HIV+HEP
POLICY INSTITUTE

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Subject: Issuer Compliance with Current and Updated USPSTF PrEP Recommendations

Dear Administrator Brooks-LaSure:

The **HIV+Hepatitis Policy Institute,** a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, **urges the federal government to issue updated guidance to issuers to reflect the most recent USPSTF recommendation for PrEP to prevent HIV and to take further actions to ensure compliance.**

On August 22, 2023, the United States Preventive Services Task Force (USPSTF) finalized an updated A-grade recommendation for HIV Pre-Exposure Prophylaxis (PrEP)[1] to include, among other things, two new medications:

- A second daily oral PrEP medication, **emtricitabine/tenofovir alafenamide or Descovy**, which was approved by the FDA in October 2019. It offers benefits to people with renal or bone density issues, comes in a much smaller pill size, and is currently approved for cisgender men and transgender women.

- The first-ever long-acting PrEP drug, **cabotegravir or Apretude**, an injectable administered every two months, was approved by the FDA in December 2021. In large-scale clinical trials it demonstrated superiority to oral PrEP in preventing HIV, with a 69 percent lower rate of HIV acquisition among cisgender men and transgender women,[2]

[1] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis
[2] https://www.hptn.org/research/studies/hptn-083

and a 90 percent lower rate among cisgender women.[3] Long-acting PrEP offers benefits to the many people who have difficulty taking daily oral formulations as prescribed, as well as to those with confidentiality or storage issues.

Section 2713 of the Affordable Care Act requires non-grandfathered health plans to cover, without cost-sharing, all USPSTF-recommended preventive services as of plan year start dates on or after the first anniversary of the date of the recommendation. **As the date approaches when plans must be in compliance with the *updated* USPSTF PrEP recommendation, we urge you and your fellow federal Departments to issue *updated* guidance to issuers reflecting the most recent USPSTF recommendation.**

A dozen years after the FDA approved the first PrEP medication, emtricitabine/tenofovir disoproxil or Truvada, in July 2012, only 36 percent of all those who would benefit from PrEP are taking PrEP, with stark and widening racial, ethnic, gender, and geographic disparities in uptake. For example, Black people comprise 39 percent of new HIV diagnoses, but only 14 percent of PrEP users; Hispanic people made up 31 percent of new HIV diagnoses, but only 18 percent of PrEP users.[4] If you examine the PrEP-to-need ratio (PNR), which is a measure that compares how many people are using PrEP to the number of new HIV diagnoses in a given population, Blacks have a PNR of only 4.6, Latinos have a PNR of 9.2, but for Whites it is 35.8.[5]

With commercially insured people estimated to make up 73 percent of PrEP users in 2022 and 55 percent of all people eligible for PrEP, access to PrEP through commercial insurance is of critical importance to ending HIV.[6] **Broad and equitable access to PrEP in all populations who may benefit from it cannot be achieved without ensuring access to PrEP through commercial insurance.**

<u>The USPSTF Recommendation Encompasses All PrEP Medications</u>

The USPSTF recommends the prescription of PrEP using "effective antiretroviral therapy" to individuals at increased risk of acquiring HIV. This recommendation is not specific to particular PrEP medications. Now that we have a range of PrEP options to prevent HIV—and with more long-acting PrEP formulations in development—people will increasingly have a choice of PrEP options to suit their clinical and personal needs. PrEP users should be able to access the medication their provider prescribes to meet their needs free of access barriers.

We urge you to apply the same standards for PrEP coverage requirements in an updated guidance to issuers as you have done for contraception, for which ACA preventive coverage has been in place since 2011. For contraception, plans and issuers are required "to cover without cost sharing any contraceptive services and FDA-approved, -cleared, or -granted contraceptive products that an individual's attending provider determined to be medically appropriate for the

[3] https://www.hptn.org/research/studies/hptn-084
[4] https://aidsvu.org/news-updates/aidsvu-releases-new-prep-data-and-launches-prepvu-org-a-new-prep-equity-platform/
[5] https://aidsvu.org/wp-content/uploads/2023/06/03-Nationl-Race-a-3.png
[6] https://hivhep.org/wp-content/uploads/2022/11/PrEP_Cost_Final_Report_21November2022.pdf

individual."[7] This guidance uses a therapeutic equivalence standard under which insurance plans must cover any contraceptive drug other than those for which an exact therapeutic equivalent is available, such as a generic formulation. **We encourage the tri-departments to clarify in updated guidance that the preventive coverage mandate applies to all medications shown to be effective as PrEP, and stress that they cannot select just one drug.**

