



September 1, 2023

Submitted via: [RA-IN-PolicyOffice@pa.gov](mailto:RA-IN-PolicyOffice@pa.gov)

Michael Humphreys  
Insurance Commissioner  
Pennsylvania Insurance Department (PID)  
1326 Strawberry Square, Harrisburg, PA 17120  
Attn: Katie Merritt, Policy Director

**RE: Commonwealth Essential Health Benefits Benchmark Plan**

Dear Commissioner Humphreys:

ViiV Healthcare Company (ViiV) appreciates the opportunity to provide comments to the Pennsylvania Insurance Department (PID) on updating the Commonwealth's essential health benefits (EHB) benchmark plan.<sup>1</sup>

**About ViiV:** ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

ViiV is a committed partner in the nation's success in reducing the number of new HIV cases and increasing viral suppression rates.<sup>2,3</sup> Viral suppression is the goal of HIV treatment, reduces complications, and promotes the wellness of persons with HIV. It also reduces the risk of sexual transmission of HIV.<sup>4</sup> Our important role as a research-based pharmaceutical company is made even stronger with the ongoing collaboration between policy makers and public health. We therefore applaud this request for information.

PID's review of EHB is an opportunity to examine the access Pennsylvanians have to quality comprehensive health insurance coverage necessary for healthcare services. We encourage PID, within this process, to examine how the state's qualified health plans (QHPs) and benchmark plan serve the needs of people with HIV. This is an opportunity to implement new policies to support people with HIV

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<sup>1</sup> Commonwealth Essential Health Benefits Benchmark Plan.

<https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-30/1017.html>. Accessed August 17, 2023.

<sup>2</sup> AIDS Vu: United States <https://aidsvu.org/local-data/United-states/>. Accessed August 11, 2023.

<sup>3</sup> America's HIV Epidemic Analysis Dashboard. Ending the HIV Epidemic in the US. <https://ahead.hiv.gov/>. Accessed August 11, 2023.

<sup>4</sup> HIV.gov. Viral Suppression and Undetectable Viral Load. February 1, 2023. <https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/viral-suppression#:~:text=In%20addition%20to%20preventing%20sexual%20transmission%20of%20HIV%2C,transmission%20risk%20of%20people%20who%20inject%20drugs.%20>. Accessed August 11, 2023.

and those who could benefit from pre-exposure prophylaxis (PrEP) and to address issues that hinder patient access and discriminate against vulnerable patient groups.

An estimated 1.2 million people in the United States are living with HIV and at least 13 percent are unaware that they have the virus.<sup>5,6</sup> In 2019, the Department of Health and Human Services (DHHS) released the “Ending the HIV Epidemic Initiative: A Plan for America” (EHE), a national effort that aims to leverage scientific advances in HIV prevention, diagnosis, treatment, and outbreak response to end the HIV epidemic in the United States.<sup>7</sup> A key strategy of the EHE is to prevent new HIV transmissions by using proven interventions, including PrEP.<sup>8</sup> The EHE focuses efforts across many federal health agencies, offices, and programs, including the DHHS Office of the Assistant Secretary for Health, the CDC, the Ryan White HIV/AIDS Program (RWHAP), the Health Resources and Services Administration (HRSA) Health Center Program, the National Institutes of Health (through its 19 Centers for AIDS Research and six AIDS Research Centers), the Indian Health Service, and the Substance Abuse and Mental Health Services Administration.<sup>9</sup> These federal agencies are working closely with state and local governments, health departments, and communities to develop jurisdictional plans to expand the use of the highest-impact HIV prevention strategies, including PrEP utilization.<sup>10</sup> Pennsylvania has an important role to play in these efforts, as Philadelphia County is one of the EHE Jurisdictions targeted for high rates of new HIV infections.<sup>11</sup>

For all of these reasons, ViiV urges the PID to consider the needs of people with HIV in the context of this RFI on EHB.

## **1. Health Equity & Addressing Disparities in Care within the EHB**

ViiV Healthcare encourages PID to focus on health equity and addressing disparities as part of its focus on non-discriminatory benefit design within this effort and ask how the EHB can address conditions that disproportionately affect underserved populations.

Although HIV can affect anyone, some racial/ethnic groups have higher rates of HIV in their communities, raising the risk of new infections with each sexual or injection drug use encounter.<sup>12</sup> In particular, Black/African American, and Hispanic/Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups. For example, in 2019, the rate of new HIV diagnoses per 100,000 for Black people (45.0) was about 8 times that of white people (5.3); Latino people (21.5) had a rate 4

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<sup>5</sup> Centers for Disease Control and Prevention (CDC). Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021;26(No. 2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf>. Published May 2021. Accessed August 23, 2023.

