



December 21, 2021

Submitted via: 1115.WaiverRenewal@dhsosha.state.or.us

Mr. Patrick Allen
Director
Oregon Health Authority (OHA)
Health Policy and Analytics Medicaid Waiver Renewal Team
Attn: Michelle Hatfield
500 Summer St. NE, E65
Salem, OR 97301

Re: Oregon 2022-2027 Medicaid 1115 Demonstration Application (Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver)

Dear Director Allen:

ViiV Healthcare Company (ViiV) appreciates the opportunity to submit comments to the Oregon Health Authority (OHA) regarding the proposed Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver, the "Oregon 2022-2027 Medicaid 1115 Demonstration Application."¹

ViiV is the only company 100 percent dedicated to combating, preventing, and ultimately curing HIV and AIDS. 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.

As an exclusive manufacturer of HIV medicines, ViiV is proud of the scientific advances in the treatment of this disease. These advances have transformed HIV from a terminal illness to a manageable chronic condition. Effective HIV treatment can help people with HIV to live longer, healthier lives and has been shown to reduce HIV-related morbidity and mortality at all stages of HIV infection.^{2,3} Furthermore, effective HIV treatment can also prevent the transmission of the disease.⁴

¹ Oregon.gov, *Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver*, "Oregon 2022-2027 Medicaid 1115 Demonstration Application," https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm_medium=email&utm_source=govdelivery, (Accessed December 15, 2021)

² Severe P, Juste MA, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med*. Jul 15 2010;363(3):257-265. Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=20647201, (Accessed August 27, 2021)

³ Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. Apr 30 2009;360(18):1815-1826. Available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19339714, (Accessed August 27, 2021)

⁴ Rodger et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *The Lancet* 2019; 393(10189):2428-2438. Available at: [https://doi.org/10.1016/S0140-6736\(19\)30418-0](https://doi.org/10.1016/S0140-6736(19)30418-0), (Accessed August 27, 2021)

The Medicaid Program Should Join Efforts to End the HIV Epidemic

An estimated 1.2 million people in the United States are living with HIV and at least thirteen percent are unaware that they have the virus.⁵ Despite groundbreaking treatments that have slowed the progression and burden of the disease, treatment of the disease is low – only half of diagnosed and undiagnosed people with HIV are retained in medical care, according to the Center for Disease Control and Prevention (CDC).⁶

Since the earliest days of the epidemic, Medicaid has played a critical role in HIV care. Nationally, Medicaid is the largest source of coverage for people with HIV.⁷ In fact, more than 42 percent of people with HIV who are engaged in medical care have incomes at or below the federal poverty level.⁸ The program is an essential source of access to medical care and antiretroviral therapy (ART) drug coverage for people with HIV. This medical care and drug treatment not only preserve the health and wellness of people with HIV and improves health outcomes, but it also prevents new HIV transmissions.

Medicaid is also a significant provider of HIV prevention, specifically pre-exposure prophylaxis (PrEP).⁹ When taken properly, PrEP can reduce the risk of acquiring HIV from sex by 99 percent and reduces risk by 74 percent among those who inject drugs.¹⁰ However, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 18 percent are receiving it.¹¹ In Oregon the state's PrEP coverage ratio was only 17.2 percent in 2019 according to CDC.¹² Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic.

In 2019, the U.S. Department of Health and Human Services (DHHS) released the "Ending the HIV Epidemic: A Plan for America (EHE)."¹³ This plan proposes to use scientific advances in antiretroviral therapy to treat people with HIV and expand proven models of effective HIV care and prevention.¹⁴ The plan coordinates efforts across government agencies to stop the HIV epidemic and focuses its efforts on local areas. The EHE Initiative is not only a landmark policy by all federal health agencies, it is also supported by the HIV community and the President's Advisory Council on HIV/AIDS (PACHA).¹⁵

As of 2019, there were 7,280 people living with HIV in Oregon, and 199 people were newly diagnosed with HIV in the state in 2019.¹⁶ We applaud the Oregon Health Authority (OHA) for launching its own initiative to end HIV in the state, the "End HIV Oregon" strategy¹⁷ following a two-year planning process with community members from across Oregon, facilitated by the Program Design & Evaluation Services (PDES) staff.¹⁸ The End HIV Oregon strategy also centers around the three goals of access to HIV testing, accelerating prevention efforts including pre-exposure prophylaxis (PrEP), and promoting effective HIV treatment to promote viral suppression.