Clinical Visits and Required Laboratory Testing Are Integral to PrEP

Insurance plans subject to the ACA preventive service mandate "must cover, without cost-sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately."[8] CDC clinical practice guidelines for PrEP, last updated in 2021, require an expanded suite of laboratory testing, including some differences in recommended laboratory testing for the three different PrEP medications, and a different cadence of testing for long-acting PrEP.[9] The updated USPSTF recommendation for PrEP refers to this suite of ancillary services, including required laboratory testing as well as clinical visits and adherence services associated with the new PrEP drugs. **Additionally, we urge that an updated PrEP FAQ reiterate that plans must cover all CDC-recommended ancillary services without cost-sharing and require plans to automatically incorporate any new recommended ancillary services as the CDC updates its clinical guidelines, instead of waiting for a multiyear process.**

People Must Be Able to Access All PrEP Medications and Ancillary Services Without Cost-Sharing

Over the years there has been mounting evidence that no-cost access to preventive services both increases uptake and reduces disparities. A recent study of claims data looked at rates of PrEP abandonment at the pharmacy counter and showed that even low out-of-pocket costs are associated with much higher rates of prescription abandonment—and that individuals who have abandoned a PrEP prescription are more likely to show an HIV diagnosis within a year. According to the modeling conducted, while there was a 5.5 percent PrEP abandonment rate when there was zero cost-sharing, when it was $10 the rate of abandonment doubled and increased to almost 43 percent when cost-sharing was more than $500.[10]

A recent study that focused on cardiovascular health showed that removing cost-sharing requirements improves or even eliminates racial/ethnic disparities in healthcare utilization. When non-white patients accessed beta-blockers and statins for the prevention of heart attacks without cost-sharing they experienced improved adherence leading to a 70 percent reduction in total health spending.[11]

The principle that all PrEP medications should be available without cost-sharing has been increasingly endorsed by both state and federal governments. Several states already prohibit

[7] https://www.erisapracticecenter.com/wp-content/uploads/sites/42/2024/02/aca-part-64.pdf
[8] https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf
[9] https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
[10] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00808
[11] https://vbidcenter.org/v-bid-in-action-the-role-of-cost-sharing-in-health-disparities/

cost-sharing for *all* PrEP medications: California,[12] Colorado, Maine,[13] New Jersey, and New York; and legislative efforts to make this a reality in other states is ongoing.[14] CMS has proposed a National Coverage Determination for PrEP in Medicare that, if finalized, would remove all cost-sharing from all current and future PrEP formulations as a preventive service through Part B.[15]

Therefore, we urge you to issue updated guidance without delay to require issuers to cover <u>all</u> forms of PrEP and all recommended ancillary services without cost-sharing.

<u>Utilization Management Should Not be Allowed for PrEP</u>

Another barrier to widespread uptake of PrEP is the imposition of cumbersome utilization management processes such as prior authorization or "fail first" step therapy. Requiring people on PrEP to "fail" a drug is absurd, as failure likely means PrEP discontinuation or the acquisition of HIV. Prior authorization processes used by insurers result in frequent denials and are rarely appealed; prior authorization denials are more frequently experienced by Black and Latino individuals.[16] Prior authorization for PrEP has also been found to be more prevalent in the South, the part of the country that has higher HIV diagnosis rates.[17] The completion of prior authorization is one of the most frequently cited barriers to PrEP in surveys of clinicians.[18] We frequently hear from clinicians that it is easier to provide PrEP to uninsured people than those who are insured. The principle that prior authorization should not generally be permitted for antiretrovirals to prevent (or treat) HIV is already acknowledged in Medicare Part D.[19]

Some states already prohibit utilization management for PrEP. For example, California prohibits prior authorization or step therapy for antiretrovirals for the prevention of HIV (except for therapeutically equivalent drugs such as a branded drug and its generic).[20] New York State recently codified into law the prohibition of all prior authorization on any antiretrovirals for the treatment or prevention of HIV.[21]

We encourage the federal government to act to ensure that protections against utilization management are not limited to Medicare Part D or to residents of certain states and use its

---

[12] https://www.insurance.ca.gov/0250-insurers/0300-insurers/0200-bulletins/bulletin-notices-commiss-opinion/upload/CDI-Bulletin-2021-10-Preventive-Services-Coverage-for-HIV-PrEP.PDF

[13] https://www.maine.gov/pfr/professionallicensing/sites/maine.gov.pfr.professionallicensing/files/inline-files/2021_public_law_chapter_265_improve_access_to_hiv_prevention_medications.pdf

[14] For example, https://malegislature.gov/Bills/193/S619

[15] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310

[16] https://hivhep.org/wp-content/uploads/2023/03/032123-NAIC-Consumer-Liaison-presentation-final.pdf

[17] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811641

[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5500978/

[19] https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf, section 30.2.5

[20] California: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB159

[21] New York: https://www.governor.ny.gov/news/governor-hochul-signs-legislation-support-lgbtq-new-yorkers-and-people-living-hivaids

powers to prohibit utilization management for PrEP nationwide. This would promote the equity needed throughout the country to improve PrEP uptake and reduce disparities.