<sup>6</sup> HIV.gov. U.S. Statistics. October, 27 2022. <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>. Accessed August 23, 2023.

<sup>7</sup> HIV.gov. Ending the HIV Epidemic. July 1, 2022. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed August 23, 2023.

<sup>8</sup> HIV.gov. Key Strategies in the Plan. July 1, 2022. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies>. Accessed August 23, 2023.

<sup>9</sup> HIV.gov. HHS Agencies Involved in Ending the HIV Epidemic. March 2, 2022. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/federal-action/agencies>. Accessed August 23, 2023.

<sup>10</sup> HIV.gov. HHS Agencies Involved in Ending the HIV Epidemic. March 2, 2022. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/federal-action/agencies>. Accessed August 23, 2023.

<sup>11</sup> HIV.gov. Ending the HIV Epidemic. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions/phase-one/>. Accessed August 23, 2023.

<sup>12</sup> Centers for Disease Control and Prevention (CDC). HIV by Group. April 14, 2022. <https://www.cdc.gov/hiv/group/raciaethnic/index.html>. Accessed August 23, 2023.

times that of white people.<sup>13</sup> And compared to all people diagnosed with HIV, African Americans have lower viral suppression rates which is critical to reducing transmission of HIV.

Populations disproportionately affected by HIV are also often affected by stigma due to their sex, sexual orientation, gender identity, race/ethnicity, drug use, sex work, or other factors.<sup>14</sup> Likewise, although use of PrEP has increased significantly in recent years across all groups, racial and ethnic stigma and disparities drive lower rates of uptake and adherence. Data from the CDC in 2017 revealed that rates of PrEP use, discussions with providers on PrEP and HIV treatments, and awareness of PrEP, were significantly lower across racial/ ethnic minorities compared to white MSM.<sup>15</sup> Also, across the U.S., only 10 percent of women who could benefit from PrEP were prescribed it in 2019.<sup>16</sup>

A report by the Kaiser Family Foundation on the “[Results from an Annual Medicaid Budget Survey for State Fiscal Years 2022 and 2023](https://www.kff.org/medicaid/report/medicaid-budget-survey-for-state-fiscal-years-2022-and-2023/)” shows that states have been incorporating equity, diversity, and social determinants of health (SDOH) in their various programs at rapid pace, increasingly tying financial incentives for managed care organizations (MCO) to health equity-related performance goals. Among other things, in 2022, 5 states required MCOs to have a health equity officer, 9 states required MCO staff training on health equity, and 10 states required MCOs to have a health equity plan in place.<sup>17</sup> If states can require this of MCOs, then we encourage the PID to set similar requirements in place for plans in the marketplaces.

ViiV encourages PID to promote exchange plans reporting Race, Ethnicity and Language (REL) and Sexual Orientation and Gender Identity (SOGI) Data. Many state Medicaid programs require managed care organizations to collect a combination of SOGI/REL data.<sup>18</sup> We support the collection of this data from beneficiaries on an opt-out basis. We urge PID to ensure patients are protected from this information being potentially used in a discriminatory manner. However, SOGI/REL data can be used to provide a basis for examining disparities in health care access and outcomes. We therefore encourage PID to require all insurers to offer beneficiaries the option to disclose SOGI/REL data. This information can be used to identify and distinguish between plans, doctors, and systems that serve particular populations. That data can also be used to assess access to coverage, as well as outcomes for vulnerable populations.

## **2. Importance of Transparency in Benefit and Formulary coverage**

We hope PID will expand requirements that EHB-benchmark plans and all plans sold in the marketplaces provide (at a minimum) clear and transparent explanations of the benefits covered, drug formularies, and provider networks. This clarity is important for patients in selecting plans and for advocates and regulators in ensuring plans comply with the ACA’s EHB standards.

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<sup>13</sup> Kaiser Family Foundation (KFF). The HIV/AIDS Epidemic in the United States: The Basics. June 7, 2021. <https://www.kff.org/hiv/aids/fact-sheet/the-hiv-aids-epidemic-in-the-united-states-the-basics/#footnote-525108-42>. Accessed August 23, 2023.

<sup>14</sup> HIV.gov. Standing Up to Stigma. February 24, 2020. <https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma>. Accessed August 23, 2023.