⁵ Centers for Disease Control and Prevention. Volume 26 Number 2 | HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html> Published May 2021. (Accessed June 2, 2021)

⁶ Centers for Disease Control and Prevention. Volume 26 Number 2 | HIV Surveillance | Reports | Resource Library | HIV/AIDS | CDC <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html> Published May 2021. (Accessed June 2, 2021)

⁷ Kaiser Family Foundation. Medicaid and HIV, <http://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>

⁸ Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. June 2019, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf> (Accessed February 2021)

⁹ Kaiser Family Foundation. Medicaid and HIV, <http://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>. (Accessed August 8, 2021)

¹⁰ "HIV Risk and Prevention: PrEP (Pre-Exposure Prophylaxis)," <https://www.cdc.gov/hiv/risk/prep/index.html>. (Accessed July 27, 2021)

¹¹ National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 1, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>. (Accessed August 27, 2021)

¹² CDC.gov, "Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2019", (Table 9b): <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf> (Accessed October 27, 2021)

¹³ HIV.gov "Ending the HIV Epidemic" <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (Accessed: April 20, 2021)

¹⁴ HIV.gov "Ending the HIV Epidemic" <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (Accessed: April 20, 2021)

¹⁵ Presidential Advisory Council on AIDS (PACHA) Resolution in Support of "Ending the HIV Epidemic: A Plan for America" <https://files.hiv.gov/s3fs-public/PACHA-End-HIV-Elimination-Resolution-passed.pdf>, (Accessed August 27, 2021)

¹⁶ AIDSvu, Oregon, <https://aidsvu.org/local-data/united-states/west/oregon/> (Accessed December 15, 2021)

¹⁷ End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

¹⁸ Oregon.gov, "End HIV Oregon launches," <https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/PROGRAMDESIGNANDEVALUATIONSERVICES/Pages/Features-EndHIV.aspx> (Accessed December 15, 2021)

In order to promote the state and federal goal to end the HIV epidemic, it is imperative that state Medicaid programs participate in local and national efforts and promote policies that contribute to HIV public health goals.

Therefore, in providing our comments, ViiV wishes to comment on several of the proposals in the demonstration. We also want to call attention to the opportunity for this waiver proposal to align with the goals of the nation's public health effort to end the HIV epidemic in order to advance the care, treatment, and prevention needs of their enrollees with HIV and those vulnerable for acquiring HIV:

1. ViiV Healthcare Opposes a Closed Formulary for Medicaid

Medicaid plays an important role in the efforts to end the HIV epidemic because almost half of people with HIV who are engaged in medical care have incomes at or below the federal poverty level.¹⁹ Medicaid is an essential source of access to medical care and antiretroviral therapy (ART) drug coverage for people living with HIV, which not only preserves the health and wellness of people with HIV, but also prevents new HIV transmissions.

The demonstration proposal²⁰ represents a substantial change to the coverage of drug therapies within Medicaid. Although we understand the state's fiscal goals in proposing a closed formulary, it would have a significant negative impact on people with HIV covered by Medicaid, and on Medicaid beneficiaries at risk for HIV who access prevention medications under the program. These changes work against the goal of ending HIV in the state by this department. We therefore offer the following comments on specific aspects of that proposal:



a. ViiV Supports Open Access to HIV Antiretrovirals Within Medicaid for HIV Treatment



The proposed demonstration would create a closed formulary in the state, which would jeopardize access to necessary antiretrovirals for people with HIV, and directly work against efforts to end HIV in the state.

The End HIV Oregon website states that the state vision is "100% of Oregonians taking HIV medications achieve the health goal of being virally suppressed," and lists the noteworthy accomplishment of the state in achieving viral suppression among 82 percent of Oregonians with HIV.²¹ The End HIV Oregon 2020 Progress Report,²² explains more about the state's successful efforts in this area, stating:

Oregon's Early Intervention Services & Outreach (EISO) Program has improved treatment outcomes for people newly diagnosed with HIV: 79% of people newly diagnosed with HIV are now linked to HIV medical care in 30 days or less through EISO compared to only 66% before the program started. The median days to viral load suppression among EISO clients newly diagnosed with HIV was 57.5 days, a result that likely contributed to Oregon reaching its 5-year goal of having 55% of all newly diagnosed Oregonians achieve viral suppression within 90 days (see metrics). We have now increased the goal to 65%.