One form of utilization management we have seen recently involves the proliferation of "copay waiver" processes solely for the purpose of allowing people to access zero cost-sharing.[22] We also urge insurance regulators to prohibit utilization management for the purpose of identifying individuals at high risk for HIV.[23] Current CDC guidance recommends that PrEP be prescribed to anyone who asks for it, since many people who need PrEP are unwilling to share stigmatized sexual and substance use behaviors to their provider. Only clinicians should determine HIV risk, not insurers.

Medical management techniques create barriers and have impeded access to PrEP. Since we need to reduce barriers in order to increase PrEP use to prevent HIV and help bring the HIV epidemic to an end, we urge you not to allow prior authorizations.

Updated Guidance Must Ensure Timely Access to Future PrEP Formulations

We believe that the USPSTF recommendation has always encompassed medications newly shown to be effective as PrEP, not just those medications approved at the time of the recommendation. For example, though the 2019 USPSTF recommendation was issued at a time when there was only a single medication approved as PrEP, the 2021 tri-department FAQ recognized that any or all of the three PrEP drugs available at that time (Truvada, its generic equivalent, and Descovy) could be covered as clinically appropriate to satisfy the ACA preventive coverage requirement. The draft Medicare National Coverage Determination for PrEP encompasses all forms of PrEP including future formulations, showing that in CMS' view the USPSTF recommendation already encompasses future PrEP medications.

Several promising long-acting antiviral medications are being investigated for use as PrEP.[24] In June, the first results of clinical trials for the use of a once every six-month injectable demonstrated that it was 100 percent effective in preventing HIV infection in cisgender women and adolescent girls. Results in cisgender men and other populations are expected to be released later in the year and early 2025. Approval of this and other PrEP drugs in development all would be game-changers and quicken the pace in ending new HIV infections, if people can access them.

All long-acting formulations have the potential to mitigate adherence problems experienced with daily oral PrEP. They offer particular promise for women and underserved populations such as the unhoused/unstably housed or justice-involved individuals for whom adherence to a

---

[22] For example, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/pdfs/ORxCommForms/HealthCareReformCopayWaiver.pdf or https://www.bluecrossnc.com/content/dam/bcbsnc/pdf/members/preventive-care/aca-copay-waiver-criteria.pdf

[23] See, for example: https://ahiporg-production.s3.amazonaws.com/documents/AHIP-Response_PrEP-Letter.pdf (page 3)

[24] https://lapal.medicinespatentpool.org/#/

daily pill is especially difficult.[25] Several modeling studies have projected that increasing uptake of cabotegravir as PrEP (Apretude), available since 2022, will yield substantial decreases in the incidence of HIV, with one study predicting 87 percent more HIV cases averted compared with use of daily oral PrEP with $4.25 billion in averted healthcare costs over 10 years.[26]

Several state legislators and insurance regulators have already acted to ensure that future PrEP formulations are incorporated automatically into coverage requirements. This ensures that people in all populations are able to benefit from scientific advances without the delays we have seen with PrEP. Merely waiting for new PrEP formulations to be assessed by a new USPSTF recommendation cycle risks multi-year delays in insurance access to scientific innovation in HIV prevention, and ultimately delays bringing the HIV epidemic to an end.

Insurance Regulators Should Take Timely Action to Implement and Enforce the Updated USPSTF Regulation

We ask the federal government to issue guidance without delay addressing the elements we have outlined above. The Departments of Labor, Health and Human Services, and the Treasury issued guidance *two years after* the initial USPSTF A-grade recommendation for PrEP, after widespread egregious non-compliance by insurance plans nationwide. The delay in issuing these guidelines is one factor that has led to issuer non-compliance. We cannot have a repeat of this for long-acting PrEP.