<sup>15</sup> Kanny D, Jeffries WL IV, Chapin-Bardales J, et al. Racial/Ethnic Disparities in HIV Preexposure Prophylaxis Among Men Who Have Sex with Men — 23 Urban Areas, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:801–806. <http://dx.doi.org/10.15585/mmwr.mm6837a2>. Accessed January 30, 2023.

<sup>16</sup> Centers for Disease Control and Prevention (CDC). HIV and Women: PrEP Coverage. September 22, 2021. <https://www.cdc.gov/hiv/group/gender/women/prep-coverage.html>. Accessed August 23, 2023.

<sup>17</sup> Hinton E, Guth M, Raphael J, et al. How the Pandemic Continues to Shape Medicaid Priorities: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2022 and 2023. Kaiser Family Foundation. <https://www.kff.org/medicaid/report/medicaid-budget-survey-for-state-fiscal-years-2022-and-2023/>. Accessed August 23, 2023.

<sup>18</sup> Hinton E, Guth M, Raphael J, et al. How the Pandemic Continues to Shape Medicaid Priorities: Results from an Annual Medicaid Budget Survey for State Fiscal Years 2022 and 2023. Kaiser Family Foundation. <https://www.kff.org/medicaid/report/medicaid-budget-survey-for-state-fiscal-years-2022-and-2023/>. Accessed August 23, 2023.

When benefits are not clear, it can be harder for patients to decipher what they are entitled to receive. It is also harder for PID to enforce and for advocates to monitor standards. Ensuring that benchmark plan information, and the plan documents based on them, are uniform and understandable is the first step in improving healthcare access and health equity.

### 3. Formulary Adequacy & Coverage of Prescription Drugs as EHB

The comprehensive health insurance benefits in the EHB provisions are particularly important in the context of prescription drug access for people with HIV. Comprehensive prescription drug coverage is necessary for both medicines covered by the outpatient pharmacy benefit or as part of the medical benefit, when administered by a provider. Antiretrovirals play a vital role in preventing HIV, treating HIV, and ensuring health and wellness for those with HIV health conditions and reducing other health care costs. The need for comprehensive and nondiscriminatory drug coverage is significant for people with HIV.

Formularies should reflect changes in medical guidelines, best practices, and scientific advancement. Scientific and technological advancements are also leading to more targeted treatments transforming the way we treat patients with a broad range of chronic conditions like HIV. In clinical settings, health care providers work closely with patients to select HIV treatment options with great specificity for each patient. Effective treatment of HIV is highly individualized and takes into account a patient's size, gender, treatment history, viral resistance, coexisting illnesses, drug interactions, immune status, side effects, and stigma. The DHHS "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV"<sup>19</sup> emphasize the need for individualized treatment regimens to enhance adherence and ensure long-term treatment success.

To ensure access of HIV medications and strengthen the drug benefit for HIV in exchanges and commercial plans, PID should adopt the Medicare Part D protected classes rule, which requires all (or substantially all) prescription drugs to be covered in six "protected" therapeutic classes including HIV.<sup>20, 21</sup> The EHB-benchmark plans coverage requirements are not nearly as comprehensive, even in the same therapeutic areas. Adopting the Medicaid Part D rule for EHB would significantly strengthen the pharmacy benefits in Exchange and other commercial insurance. PID adopted the Part D policy to ensure patients "reliant upon these drugs would not be substantially discouraged from enrolling" and to "mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."<sup>22</sup> The same policy rationale should support extending this rule to EHB coverage. Ensuring adequate coverage for vulnerable populations in the exchanges is critical.

In the case of HIV, access to medications also has the dual benefit of preventing further transmission of HIV to other individuals. If taken as prescribed, antiretrovirals have the potential to reduce the amount of HIV in the blood to a very low level — below what can be measured by a lab test— which promotes a

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<sup>19</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines>. Accessed August 23, 2023.

<sup>20</sup> Kaiser Family Foundation. Medicare and HIV. Oct 14, 2016. <https://www.kff.org/hiv/aids/fact-sheet/medicare-and-hiv/>. Accessed August 18, 2023

<sup>21</sup> Polycymed.com. CMS Announces Medicare Part D Final Rule Maintaining Current Policy on Six Protected Classes – Policy & Medicine. Jun 3, 2019. <https://www.policymed.com/2019/06/cms-announces-medicare-part-d-final-rule-maintaining-current-policy-on-six-protected-classes.html> - <https://www.policymed.com/2019/06/cms-announces-medicare-part-d-final-rule-maintaining-current-policy-on-six-protected-classes.html#:~:text=Consequently%2C%20CMS%20identified%20six%20categories%20of%20drugs%2C%20commonly,are%3A%20anticonvulsants%2C%20antidepressants%2C%20antineoplastics%2C%20antipsychotics%2C%20antiretrovirals%20and%20immunosuppressants>. Accessed August 18, 2023

