HIV+HEP
POLICY INSTITUTE

November 23, 2026

Mr. Michael Yaworsky
Insurance Commissioner
Florida Office of Insurance Regulation
200 East Gaines Street
Tallahassee FL 32399

Subject: Complaint on Florida Blue Coverage of HIV PrEP

Dear Commissioner Yaworsky:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people and communities affected by HIV, hepatitis, and other serious and chronic health conditions. We are submitting this formal complaint against **Blue Cross and Blue Shield of Florida**, **Inc.,** including its subsidiary Health Options, Inc. (together, Florida Blue) regarding inadequate coverage of HIV pre-exposure prophylaxis (PrEP) in its individual, Marketplace, and fully insured group plans.

First, we believe Florida Blue is **violating federal preventive services requirements** by omitting Descovy from some of its formularies, and elsewhere by covering it without cost-sharing only through an impermissible "Tier Exception" process that steers enrollees towards generic Truvada. Second, Florida Blue has adopted a medical policy **deeming Yeztugo (lenacapavir), the longest-acting injectable for the prevention of HIV, "not medically necessary,"** which excludes an FDA-approved PrEP drug from coverage in violation of federal preventive services and Essential Health Benefit (EHB) requirements.

Florida Blue's coverage decisions are of considerable interest to people affected by HIV. Florida is heavily burdened by HIV, with 4,438 new diagnoses in 2023 and the second-highest diagnosis rate of any state.[1] Florida Blue is the largest issuer on Florida's individual market, and Florida's Marketplace enrolls more people than any other state Exchange.

Florida Blue Violates PrEP Coverage Requirements

Under the ACA, non-grandfathered plans must cover without cost-sharing preventive services that have been given an "A" or "B" grade by the United States Preventive Services Task Force (USPSTF), including PrEP, which has had an "A" grade since its first recommendation in 2019.

[1] KFF, Estimated Numbers of HIV Diagnoses, Adults and Adolescents (2023 data). https://www.kff.org/hiv-aids/state-indicator/hiv-diagnoses-adults-and-adolescents

The most recent federal guidance, issued in October 2024, required plans to cover FDA-approved PrEP without cost-sharing, naming the three drugs approved at the time – Truvada, Descovy, and Apretude – and also prohibited "medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another."[2] Florida Blue does not appear to have revised its own policies to conform with this guidance. For example, its Preventive Services medical coverage guideline simply restates the USPSTF recommendation without listing PrEP drugs, and although Florida Blue revised the guideline five times after October 2024, its PrEP language was last revised in July 2024. [3]

Based on a review of their plan documents, we believe Florida Blue violates these requirements. Its January 2027 individual market Essentials and ValueScript Six-Tier formularies list only generic Truvada (emtricitabine/tenofovir disoproxil) on tier 1, its zero-cost preventive tier. Descovy, the most widely prescribed PrEP drug, is listed on tier 5, which Florida Blue describes as the "high-cost" tier, without any indication that it is on a zero-cost preventive tier when prescribed as PrEP. Florida Blue's large-group Essentials formulary goes further, omitting Descovy from coverage altogether.[4]

Florida Blue's list of provider-administered specialty drugs includes Yeztugo,[5] though subject to prior authorization, but as discussed below, Florida Blue's medical policy means no prior authorization will be approved. Florida Blue's Preventive Medications List only includes generic Truvada (emtricitabine/tenofovir disoproxil) and, unusually, tenofovir disoproxil (TDF) monotherapy, which has not been approved by FDA for use on its own as PrEP, and has not been shown to be effective for men who have sex with men.[6]

In order to access any PrEP medications other than generic Truvada without cost-sharing through the pharmacy benefit, prescribers must submit a "Tier Exception Request" attesting to whether it is "medically necessary compared to other available PrEP agents," listing medications the patient "has previously tried and failed," and stating "all reasons for selecting the requested medication…over alternatives." For long-acting PrEP, the form requires the prescriber to show that oral options – generic Truvada, Descovy, or TDF monotherapy – are "contraindicated, likely to be less effective, or will cause an adverse reaction or other harm for

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[2] Departments of Labor, HHS, and Treasury, *FAQs About Affordable Care Act and Women's Health and Cancer Rights Act Implementation Part 68* (October 21, 2024). https://www.cms.gov/files/document/faqs-implementation-part-68.pdf

[3] Florida Blue. Medical Coverage Guideline 01-99385-03 Preventive Services (revised January 1, 2026). https://mcgs.bcbsfl.com/MCG?mcgId=01-99385-03&pv=false

[4] Florida Blue, January 2027 Essentials Rx Medication Guide (individual market), https://www.myprime.com/content/dam/prime/memberportal/WebDocs/2027/Formularies/HIM/2027_FL_6T_Essential.pdf; Florida Blue, January 2027 ValueScript Rx Medication Guide (individual and small group market), https://www.myprime.com/content/dam/prime/memberportal/WebDocs/2027/Formularies/HIM/2027_FL_6T_ValueScript.pdf; Florida Blue 2027 Essentials Rx Medication Guide (large group), https://www.bcbsfl.com/DocumentLibrary/Providers/Content/LGEssentialsRxMedicationGuide.pdf; and see also Florida Blue, Medication Guides, https://www.floridablue.com/members/tools-resources/pharmacy/medication-guide, identifying formularies used in the individual, small group, and large group markets.