These accomplishments will be put in jeopardy if antiretrovirals and the other necessary medications utilized by people with HIV are subjected to a closed formulary.

¹⁹ Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. June 2019, <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf> (Accessed February 2021)

²⁰ Oregon.gov, Application For Renewal And Amendment Oregon Health Plan 1115 Demonstration Waiver, "Oregon 2022-2027 Medicaid 1115 Demonstration Application," https://www.oregon.gov/oha/HSD/Medicaid-Policy/Documents/Waiver-Renewal-Application.pdf?utm_medium=email&utm_source=govdelivery, (Accessed December 15, 2021)

²¹ End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

²² Oregon.gov, End HIV Oregon, "End HIV Oregon 2020 Progress Report" https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf (Accessed December 15, 2021)

Open access to antiretroviral therapies is important for people with HIV to achieve viral suppression and maintain wellness. Effective treatment of HIV not only improves the health outcomes of people with HIV, but also can prevent transmission of HIV to others. When a person with HIV receives and maintains effective HIV treatment and receives quality medical care, they can reach viral suppression. Viral suppression means that the virus has been reduced to an undetectable level in the body with standard tests.²³ Viral suppression results in reduced mortality and morbidity and leads to fewer costly medical interventions.²⁴

Viral suppression also helps to prevent new transmissions of the virus. When successful treatment with an antiretroviral regimen results in virologic suppression, secondary HIV transmission to others is effectively eliminated. The National Institute of Allergy and Infectious Diseases (NIAID) supported research that demonstrated when people with HIV achieve and maintain viral suppression, there is no risk scientifically of transmitting HIV to their HIV-negative sexual partner.²⁵ Multiple subsequent studies also showed that people with HIV on ART who had undetectable HIV levels in their blood, had essentially no risk of passing the virus on to their HIV-negative partners sexually.^{26, 27} As a result, the CDC estimates viral suppression effectiveness in preventing HIV transmission at 100 percent.²⁸

Reduced transmissions not only improve public health, but also saves money. Preventing new transmissions offers a substantial fiscal benefit to the state. It is estimated people with HIV who are not retained in medical care may transmit the virus to an average of 5.3 additional people per 100-person years.²⁹ A recent study of commercially insured people with HIV compared to individuals without HIV found that mean all-cause costs were almost seven times higher in those with HIV, culminating in an average discounted incremental cost of \$850,557 in cumulative costs from ages 25-69.³⁰ Successful treatment with an antiretroviral regimen results in virologic suppression and virtually eliminates secondary HIV transmission to others. As a result, it is possible to extrapolate that successful HIV treatment and medical care of each infected patient may save the system up to \$4.5 million by preventing further transmission to others. These savings can only occur if people with HIV have access to medical care, receive treatment, and remain adherent to their prescribed therapy.

Subjecting antiretrovirals to a closed formulary is not consistent with clinical guidelines for HIV treatment. We encourage the state of Oregon to cover all antiretrovirals in alignment with the DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (DHHS Guidelines), as some innovations in time release, active ingredient, or dosage forms may provide benefit to patients in staying adherent to treatment regimens.

For people with HIV, adherence to antiretroviral medication is paramount in maintaining health, avoiding viral resistance, and preventing medical complications and co-morbidities.^{31,32} Nonadherence – or

²³ National Institutes of Health (NIH) "Ten things to Know about HIV Suppression" <https://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression>, (Accessed August 27, 2021)

²⁴ "Retention in Care and Adherence to ART are Critical Elements of HIV Care Interventions," Stricker, et al, AIDS and Behavior, October 2014, Volume 18, Supplement 5, pp 465–47, <https://link.springer.com/article/10.1007/s10461-013-0598-6>

²⁵ HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention | NIH: National Institute of Allergy and Infectious Diseases (Accessed June 21, 2021)

²⁶ Bavinton, et al. The Opposites Attract Study of viral load, HIV treatment and HIV transmission in serodiscordant homosexual male couples: design and methods. BMC Public Health. 2014; 14: 917. doi: [10.1186/1471-2458-14-917](https://doi.org/10.1186/1471-2458-14-917).

²⁷ Cohen, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. September 1, 2016. N Engl J Med 2016; 375:830-839. <https://www.nejm.org/doi/10.1056/NEJMoa1600693> (Accessed August 27, 2021)

²⁸ Centers for Disease Control and Prevention (CDC) "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV" <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> Accessed September 20, 2019.