<sup>22</sup> CMS.gov. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. January 15, 2016. <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>. Accessed August 18, 2023

long and healthy life for a person living with HIV.<sup>23</sup> Effective ARV treatment that reduces the amount of HIV in the blood to undetectable levels has a secondary public health benefit of preventing new transmission of HIV to others. This is commonly referred to as Treatment as Prevention,<sup>24</sup> or Undetectable = Untransmissible (U=U).<sup>25</sup>

The Pennsylvania Department of health has promoted information on U=U in the state.<sup>26,27</sup> However, more needs to be done. We encourage the PID to also provide information on PrEP to all insurers, and to require them to provide information on PrEP to their networks of care providers.

#### 4. EHB Preventives Services Coverage and HIV

We urge PID to increase enforcement around EHB coverage requirements for preventive services, which is one of the 10 required EHB categories. Prevention of HIV through the use of HIV PrEP is one of the main pillars of the EHE initiative.

According to DHHS, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 23.4 percent were receiving it as of 2019.<sup>28</sup> The Pennsylvania Department of health has promoted information on PrEP access throughout the state on their website.<sup>29</sup> However, more needs to be done. We encourage the PID to also provide information on PrEP to all insurers, and to require them to provide information on PrEP to their networks of care providers.

The outcomes of lower utilization of HIV prevention can be seen in terms of the high rates of HIV impact in certain groups. The HIV epidemic continues to have a disproportionate impact on some communities. Although HIV can affect anyone, some racial/ethnic groups in the United States are more affected than others. Some groups have higher rates of HIV in their communities, raising the risk of new infections with each sexual or injection drug use encounter.<sup>30</sup> In particular, Black/African American, and Hispanic/Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups. For example, in 2019, the rate of new HIV diagnoses per 100,000 for Black people (45.0) was about 8 times that of white people (5.3); Latino people (21.5) had a rate 4 times that of white people.<sup>31</sup>

PrEP has the potential to address HIV specific disparities and possibly other disparities in health care as PrEP use is also associated with increased engagement in ongoing health care.<sup>32</sup> However, regional and demographic disparities exist in PrEP usage and access across the U.S. For example, the Southern U.S.

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<sup>23</sup> HIV.gov. Viral Suppression and Undetectable Viral Load. June 7, 2022. [Viral Suppression and an Undetectable Viral Load | HIV.gov](#). Accessed August 18, 2023

<sup>24</sup> Centers for Disease Control and Prevention (CDC). HIV Treatment as Prevention. July 21, 2022. [HIV Treatment as Prevention | HIV Risk and Prevention | HIV/AIDS | CDC](#). Accessed August 18, 2023

<sup>25</sup> National Institutes of Health (NIH). May 21, 2019. [HIV Undetectable=Untransmittable \(U=U\), or Treatment as Prevention | NIH: National Institute of Allergy and Infectious Diseases](#). Accessed August 23, 2023

<sup>26</sup> Pennsylvania Department of Health. Department Of Health Works To Reduce Stigma Of HIV, Discusses Health Impacts On Youth April 14, 2019. <https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=585>. Accessed August 18, 2023.

<sup>27</sup> Pennsylvania Department of Health. HIV Information for Individuals. <https://www.health.pa.gov/topics/HIV/Pages/Individuals.aspx>. Accessed August 23, 2023.

<sup>28</sup> Centers for Disease Control and Prevention (CDC). Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021;26(No. 2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf>. Published May 2021. Accessed August 18, 2023

<sup>29</sup> Pennsylvania Department of Health. Pre-exposure Prophylaxis (PrEP). <https://www.health.pa.gov/topics/Documents/Programs/HIV/What%20is%20PrEP.pdf>. Accessed August 18, 2023.

<sup>30</sup> Centers for Disease Control and Prevention (CDC). HIV by Group. April 14, 2022. <https://www.cdc.gov/hiv/group/raciaethnic/index.html>. Accessed August 18, 2023

<sup>31</sup> Kaiser Family Foundation (KFF). The HIV/AIDS Epidemic in the United States: The Basics. June 7, 2021. <https://www.kff.org/hiv/aids/fact-sheet/the-hiv-aids-epidemic-in-the-united-states-the-basics/#footnote-525108-42>. Accessed August 18, 2023.