[5] Florida Blue, Provider Administered Specialty Drugs (October 1, 2026). https://www.bcbsfl.com/DocumentLibrary/Providers/Content/RxF_Specialty_Table_Prov.pdf

[6] Florida Blue, Preventive Medications List (January 1, 2026). https://www.bcbsfl.com/DocumentLibrary/Providers/Content/RxF_PreventiveMedications.pdf

the patient."[7] This is medical management of the exact type prohibited by current guidance, "to direct individuals prescribed PrEP to utilize one formulation over another." The Tier Exception process is the only path Florida Blue appears to provide for no-cost coverage of Descovy. Florida Blue does cover Apretude without cost-sharing or prior authorization in the medical benefit, and, as described below, deems Yeztugo never medically necessary.[8]

Florida Blue Deems Yeztugo Never Medically Necessary

Yeztugo (lenacapavir) is the most recently approved PrEP formulation, the longer acting of the two injectable drugs, with twice-yearly dosing. Florida Blue's Medical Coverage Guideline for Yeztugo states that the drug "does not meet the definition of medical necessity, as medical necessity is not primarily for the member's convenience."[9] Although Florida Blue lists Yeztugo as available through the medical benefit with prior authorization, its Medical Coverage Guideline means no coverage will be approved.

To deem twice-yearly dosing as merely for a member's convenience is to ignore the significance of long-acting PrEP. Daily oral PrEP does not work for the many people who cannot take a pill every day, with adherence hardest for many of those at greatest risk, including young people, the unstably housed, people with mental illness or substance use, and people who lack a safe place to store pills. Florida Blue's guideline notes that all PrEP products work well "when taken as prescribed," glossing over the voluminous evidence that many of those at substantial risk for HIV are unable to adhere to a daily oral regimen.

Quite perversely, Florida Blue's own medical policy restates the results of the clinical trials that established the superiority of Yeztugo to oral PrEP, noting that zero out of 2,134 women taking Yeztugo acquired HIV in PURPOSE 1, and that Yeztugo was 89 percent more effective than daily oral PrEP in PURPOSE 2. Both trials had to be stopped early as continuing to provide daily orals after superiority had been demonstrated would pose an ethical challenge.

Florida Blue's policy also violates federal preventive services requirements. The USPSTF recommends PrEP "using effective antiretroviral therapy," not specific PrEP products. Federal regulators have consistently read the recommendation to encompass FDA-approved PrEP, including drugs approved by the FDA as PrEP after the USPSTF recommendation. For example, when federal regulators first issued PrEP coverage guidance in 2021, they stated that the recommendation "encompasses FDA-approved PrEP antiretroviral medications," including Descovy, which had not yet been approved at the time of the 2019 USPSTF recommendation.[10] Similarly, the Medicare National Coverage Determination for PrEP covers any drug approved by

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[7] Florida Blue, HIV PrEP Tier Exception Request Provider Fax Form (FL_CRU_HIV_Prep_TE_Fax7007_09). https://files.guidewell.com/m/7d7fa50dc55d3774/original/providers-forms-pharmacy-hiv-prep-tier-exception.pdf

[8] Florida Blue, Medical Coverage Guideline 09-J0000-68, Drugs and Biologics without a Medical Coverage Guideline (September 15, 2026), https://mcgs.bcbsfl.com/MCG?mcgId=09-J0000-68&pv=false.

[9] Florida Blue, Medical Coverage Guideline 09-J5000-23, Yeztugo (lenacapavir). July 15, 2026. https://mcgs.bcbsfl.com/MCG?mcgId=09-J5000-23&pv=false

[10] Departments of Labor, HHS, and Treasury, *FAQs About Affordable Care Act Implementation Part 47* (July 19, 2021) https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-47

the FDA for use as PrEP,[11] and, as discussed below, CMS counts Yeztugo in ACA risk adjustment. Any other approach would mean that Floridians would have to wait three to six years to benefit from the results of the latest innovations in HIV prevention, assuming the USPSTF continues to operate on its usual five-year cycle.

Nothing in federal guidance permits Florida Blue's categorical exclusion of an FDA-approved PrEP drug. Since 2021, federal guidance has required that any medical management of PrEP be accompanied by an "easily accessible, transparent, and sufficiently expedient" exceptions process that waives cost-sharing when a provider deems the covered PrEP drug or drugs medically inappropriate for the patient.[12] Florida Blue's medical policy ensures that no prior authorization or exceptions process can ever succeed for Yeztugo, and therefore is prohibited among all non-grandfathered plans in the individual, small group and large group fully-insured markets.