²⁹ Skarbinski, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med.* 2015;175(4):588-596, (Accessed August 27, 2021)

³⁰ Cohen JP, et al. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *PharmacoEconomics - Open* (2020) 4:687–696. <https://doi.org/10.1007/s41669-020-00209-8>, (Accessed August 27, 2021)

³¹ Chesney MA. The elusive gold standard. Future perspectives for HIV adherence assessment and intervention. *J Acquir Immune Defic Syndr.* 2006;43 Suppl 1:S149-155, <http://www.ncbi.nlm.nih.gov/pubmed/17133199>.

³² HRSA, Guide for HIV/AIDS Clinical Care (April 2014), <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf>. Accessed October 13, 2017.

skipping HIV medicines – may lead to drug-resistance, and reduce or eliminate the effectiveness of treatment with some HIV medicines.³³ Due to the individualized nature of HIV treatment, it is important that treatment decisions not be subject to management processes which run the risk of disrupting established treatment regimens. A review of 29 studies evaluating the impact of non-medical switching (the practice of switching to a chemically distinct but similar medicine for reasons other than lack of clinical efficacy/response) found that among patients with stable, well-controlled disease switching led to poor side effects or nonadherence and was associated with mostly negative outcomes.³⁴ In one study, people with HIV who faced drug benefit design changes were found to be nearly six times more likely to face treatment interruptions than those with more stable coverage, which can increase virologic rebound, drug resistance, and increased morbidity and mortality.³⁵

Health care providers work closely with patients to select HIV treatment options with great specificity for each patient. People with HIV often face a variety of medical challenges that impede access to, retention in, and adherence to HIV care and treatment. PLWH rely on open formularies because the 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, and side effects. In fact, the DHHS Guidelines³⁶ state that, "[r]egimens should be tailored for the individual patient to enhance adherence and support long-term treatment success."³⁷ The guidelines also recognize that "[s]election of a regimen should be individualized based on virologic efficacy, potential adverse effects, childbearing potential and use of effective contraception, pill burden, dosing frequency, drug-drug interaction potential, comorbid conditions, cost, access, and resistance test results."³⁸ Patients often respond differently to the same drug. Even drugs in the same class can have different side-effect profiles, with some patients best suited to one particular drug.

For these reasons, ViiV encourages the state to protect antiretrovirals from a closed formulary under this demonstration proposal as doing so would directly work against the state's own End HIV Oregon efforts, and against national efforts to end the HIV epidemic.

b. ViiV Supports the Protection of Access to Antiretrovirals for HIV Prevention (PrEP) Within Medicaid



ViiV supports coverage of pre-exposure prophylaxis (PrEP) to all at-risk populations. We urge the state to advance goals related to the EHE Initiative through working with the state to also provide counseling and education related to HIV prevention, specifically HIV PrEP.

According to DHHS, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 18 percent are receiving it.³⁹ Again, in Oregon the state's PrEP coverage ratio was only 17.2 percent in

³³ AIDS Info, HIV Treatment Fact Sheet (March 2, 2017), <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance>. Accessed October 13, 2017.

³⁴ Nguyen E, Weeda E, Sobieraj D, et al. Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review. *Current Medical Research and Opinion*. 2016;32(7):1281-1290. Accessible at <https://www.ncbi.nlm.nih.gov/pubmed/27033747>.

³⁵ Das-Douglas, Moupali, et al. "Implementation of the Medicare Part D prescription drug benefit is associated with antiretroviral therapy interruptions." *AIDS and Behavior* 13.1 (2009): 1-9

³⁶ DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines> (Accessed December 17, 2021).

³⁷ Id.

³⁸ Id.

³⁹ National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 1, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>, (Accessed August 27, 2021)

2019 according to CDC.⁴⁰ Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic.

Making PrEP available and accessible is also a key part of health equity initiatives. The HIV epidemic continues to have a disproportional impact on some communities. PrEP has the potential to address HIV specific disparities and, possibly, other disparities in health care. For instance, studies have shown a correlation between increased PrEP uptake and decreases in new HIV diagnoses in the U.S., and PrEP use is also associated with increased engagement in ongoing health care.⁴¹ However, disparities in PrEP usage persist. 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.⁴² 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.