<sup>32</sup> U.S. Department of Health and Human Services. 2021. HIV National Strategic Plan for the United States: A Roadmap to End the Epidemic 2021–2025. Washington, DC. <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>. Accessed August 18, 2023.

accounted for more than half (52 percent) of all new HIV diagnoses but represented only 30 percent of all PrEP users in 2016.<sup>33</sup>

Research from the Infectious Diseases Society of America has shown that despite equal levels of willingness to use PrEP between Black and White men who have sex with men (MSM), PrEP use was significantly higher among White MSM.<sup>34</sup> Inequities in access to PrEP across populations at high-risk have led to increasing disparities in HIV incidence, transmission, and viral suppression. Therefore, it is crucial to address disparities in PrEP uptake in order to address greater disparities present within the HIV epidemic. ViiV urges DHHS to examine how the effects of utilization management (UM) of HIV prevention medications (such as step therapy, prior authorizations, and adverse tiering) may amount to discriminatory coverage practices against entire classes of patients who are vulnerable to HIV. In the same manner as with HIV treatment, prior Authorizations and Step therapy requirements that do not follow the FDA approved label or are more restrictive than the clinical guidelines for a particular drug, should be subject to scrutiny. Unnecessarily restricting access to prevention options of a particular modality—such as injectable PrEP—could prevent entire classes of patients from accessing this option.

Furthermore, there is evidence that insurers are failing to follow the ACA requirements intended to ensure access to preventive services for low-income patients purchasing commercial insurance. In 2019, the United States Preventive Services Task Force (USPSTF) assigned a “Grade A” rating to PrEP as an intervention.<sup>35</sup> Under the Affordable Care Act (ACA), preventative services with a USPSTF Grade A or B recommendation must be covered without cost-sharing in certain commercial plans and the Medicaid expansion markets.<sup>36</sup> In addition, the Departments of Labor, Treasury and Health and Human Services recently issued guidance to clarify that PrEP and related costs for items and services integral to furnishing PrEP must be covered by insurers without cost-sharing.<sup>37</sup>

State officials have undertaken similar efforts to remind insurers of these coverage requirements. According to a recent article published in USA Today, on Sept. 12, 2022, New Mexico's Office of Superintendent of Insurance reminded insurers that PrEP and contraceptives must be covered at no cost to insured consumers. New Mexico ordered insurers to audit all PrEP-related claims since July 2020 and reimburse customers “who are found to have been erroneously charged cost-sharing.”<sup>38</sup> The article reports that Michigan state officials informed insurers that they must cover the medication, labs and appointments and urged people who might need the medication to get it. Per the article, Sen. Jeff Merkley, D-Ore., and seven other senators also sent a letter to America's Health Insurance Plans, a health insurance industry group, about the failure of insurers to follow federal regulations. The article quotes these Senators as saying consumers “continue to be charged for necessary medications and ancillary services” and expressed “deep concern with these erroneous and unlawful charges.”

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<sup>33</sup> AIDSvu. Mapping PrEP: First Ever Data on PrEP Users Across the US. March 6, 2018. <https://aidsvu.org/prep/>. Accessed August 18, 2023.

<sup>34</sup> Avalere Health, “PACHA Highlights Need to Address HIV PrEP Coverage Disparities, April 7, 2021.

<https://avalere.com/insights/pacha-highlights-need-to-address-hiv-prep-coverage-disparities>, Accessed August 18, 2023.

<sup>35</sup> US Preventive Services Task Force, “Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis” June 2019. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#fullrecommendationstart>. Accessed August 18, 2023.

<sup>36</sup> Presidential Advisory Council on AIDS (PACHA). March 2021 meeting. PACHA Highlights Need to Address HIV PrEP Coverage Disparities. <https://avalere.com/insights/pacha-highlights-need-to-address-hiv-prep-coverage-disparities>, April 7, 2021. Accessed August 18, 2023.

<sup>37</sup> U.S. Department of Labor. FAQs About Affordable Care Act Implementation Part 47. July 19, 2021.

<https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-47.pdf>. Accessed August 18, 2023.

<sup>38</sup> USA TODAY, “HIV groups struggle to get insurance coverage for expensive prevention drugs, lab tests,” Ken Alltucker, Mon, September 26, 2022 <https://news.yahoo.com/hiv-groups-struggle-insurance-coverage-090046317.html>. Accessed August 18, 2023.

We urge PID to hold plans accountable to USPSTF recommended prevention guidelines as well as CDC guidance and enforcing the federal guidance on this coverage.

