

May 10, 2024

Re: Maryland Prescription Drug Affordability Board's Decision to Proceed with Drug Cost Reviews and Draft Upper Payment Limit Action Plan

Honorable Members of the Maryland Prescription Drug Affordability Board,

The Alliance for Health Innovation (Alliance) is a group of cross-sector stakeholders representing patients, providers, caregivers, academia, biopharmaceutical innovators, and business communities.

Led by the Global Coalition on Aging (GCOA), the Alliance is committed to establishing the importance of innovation in achieving healthy aging. We advocate for state policy solutions that support a thriving innovation sector, enabling Maryland residents and other communities to live longer and healthier lives.

We are writing to express our deep concerns about the decision to proceed with drug cost reviews and the Board's consideration of therapeutic alternatives for drugs selected for review. We are particularly troubled by the lack of clarity on how the PDAB will implement any upper payment limit (UPL) that may be established through such a review. This uncertainty could jeopardize access to life-saving medications for patients, particularly for communities disproportionately impacted by chronic and complex conditions such as HIV. Furthermore, we are concerned about the absence of clear safeguards to ensure that the perspectives of patients, caregivers, and other stakeholders are fully integrated into the review process.

Many diseases that once burdened aging populations have evolved into manageable chronic conditions due to modern, safer, and more effective treatments. These treatments allow many patients to live longer, healthier lives. Much of this progress is owed specifically to patient advocacy efforts and opportunities that patients have been given to weigh in on the value of treatments from their unique and individual perspectives. HIV is a powerful and critical example of this, as specific disadvantaged populations – such as older adults living with HIV – are even more dependent on access to innovative medicines than average. By 2030, over 70% of the HIV-positive population in the US will be over 50, and in 2021, over 53% of new HIV diagnoses in the United States were in people aged 50 and older.^{1,2}

¹Wing E. J. (2017). The Aging Population with HIV Infection. Transactions of the American Clinical and Climatological Association, 128, 131-144.

²Centers for Disease Control and Prevention. HIV in the United States by Age: HIV Diagnoses. <https://www.cdc.gov/hiv/group/age/diagnoses.html>

UPL policies typically lead to significant patient access restrictions, which disproportionately affect the disadvantaged populations these policies are meant to protect. A recent survey of healthcare payers indicates that patients would likely experience increased utilization management (UM) protocols around drugs subject to a UPL.³ Complex UM protocols – such as prior authorization or step therapy – can compromise or delay effective treatment plans. While the PDAB has claimed that patients will receive benefits in the form of lower costs for prescription drugs, setting a UPL on treatment for HIV or any other medication would achieve neither patient affordability nor savings for the state of Maryland.

In 2021, people aged 55 and older represented 41% of the U.S. population living with HIV, with 68% of those individuals being virally suppressed.⁴ People living with HIV are more likely to develop additional health issues and tend to develop them earlier compared to those who do not have HIV.⁵ Threatening recent progress toward ending the HIV epidemic for older Marylanders and other patients in the state and threatening to exacerbate co-morbidities will only increase the burden on the broader healthcare system.

Patients living with HIV work closely with their providers to determine a treatment plan that works best for them. UM tactics impose significant administrative burdens on providers while forcing patients to spend precious time waiting to access the treatments best suited to their needs. One such tactic, known as non-medical switching, can be observed when a payer forces a patient on a stable regimen to switch from the treatment recommended by their provider to a cheaper medicine. Non-medical switching undermines the essential relationship between a patient and their provider. It ignores potential drug-drug interactions and side effects that could have been avoided with the recommended treatment. Conversely, improvements to HIV treatment adherence, unburdened by complex barriers to access like UM, can decrease overall hospitalization rates and lead to lower overall health system costs.

Interruptions to an individual's HIV treatment regimen can lead to impacts both at the personal and public health levels, with the potential for more significant and widespread consequences than other therapeutic areas. Ultimately, barriers to timely access to effective HIV treatments could lead to the progression of costly resistant viruses and could further complicate HIV care for older adults living with HIV and comorbid conditions.

³ Partnership to Fight Chronic Disease. Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs.

<https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf>

⁴ AIDSvu. National HIV/AIDS and Aging Awareness Day 2023. <https://aidsvu.org/news-updates/national-hiv-aids-and-aging-awareness-day-2023/>

⁵ Gross, AM, et al. Methyloome-wide analysis of chronic HIV infection reveals five-year increase in biological age and epigenetic targeting of HLA. *Molecular Cell*. 2016, 62(2). 157-168.



Across therapeutic areas, medication nonadherence for patients living with chronic diseases is thought to generate upwards of \$100 billion in preventable healthcare costs.⁶ There is no doubt that out-of-pocket costs can be a significant barrier between patients and their prescription drugs. Thirty-five percent of patients abandon their treatment plan when out-of-pocket costs reach \$75-\$125, leading to substantial long-term health and financial consequences for the individual patient and the health care system.⁷ However, in the case of HIV and its unique public health impact, there are local, state, and national safety-net programs in place to ensure that patients can access their HIV treatments. For patients covered through Medicaid and state-purchased plans, out-of-pocket costs for HIV treatments are typically between zero and three dollars.

While the PDAB has yet to establish its UPL action plan, the potential negative impacts of setting a UPL on HIV treatments – both for patients and the state more broadly – are clear. To ensure that all patients in Maryland have a pathway to longer and healthier lives, those living with and at increased risk for HIV must be afforded timely and unburdened access to the treatment options recommended by their healthcare provider.

We urge the Board to pause its activity and ensure that there is clarity on how the PDAB will implement any upper payment limit (UPL) that may be established and allow for proactive engagement with patients, caregivers, and other stakeholders to ensure that concerns about access and innovation are carefully considered to prevent access barriers from excessively impacting the most vulnerable of Marylanders.

Thank you for allowing us to share our concerns and for your commitment to finding solutions to the affordability challenges that Maryland patients face. We would be happy to discuss these concerns further or answer any questions.

Sincerely,

Michiel Peters

Michiel Peters

Head of Advocacy Initiatives, Global Coalition on Aging

⁶ Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6045499/>

⁷ IQVIA. Medicine Spending and Affordability in the U.S. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us>