The End HIV Oregon website states that the state vision is “100% of Oregonians most in need of PrEP, a daily pill to prevent HIV, have access to it.”⁴³ The End HIV Oregon 2020 Progress Report⁴⁴ shows significant success by the state on PrEP access, noting people living in all 36 Oregon counties have access to PrEP navigation services. Navigators can link new PrEP users to more than 350 Oregon medical providers listed on the PrEP directory, including 30 new providers in rural and frontier communities.⁴⁵

These accomplishments will be put in jeopardy if antiretrovirals and the other necessary medications utilized by people with HIV are subjected to a closed formulary. The demonstration proposal therefore works against the state’s own End HIV Oregon efforts, and against national efforts to end the HIV epidemic.

c. Precedent of Antiretroviral protection

We urge the state to further protect access to antiretrovirals for both HIV treatment and prevention within any policy initiative, including this demonstration. The state has previously cited a policy that is utilized to protect access to antiretrovirals (ARV) within Medicaid, (Attachment A: “Recommendations Of Drug Use Review / Pharmacy And Therapeutics Committee August 2015,”⁴⁶) which states:



HIV Class Review / Drug Use Evaluation

The Committee recommended creating a voluntary Preferred Drug List (PDL) class for HIV antiretroviral drugs and combination products and to designate all drugs as preferred at this time. The Committee directed staff to work with established, high Medicaid volume HIV clinics to

⁴⁰ CDC.gov, “Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2019”, (Table 9b): <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf> (Accessed October 27, 2021)

⁴¹ National Strategic Plan A Roadmap to End the Epidemic for the United States | 2021–2025, page 19-20, <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>, (Accessed August 27, 2021)

⁴² Avalere Health, “PACHA Highlights Need to Address HIV PrEP Coverage Disparities,” <https://avalere.com/insights/pacha-highlights-need-to-address-hiv-prep-coverage-disparities>, (Accessed August 27, 2021)

⁴³ End HIV Oregon, <https://www.endhivoregon.org/#end-hiv-2> (Accessed December 15, 2021)

⁴⁴ Oregon.gov, End HIV Oregon, “End HIV Oregon 2020 Progress Report” https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf (Accessed December 15, 2021)

⁴⁵ Oregon.gov, End HIV Oregon, “End HIV Oregon 2020 Progress Report” https://static1.squarespace.com/static/581d04a2f5e231b25f875be2/t/5fc7fe90f118982ab231f6b6/1606942357898/OHA_EndHIV_2020ProgressReport+FINAL.pdf (Accessed December 15, 2021)

⁴⁶ Oregon Health Authority, Office of the Director, Official Website Notice, www.health.oregon.gov “RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE,” Posting Date: August 27, 2015

try to identify ARV regimens with broad tolerability and high viral response rates in most patients and that have favorable or equivalent comparative price (preferred) and try to identify ARV regimens with common tolerability problems or lower viral response rates in most patients and with an unfavorable comparative price (non-preferred).⁴⁷

Although we applaud this provision, we do not believe it would be sufficient to protect access to ART under the closed formulary proposed in this demonstration. We do not support a closed formulary within Medicaid; however, if the state intends to move forward with pursuit of a closed formulary and this demonstration, we urge the state to encapsulate this protection as a clearly stated provision within this demonstration – a carve out of HIV antiretrovirals from the closed formulary.

Although we are categorically opposed to closed formularies in Medicaid, we wish to draw the state's attention to a recent policy precedent set by another state pursuing more control over its Medicaid formulary. Recently the state of Tennessee proposed a closed formulary within its "TennCare III" demonstration. The demonstration created a closed formulary in the state but contained a provision which requires coverage of "substantially all" antiretroviral drugs in accordance with Medicare Part D coverage rules. It also further extended Part D coverage protection to also include required coverage of antiretroviral drugs when used for PrEP.⁴⁸ It stated:

The formulary must comply with: ... 2) the "substantially all" Part D coverage rules for antidepressants, anticonvulsants, antipsychotics, immunosuppressants, antineoplastics, and antiretroviral drugs (including PrEP).⁴⁹

Although ViiV opposed the creation of closed formulary within the Tennessee Medicaid program, and provided public comments in opposition of the demonstration to both the state and to CMS, ViiV highly supports policy efforts to bring Medicare Part D-like protections into Medicaid.