## **5. Impact of utilization management on patient access**

ViiV urges PID to examine the effects of utilization management (UM) of drugs (such as step therapy, prior authorizations, and adverse tiering) on access to treatment for HIV and prevention of HIV. These practices can, in some cases, amount to discriminatory coverage practices against patients by making certain medications inaccessible to them. Some examples of these types of practices include:

- Prior Authorizations that do not follow the FDA approved label;
- Step therapy requirements that are more restrictive than the clinical guidelines for a particular drug;
- Restricting access to all of the drugs of a particular modality (such as injectable vs. oral medicines) through prior authorizations or by placing in highest cost-sharing tiers;
- Placing all single-tablet HIV regimens on the highest cost tier; and
- Placing generic and branded PrEP on the highest cost tier.

When these types of barriers are put into place, patients struggle to get access to necessary medications and may be limited to non-preferred treatment options—which could reduce their likelihood of adherence and result in sub-optimal treatment outcomes.

In clinical settings, health care providers work closely with patients to select HIV treatment options with great specificity for each patient. Effective treatment of HIV is highly individualized and accounts for a patient's size, gender, treatment history, viral resistance, coexisting illnesses, drug interactions, immune status, side effects, and stigma. The U.S. Department of Health and Human Services' "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV"<sup>39</sup> emphasize the need for individualized treatment regimens to enhance adherence and ensure long-term treatment success. The science of HIV has evolved and provided new treatment options in the form of long-acting injectable ARVs that are provider-administered.

Exchange plans are more likely to impose UM requirements than employer plans, which suggests that exchange plan enrollees are disproportionately impacted as a group by these practices.<sup>40,41</sup> Meanwhile, these plans also benefit from federal subsidies and should be held to account for engaging in discriminatory practices. ViiV encourages PID to create real enforcement mechanisms for the non-discrimination laws that exist.

We urge PID to review whether administrative burdens and coverage restrictions placed on HIV treatments effectively discriminate against people with HIV, low-income populations, minority populations, LGBTQ populations, and/or underserved communities.

### **a. Impact of Adverse tiering on patient access**

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<sup>39</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines>. Accessed August 18, 2023.

<sup>40</sup> Meyer T, Yip R, Mengesha Y, Santiesteban D, Hamilton R. Utilization Management Trends in the Commercial Market, 2014-2020. Avalere Health. November 24, 2021. <https://avalere.com/wp-content/uploads/2021/11/UM-Trends-in-the-Commercial-Market.pdf>. Accessed August 18, 2023.

<sup>41</sup> Lenahan K, Nichols DE, Gertler RM, Chambers JD. Variation in use and content of prescription drug step therapy protocols, within and across health plans. *Health Aff (Millwood)*. 2021 Nov;40(11):1749-1757. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/34724434/>.

ViiV urges PID to examine plans that place all drugs for HIV in the highest cost-sharing tiers—a practice known as adverse tiering. As with utilization management, these types of barriers limit patients’ access to necessary medications, including preferred treatment options that could increase their likelihood of adherence and result better treatment outcomes.

We therefore urge PID to review adverse tiering practices, where all or most drugs for a particular condition fall into high cost-sharing tiers. PID should use CCIIO tools to determine whether the tiering of drugs for a particular condition represents discriminatory practice.

ViiV encourages PID to review complaints that were filed with the DHHS Office of Civil Rights (OCR) on behalf of people with HIV.<sup>42,43</sup> For example, in 2016, CHLPI, along with partners in other states alleging that insurers “routinely denied coverage for HIV medications or limited access to needed medications through prohibitively high cost-sharing plans.”<sup>44</sup> In another example, the [HIV+Hepatitis Policy Institute](#) and the [North Carolina AIDS Action Network](#) filed discrimination complaints against Blue Cross and Blue Shield of North Carolina for placing almost all HIV drugs, including generic Pre-Exposure Prophylaxis (PrEP), on the highest drug tiers, thus forcing people living with and vulnerable to HIV to pay excessive high costs to take their drugs.<sup>45</sup>

## **6. Network Adequacy Standards Should Ensure Access to HIV-Specialized Providers and Essential Community Providers**

ViiV encourages PID to require plans to include HIV-specialized providers in their networks of care. Access to qualified medical care providers is important for people with HIV in order to monitor disease progression and ensure viral suppression is maintained.<sup>46,47</sup> Access to infectious disease specialists and HIV-specialized providers<sup>48</sup> is vital for people with HIV, as HIV patients see better outcomes when treated by an experienced HIV provider.<sup>49</sup>

Since the beginning of the HIV epidemic, providers from a variety of specialties (such as Infectious Disease Specialists and family medicine) and licensures (physician’s assistants, nurses, nurse practitioners) have focused on HIV care and treatment and served this vulnerable population. There is no

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<sup>42</sup> Office of Civil Rights, U.S. Department of Health and Human Services. Complaint: Re: Discriminatory Pharmacy Benefits Design In Humana Qualified Health Plans Offered In Georgia. September 6, 2016. <https://chlpi.org/wp-content/uploads/2013/12/LA-Humana.pdf>. Accessed August 23, 2023.