Setting the preventive services requirement aside, Florida Blue's medical policy for Yeztugo also violates the federal Essential Health Benefit requirement that individual and small-group plans provide an exceptions process through which enrollees can obtain clinically appropriate drugs not otherwise covered.[13] There is no meaningful exceptions process when an insurer has decided in advance that no request could ever be medically necessary.

Florida Blue Asked to Be Compensated for Covering PrEP, and It Now Can Be

For years, Florida Blue and the Blue Cross Blue Shield Association urged CMS to account for PrEP use in the ACA risk-adjustment program, so that plans enrolling many PrEP users would not be financially penalized. In 2024, Florida Blue told CMS that it would "continue to advocate for a PrEP RxC [prescription drug category]," and warning that the alternative would be "creating incentives for narrow networks and discriminatory benefit designs."[14] Florida Blue framed its interest in risk adjustment as a matter of principle, telling CMS that "good policy means we do not have to choose between our social mandate and our success as a business,"[15] and that it "takes its social mandate seriously."[16]

When CMS finally did propose a PrEP cost factor for the risk adjustment calculation, Florida Blue noted that without one, an issuer who successfully gets people at risk for HIV on PrEP would be "incurring costs to reduce revenue," and that adding the PrEP factor "removes this perverse incentive, so issuers do not have to choose between revenue and doing the right thing for our enrollees." Florida Blue also acknowledged that without a new PrEP cost factor, barriers

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[11] CMS, *National Coverage Determination 210.15, Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention* (September 30, 2024). https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=377

[12] Part 47, q3.

[13] 45 CFR 156.122(c)

[14] Florida Blue, Comments on the Proposed HHS Notice of Benefit and Payment Parameters for 2025 (January 8, 2024). https://www.regulations.gov/comment/CMS-2023-0191-0192

[15] Florida Blue, Comments on the Proposed HHS Notice of Benefit and Payment Parameters for 2024, page 1 (January 30, 2023). https://www.regulations.gov/comment/CMS-2022-0192-0148

[16] Florida Blue, Comments on the Proposed HHS Notice of Benefit and Payment Parameters for 2026, page 11 (November 11, 2024), https://www.regulations.gov/comment/CMS-2024-0311-0069

to PrEP benefit insurers financially, "[e]ven if there was no intentional effort to create barriers to PrEP." [17].

CMS adopted the PrEP factor suggested by Florida Blue, creating a new type of risk adjustment factor to account for PrEP use beginning with the 2026 benefit year. The CMS rule noted that issuers of risk adjustment covered plans are "required to cover PrEP and its ancillary services at zero cost sharing."[18] The new risk adjustment factor excludes generics, only accounting for branded PrEP use, and CMS' list of the drugs included in the calculation lists Yeztugo alongside Descovy and Apretude.[19] ACA plan issuers are now compensated for enrollees using exactly the drugs Florida Blue now restricts. In Florida Blue's own words, it maintains the "discriminatory benefit designs" it told CMS that adequate risk adjustment would discourage.[20]

Conclusion

Florida cannot fully benefit from the latest scientific advances in HIV prevention and help to bring its substantial HIV epidemic to an end if the state's largest commercial insurer flouts the law by limiting no-cost access to PrEP, and by excluding a PrEP drug that *Science* magazine named its 2024 "Breakthrough of the Year."[21]

We urge the Office of Insurance Regulation (OIR) to **require Florida Blue to comply with PrEP coverage requirements by covering all FDA-approved PrEP drugs without cost-sharing and without tier exceptions, prior authorization, or other requirements steering enrollees towards particular PrEP formulations, before the beginning of the 2027 plan year.** We further urge OIR to **require Florida Blue to rescind its medical policy deeming Yeztugo not medically necessary,** and to **require Florida Blue to refund any cost-sharing enrollees have paid for PrEP since January 1, 2025.** Finally, we ask OIR to review Florida Blue's PrEP coverage across all state-regulated markets**.**

If you have any questions, comments, or would like to discuss these issues further, please contact Carl Schmid, Executive Director, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042, or Kevin Herwig, Health Policy Director, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634.

[17] Florida Blue, 2026 NBPP comments, page 11
[18] 89 FR 82323-24 (October 10, 2024). https://www.govinfo.gov/content/pkg/FR-2024-10-10/pdf/2024-23103.pdf
[19] CMS, *2026 Benefit Year Risk Adjustment Model Software Instructions (DIY)*, https://www.cms.gov/files/document/cy2026-diy-instructions-07-31-26.pdf and CMS, 2026 Benefit Year Risk Adjustment HHS-Developed Risk Adjustment Model Algorithm "Do It Yourself (DIY)" Software, Tables 10c and 10d (July 31, 2026), https://www.cms.gov/marketplace/resources/regulations-guidance
[20] Florida Blue, 2025 NBPP comments, page 3.
[21] Jon Cohen, "2024 Breakthrough of the Year: The Long Shot," *Science* (December 12, 2024), https://www.science.org/content/article/breakthrough-2024

Sincerely,



Carl E. Schmid, II
Executive Director

cc: Peter Nelson, Director, CCIIO
Jeff Wu, Deputy Director for Policy, CCIIO