Within the Medicare Part D program, antiretrovirals are a protected drug class. Therefore, substantially all antiretroviral drugs must be included in formularies. Furthermore, within the Medicare Part D program, antiretrovirals are not subject to utilization management. The Medicare Prescription Drug Benefit Manual states:

"For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."⁵⁰

CMS set a policy precedent at the federal level for efforts to create Part D-like protections for antiretrovirals in Medicaid, in their guidance around the Healthy Adult Opportunity waiver. In 2020, CMS declared support for applying the Medicare Part D protected classes protection for HIV treatment to the Medicaid program in guidance, stating:⁵¹

In addition, to ensure that this demonstration supports CMS's objectives related to the treatment of HIV... CMS expects states to provide coverage of...

⁴⁷ Oregon Health Authority, Office of the Director, Official Website Notice, www.health.oregon.gov "RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPEUTICS COMMITTEE," Posting Date: August 27, 2015

⁴⁸ Tennessee, approved TennCare III demonstration, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf> (Accessed September 1, 2021)

⁴⁹ Tennessee, approved TennCare III demonstration, <https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/tn-cms-aprvl.pdf> (Accessed September 1, 2021)

⁵⁰ CMS.gov "Prescription Drug Benefit Manual," Chapter 6, "Part D Drugs and Formulary Requirements," Section 30.2.5, "Protected Classes," <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>. (Accessed Dec 20, 2021)

⁵¹ Medicaid.gov, SMD# 20-001, Re: Healthy Adult Opportunity SMD, January 30, 2020: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>. Accessed July 8, 2020.

substantially all antiretroviral drugs (including PrEP) consistent with Medicare Part D coverage...⁵²

We urge the state to consider supporting policies to protect open access to antiretroviral drugs in Medicaid, similar to the protections found in Medicare Part D, and to also support extension of this protection to antiretroviral drugs utilized for PrEP.

d. A Closed Formulary May Also Have Negative Impact on People with HIV's Ability to Manage Comorbidities

In general, proposals related to closed formularies or to therapeutic drug class limitations are specifically problematic for people with HIV. Medical challenges for people with HIV include an increased risk for, and prevalence of, comorbidities that require additional drug treatment such as depression and substance use disorders, as well as cardiovascular disease, hepatic and renal disease, osteoporosis, metabolic disorders, and several non-AIDS-defining cancers.^{53,54,55,56} The most common non-infectious co-morbidities of HIV are hypertension, hyperlipidemia, and endocrine disease.⁵⁷ Thus, people with HIV must have access to a robust formulary that provides physicians with the ability to prescribe the right treatments at the right time for their patients.

Aging people with HIV often experience non-HIV related comorbidities⁵⁸ that require polypharmacy which can increase risk for drug-drug interactions. In 2018, over half (51 percent) of people in the U.S. living with diagnosed HIV were aged 50 and older.⁵⁹ Polypharmacy is common in older patients with HIV; therefore, there is a greater risk of drug-drug interactions between antiretroviral drugs and concomitant medications. Clinically significant drug interactions have been reported in 27 to 40 percent of HIV patients taking antiretroviral therapy requiring regimen changes or dose modifications.^{60,61} Potential for drug-drug interactions should be assessed regularly, especially when starting or switching antiretroviral therapy and concomitant medications.⁶²

Therefore, we urge the state to discard its pursuit of a closed formulary, as it may have a negative impact on the health and wellness of people with HIV.

e. We Oppose the Violation of OBRA 90



⁵² Medicaid.gov, SMD# 20-001, Re: Healthy Adult Opportunity SMD, January 30, 2020 (Page 9):

<https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>, Accessed July 8, 2020

⁵³ CDC. Behavioral and Clinical Characteristics of Persons Receiving Medical Care for HIV Infection. Medical Monitoring Project United States, 2013 Cycle (June 2013–May 2014). HIV Surveillance Report 16. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-hssr-mmp-2013.pdf>

⁵⁴ Joel Gallant, Priscilla Y Hsue, Sanatan Shrey, Nicole Meyer; Comorbidities Among US Patients With Prevalent HIV Infection—A Trend Analysis, The Journal of Infectious Diseases, Volume 216, Issue 12, 19 December 2017, Pages 1525–1533, <https://doi.org/10.1093/infdis/jix518>

⁵⁵ Rodriguez-Penney, Alan T. et al. "Co-Morbidities in Persons Infected with HIV: Increased Burden with Older Age and Negative Effects on Health-Related Quality of Life." AIDS Patient Care and STDs 27.1 (2013): 5–16. PMC. Web. 21 June 2018. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3545369/>

⁵⁶ Joint HHS, CMCS, HRSA, and CDC Informational Bulletin, Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries, p. 9 (December 1, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf> (Accessed September 8, 2021).