<sup>43</sup> Harvard Law School. Center for Health Law and Policy Innovation of (CHLPI). Press Release. Center For Health Law And Policy Innovation Of Harvard Law School Launching Groundbreaking Campaign To Enforce Health Care Rights For People Living With HIV In Seven States Landmark Complaints Filed with the Federal Office for Civil Rights. September 6, 2016. [https://chlpi.org/wp-content/uploads/2013/12/CHLPI\\_OCR-Complaint-Press-Release\\_web.pdf](https://chlpi.org/wp-content/uploads/2013/12/CHLPI_OCR-Complaint-Press-Release_web.pdf). Accessed August 23, 2023.

<sup>44</sup> Harvard Law School. Center for Health Law and Policy Innovation of (CHLPI). Press Release. Center For Health Law And Policy Innovation Of Harvard Law School Launching Groundbreaking Campaign To Enforce Health Care Rights For People Living With HIV In Seven States Landmark Complaints Filed with the Federal Office for Civil Rights. September 6, 2016. [https://chlpi.org/wp-content/uploads/2013/12/CHLPI\\_OCR-Complaint-Press-Release\\_web.pdf](https://chlpi.org/wp-content/uploads/2013/12/CHLPI_OCR-Complaint-Press-Release_web.pdf). Accessed August 23, 2023.

<sup>45</sup> HIV+HEP Policy Institute. HIV organizations file discrimination complaints against North Carolina Blue Cross Blue Shield - HIV+Hepatitis Policy Institute. Press Release. December 2, 2022. <https://hivhep.org/press-releases/hiv-organizations-file-discrimination-complaints-against-north-carolina-blue-cross-blue-shield/>. Accessed August 23, 2023.

<sup>46</sup> Kitahata MM, Koepsell TD, Deyo RA, et al.. Physicians’ experience with the acquired immunodeficiency syndrome as a factor in patients’ survival. N Engl J Med. 1996 Mar 14;334(11):701-6. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/8594430/>.

<sup>47</sup> Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV care: a policy paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. Clin Infect Dis. 2011 Dec;53(11):1043-50. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/22021928/>.

<sup>48</sup> HIV Medicine Association. Identifying Providers Qualified to Manage the Longitudinal Treatment of Patients with HIV Infection and Resources to Support Quality HIV Care. March 2013. <https://www.hivma.org/globalassets/hivma/logos/revised-qualified-hiv-provider-policy-statement-approved-3-16-13-1.pdf>. Accessed August 23, 2023.

<sup>49</sup> Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV care: a policy paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. Clin Infect Dis. 2011 Dec;53(11):1043-50. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/22021928/>.



board certification for HIV medicine, but several professional organizations have identified criteria for designation of HIV specialists,<sup>50,51</sup> and some states have also codified HIV specialty.<sup>52</sup>

Despite the requirements for network adequacy put in place by the ACA for commercial insurers, enforcement of these requirements needs to be increased, and as does transparency around covered providers networks. Allowing patients to choose their health care professionals is aligned with achieving health equity.

## 7. Support services

ViiV urges PID to recognize that addressing the Social Determinants of Health (SDOH) health are critical to health outcomes, especially in marginalized communities. These services have been demonstrated to significantly improve patient outcomes for people with HIV.

In terms of SDOH best practices, ViiV wishes to highlight the example of the Ryan White HIV/AIDS Program (RWHAP),<sup>53</sup> a federal program that has addressed health disparities and promoted health equity in health programs across the nation and requires community engagement and rigorous data collection. Specifically, the RWHAP has proven to be effective in supporting optimal patient care, addressing health disparities, and driving treatment success in HIV for over 30 years.<sup>54</sup> The RWHAP reported a viral suppression rate of 89.4 percent in program participants in 2020, far above the national average.<sup>55</sup> The RWHAP has demonstrated how interventions such as addressing SDOH, providing medical transportation, and effective case management can promote health care outcomes. Those experiencing unstable housing face the lowest rates of retention in care (72.7% vs. 80.3%), as well as viral suppression (76.8% vs. 90.4%) rates, compared to those with stable housing.<sup>56</sup> Ryan White addresses SDOH such as housing, food, and transportation, as well as clinical care, through direct services and demonstration projects.<sup>57</sup> We encourage PID to work with the Pennsylvania Ryan White Program to consider which SDOH programs that have demonstrated success in the RWHAP can be replicated within insurer benefits programs.

