medications to treat countless other conditions. Drug companies operate in a global environment, as exemplified in the HIV and hepatitis arenas, and provide medications to millions of people in underdeveloped and underserved nations. Given the many complexities and factors that go into setting a price of a drug, we do not believe it is appropriate or possible for a state to fairly do it.

Setting prices on medications to treat HIV, and offering other drugs as alternative treatment options, fails to consider the nuances of HIV treatment and individual patient needs.

Thank you for the opportunity to comment on the Board's proposed cost review process of the initial list of selected drugs. If you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director

[7] Partnership to Fight Chronic Disease: Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design but Won't Reduce Patient Cost