⁵⁷ Joel Gallant, Priscilla Y Hsue, Sanatan Shrey, Nicole Meyer; Comorbidities Among US Patients With Prevalent HIV Infection—A Trend Analysis, The Journal of Infectious Diseases, Volume 216, Issue 12, 19 December 2017, Pages 1525–1533, <https://doi.org/10.1093/infdis/jix518>

⁵⁸ Schouten J, et al. Cross-sectional comparison of the prevalence of age-associated comorbidities and their risk factors between HIV-infected and uninfected individuals: the AGEHIV cohort study. Clin Infect Dis. 2014 Dec 15;59(12):1787-97.

⁵⁹ "HIV and Older Americans," CDC, <https://www.cdc.gov/hiv/group/age/olderamericans/index.html>

⁶⁰ Evans-Jones JG et al. Recognition of risk for clinically significant drug interactions among HIV-infected patients receiving antiretroviral therapy. Clin Infect Dis 2010;50:1419–1421

⁶¹ Marzolini C et al. Prevalence of comedications and effect of potential drug-drug interactions in the Swiss HIV Cohort Study. Antivir Ther 2010;15:413–423.

⁶² DHHS guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. August 16, 2021.. Accessible at <https://aidsinfo.nih.gov/guidelines> (Accessed September 8, 2021)

Under the Medicaid Drug Rebate Program (MDRP), drug manufacturers pay rebates on Medicaid utilization of their products in return for state Medicaid programs covering their products, subject only to certain “permissible restrictions” listed in the statute.^{63,64} The proposed demonstration violates these coverage requirements by establishing a closed formulary that may include only one drug in each therapeutic class. This does not comply with the rebate statute’s more patient-protective formulary standards. The case *PhRMA v. Thompson* held that the statute (SSA § 1115) does not authorize waivers of the Medicaid Drug Rebate Program laws.⁶⁵

Even if a waiver of the rebate statute were permitted, waiving its coverage requirements alone (without waiving the requirements for manufacturers to pay rebates) would violate the legislative bargain reflected in the rebate statute. As CMS has explained: [The Medicaid rebate statute] sets forth requirements for covered outpatient drugs, whereby drug manufacturers must pay statutorily defined rebates to the states through the Medicaid drug rebate program. In return, any state that provides payment for drugs must cover all covered outpatient drugs, which may include appropriate limitations on amount, duration, and scope, for the drug manufacturers that participate in the Medicaid drug rebate program.⁶⁶

The rebate statute’s legislative history⁶⁷ also emphasizes that the statute links manufacturer rebate obligations and Medicaid coverage obligations. Congress required states to cover all products of a manufacturer with a Medicaid rebate agreement (with specified exceptions), to ensure beneficiary access to the full range of drugs that are available to private patients. The statute purposely coupled the rebate requirements on manufacturers with the coverage requirements on states; it was described by Congressman Henry Waxman, a key sponsor, as a “government-industry compact.”⁶⁸

Thus, the state of Oregon cannot retain the mandatory rebate for some classes and have a closed formulary for others. For further indications of this, we refer the state of Oregon to review the decisions previously made by CMS in response to a similar proposal from Massachusetts in 2018.⁶⁹

Conclusion

Thank you for your consideration of these comments. We hope that the state will continue its work to end the HIV epidemic in Oregon, and support national efforts to do the same.

Sincerely,

A handwritten signature in black ink that reads "Kristen Tjaden". The signature is fluid and cursive, with a long horizontal stroke at the end.

Kristen Tjaden
Government Relations
ViiV Healthcare

⁶³ SSA § 1927(d)(1)(B))

⁶⁴ Medicaid rebates for covered outpatient drugs, codified at 42 U.S.C. § 1396r-8

⁶⁵ *PhRMA v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001)

⁶⁶ 78 Fed. Reg. 4594, 4631 (Jan. 22, 2013)

⁶⁷ H. Rpt. 101-881, 101st Congress, 2d Session (Oct. 16, 1990)

⁶⁸ Medicare and Medicaid Reconciliation: Hearings Before the Subcomm. on Health and the Environment of the Committee on Energy and Commerce, H. Hrg. 103-61, 103rd Cong. 453 (1993) (statement of Rep. Waxman).

⁶⁹ CMS letter to Daniel Tsai, Assistant Secretary, MassHealth, June 27, 2018