Additionally, ViiV urges PID to review the HHS Office of Infectious Diseases (OIDP) work on the HIV Quality of Life (QoL) indicator, which was recently released by the White House Office of National AIDS Policy.<sup>58</sup> The White House Office of National AIDS Policy (ONAP) convened a Federal Interagency

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<sup>50</sup> American Academy of HIV Medicine (AAHIVM). Credentialing Handbook. March 2019. <https://aahivm.org/wp-content/uploads/2019/04/AAHIVM-Credentialing-Handbook-4.4.19.pdf>. Accessed August 18, 2023.

<sup>51</sup> Association of Nurses in AIDS Care (ANAC). HANCB AACRN Certification Application. <https://www.nursesinaidscare.org/i4a/forms/index.cfm?id=196>. Accessed August 18, 2023.

<sup>52</sup> Florida Agency for Healthcare Administration, Medicaid Managed Care Contract, The HIV/AIDS Specialty Plan, Attachment II, Exhibit II-C, HIV/AIDS Specialty Plan, November 1, 2015, [https://ahca.myflorida.com/medicaid/statewide\\_mc/pdf/Contracts/2015-11-01/Exhibit\\_II-C-HIV-AIDS\\_2015-11-01.pdf](https://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2015-11-01/Exhibit_II-C-HIV-AIDS_2015-11-01.pdf). Accessed August 18, 2023.

<sup>53</sup> HRSA.gov. HRSA Ryan White HIV/AIDS Program. About the Ryan White HIV/AIDS Program. <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/about-ryan-white-hiv-aids-program>. Accessed August 11, 2023.

<sup>54</sup> HRSA.gov. HRSA Ryan White HIV/AIDS Program. About the Ryan White HIV/AIDS Program. <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/about-ryan-white-hiv-aids-program>. Accessed August 18, 2023.

<sup>55</sup> HIV.gov. HRSA Announces Increase in HIV Viral Suppression Rate in New 2020 Ryan White HIV/AIDS Program Client-Level Data Report. December 8, 2021. <https://www.hiv.gov/blog/hrsa-announces-increase-hiv-viral-suppression-rate-new-2020-ryan-white-hiv-aids-program-client?msclkid=5f721693b1d311ecbcaeebb1e84138f>. Accessed August 11, 2023.

<sup>56</sup> Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2020. December 2021. <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/data/rwhap-annual-client-level-data-report-2020.pdf>. Accessed August 11, 2023.

<sup>57</sup> Cheever L, Matosky M. Ryan White HIV/AIDS Program Overview and Update. Presentation to Association of Nurses in AIDS Care (ANAC) National Webinar. March 1, 2022. [https://www.nursesinaidscare.org/files/2022%20Attachments/Ryan\\_White\\_ANAC\\_March\\_22\\_Final\\_to\\_share\\_3\\_1\\_22.pdf](https://www.nursesinaidscare.org/files/2022%20Attachments/Ryan_White_ANAC_March_22_Final_to_share_3_1_22.pdf). Accessed August 11, 2023.

<sup>58</sup> HIV.gov. Webinar on the NHAS Federal Implementation Plan. September 9, 2022. <https://www.hiv.gov/blog/register-now-webinar-nhas-federal-implementation-plan>. Accessed August 18, 2023.

Workgroup to develop the quality of life (QoL) indicators proposed in the National HIV/AIDS Plan (NHAS) 2025. The QOL is a multi-dimensional concept that assesses key SDOH such as unemployment, food insecurity, and housing instability, to produce comparable estimates of QoL for people with HIV. This effort shows an effective way to quantify and compare the SDOH impact on healthcare within a patient group.

ViiV Healthcare appreciates the PID's consideration of these comments on EHB and applauds the agency for its commitment to enforcing prohibitions against discrimination in the nation's health programs. Please feel free to contact me at (215) 868-9736 or [j.maurice.m.mccants-pearsall@viivhealthcare.com](mailto:j.maurice.m.mccants-pearsall@viivhealthcare.com) should you have any questions.

**Sincerely,**

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