Even though the July 2021 tri-department FAQ gave issuers 60 days to comply with the PrEP coverage mandate *already in effect,* widespread non-compliance continued. Since then, there have been additional reminders and enforcement actions by some state insurance regulators, but non-compliance continues.[27]

Providers and advocates encounter cases of cost-sharing being charged for PrEP very frequently. One recent analysis of claims data after the FAQ was issued and into 2023 found that 36 percent of PrEP users were charged cost-sharing for PrEP *drugs*. Even for generic PrEP, 31 percent of PrEP users faced cost-sharing.[28] In a claims data study conducted by the CDC examining cost-sharing for PrEP *ancillary services*, including provider visits, they found that one out of three commercially insured persons were charged cost-sharing in 2022 for ancillary services, with the mean out-of-pocket payment of $222. Fifty percent of these costs were for the provider visits, while the remainder were for other lab tests and counseling.[29]

---

[25] https://www.hiv.gov/blog/long-acting-antiretroviral-therapy-suppresses-hiv-among-people-with-unstable-housing-mental-illnesses-substance-use-disorders/

[26] https://hivhep.org/wp-content/uploads/2024/02/PrEP_Cost_HIV_Incidence_Updates_Memo_20231128.pdf and https://www.ingentaconnect.com/content/wk/qai/2022/00000091/00000002/art00006

[27] https://hivhep.org/wp-content/uploads/2024/05/Key-PrEP-Policy-Issues-Impacting-Access-for-Insured-Populations-5.29.24.pdf (slides 11 and 12)

[28] Slide 11, https://hivhep.org/wp-content/uploads/2024/05/Key-PrEP-Policy-Issues-Impacting-Access-for-Insured-Populations-5.29.24.pdf. From Zachry et al, Impact of the United States Preventive Task Force Guidelines on Pre-Exposure Prophylaxis (PrEP) Claims and HIV-1 Infection Incidence: An Interrupted Time Series with Segmented Regression Analysis. AMCP-Nexus 2023, Orlando FL.

[29] https://www.croiconference.org/wp-content/uploads/sites/2/posters/2024/1117.pdf

We urge federal and state insurance regulators to undertake bolder enforcement actions to ensure that insurance plans do not continue to collect cost-sharing for PrEP. Insurance regulators must move beyond responding to individual insurance complaints—which can be undertaken only by individuals with time, resources, information, and patience—and investigate patterns of non-compliance with ACA preventive service mandates and compel plans to follow the law.

The new CDC ICD-10 code for PrEP, combined with Modifier 33 to flag $0 cost-sharing ACA preventive services, means that PrEP services can be unambiguously flagged. Insurers should no longer be able to use complex coding requirements that vary from issuer to issuer to excuse wholesale non-compliance with the law.[30]

No-Cost PrEP Should Be Clearly Discernible on Formularies and Plan Documents

Several groups have pointed out that even if a health insurance plan makes PrEP medications, ancillary services, and medical visits available without cost-sharing, this may not be apparent to a consumer from formularies and other plan documents.[31] We urge all insurance regulators to take steps to ensure that the availability of PrEP drugs on an ACA preventive cost-sharing tier should be clearly marked on formularies as well as on preventive drug lists. The availability of laboratory services and clinical visits integral to PrEP should be readily discernible on preventive service lists and other plan documents as well.

Increasing PrEP uptake and improving disparities in uptake are key pillars in the federal government's National HIV/AIDS Strategy[32] as well as of the *Ending the HIV Epidemic in the U.S.* initiative,[33] which aims for a 90 percent reduction in HIV transmission by 2030. The updated USPSTF recommendation for PrEP is a critical step forward in efforts to end the HIV epidemic in the United States and to reduce ethnic, racial, and other disparities. We appreciate CMS' role in implementing and enforcing ACA preventive coverage mandates for PrEP and look forward to working with you to ensure success.

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

---

[30] https://nastad.org/sites/default/files/2023-10/PDF-HIV-Prevention-BillingAndCoding-101223.pdf

[31] https://hivhep.org/wp-content/uploads/2021/07/PrEP-ACA-coverage-FAQ-july-2021.pdf (page 2); https://www.theaidsinstitute.org/eliminating-hiv/marketplace-insurance-plan-prep-compliance

[32] https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025

[33] https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

Sincerely,

Carl E. Schmid II
Executive Director

cc: Ellen Montz, Deputy Administrator, CMS, and Director, CCIIO
Jeff Wu, Deputy Director for Policy, CCIIO
ADM Rachel Levine MD, Assistant Secretary for Health, HHS
Adrian Shanker, Acting Deputy Assistant Secretary for Health Policy & Senior Advisor on LGBTQI+ Health Equity, Office of the Assistant Secretary for Health
Jonathan Mermin MD MPH, Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), CDC
CAPT Robyn Fanfair Neblett MD MPH, Director, Division of HIV Prevention (DHP), NCHHSTP
Amber Rivers, Director, Office of Health Plan Standards & Compliance Assistance, Employee Benefits Security Administration, DOL
Francisco Ruiz, Director, Office of National AIDS Policy, White House Domestic Policy Council