



June 18, 2020

To: State Insurance Commissioners

Re: Considerations for USPSTF PrEP Recommendation Implementation

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV and hepatitis C-related healthcare and support services. In June 2019, the U.S. Preventive Services Task Force (USPSTF) finalized a Grade A recommendation for pre-exposure prophylaxis (PrEP).<sup>1</sup> PrEP is a once-daily anti-retroviral medication that when taken regularly prevents acquisition of HIV.<sup>2</sup> The USPSTF final recommendation is a necessary step to increase access to this highly effective prevention tool.

In the U.S., there are more than a million people living with HIV and nearly 40,000 new cases occur annually. Just over 50 percent of people living with HIV are on effective treatment, meaning the virus is suppressed in their bodies to undetectable levels, which allows them to stay healthy and stops their risk of transmitting HIV to their sexual partners. Increasing access to HIV treatment and to PrEP is critical to reduce the number of new HIV transmissions. Currently, only 35% of men who have sex with men and 7% of all individuals (approximately 1.1 million people) in the U.S. who could benefit from PrEP had been prescribed PrEP.<sup>3,4</sup> For insured individuals, cost sharing associated with both the medication and the clinic and lab visits has been a persistent barrier to PrEP, making the public and private insurance coverage and cost-sharing requirements associated with the USPSTF Grade A rating for PrEP an important opportunity to expand access.

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<sup>1</sup> USPSTF Final Grade A Recommendation for PrEP (June 2019), available at <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

<sup>2</sup> Pacific AIDS Education & Training Center, PrEP Efficacy Trial Results, available at [http://paetc.org/wp-content/uploads/2018/02/PAETC\\_PrEP\\_Efficacy.pdf](http://paetc.org/wp-content/uploads/2018/02/PAETC_PrEP_Efficacy.pdf). A recent study examining PrEP persistence among those on employer-sponsored insurance found that of those taking PrEP remained on it for an average of 14.5 months. Huang Y-L A et al., Persistence with HIV preexposure prophylaxis in the United States, 2012-2016. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 106, 2019.

<sup>3</sup> Finlayson T, Cha S, Zia M, et al. Changes in HIV Preexposure Prophylaxis Awareness and use Among Men who Have Sex with Men – 20 Urban Areas, 2014 and 2017. MMWR. 2019 Jul 12;68(27):597-603

<sup>4</sup> Huang YA, Zhu W, Smith DK, et al. HIV Preexposure Prophylaxis, by Race and Ethnicity - United States, 2014-2016. MMWR. 2018 Oct 19;67(41):1147-1150.

The Administration’s Ending the HIV Epidemic initiative, which aims to reduce new HIV transmissions by 90 percent by 2030, includes increasing PrEP utilization as a core pillar of the initiative.<sup>5</sup> Full implementation of the USPSTF recommendation is critical to meet the ambitious plan to scale up PrEP access in this country, and we urge state and federal regulators to consider the following recommendations.

**Access to Clinical Visits and Recommended Lab Services Are Critical Components of PrEP and Must Be Covered with No Cost Sharing**

According to the CDC PrEP Guideline, there are a number of services in addition to the medication itself that are integral to the PrEP intervention. To ensure meaningful access to PrEP, and to avoid a “bait and switch” for consumers seeking a prescription for PrEP with the understanding that it is available without cost sharing, these services must be covered without cost sharing. Existing sub-regulatory guidance on other USPSTF recommended services have similarly required coverage of ancillary services that are inextricable from the underlying intervention (for example, CCIIO has stated that a polyp removal that occurs in the course of a colonoscopy that meets USPSTF criteria must also be covered without cost sharing as polyp removal is “an integral part of a colonoscopy”).<sup>6</sup> The chart below shows the services that are currently inextricably linked to PrEP and should be covered without cost sharing; however, any guidance for plans should be explicitly tethered to the CDC PrEP Guideline, which is updated regularly in line with best clinical practice. For instance, CDC will be updating the PrEP Guideline with new recommendations for clinic and lab services specific to Descovy, a drug approved for PrEP in October of 2019.

<b>PrEP Clinic/Lab Service at Regular Intervals</b>
Clinical visit (w/ primary care, infectious disease specialist, pharmacist, or public health clinic)
HIV test
Pregnancy testing of all cisgender women and transgender men with reproductive potential
Hepatitis B test
Medication adverse event assessment, adherence counseling, and behavioral risk reduction support
Bacterial STI tests, including three-site extragenital testing for chlamydia and gonorrhea
Renal functioning test

<sup>5</sup> HIV.gov, Ending the HIV Epidemic: A Plan for America, available at <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

<sup>6</sup> CCIIO, Affordable Care Act Implementation FAQs – Set 12, available at [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\\_implementation\\_faqs12.html](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html).

## **Utilization Management Must Be Monitored to Ensure Clinically Appropriate and Non-Discriminatory Access to PrEP**

Prior authorization is not an appropriate utilization management tool to identify individuals indicated for PrEP. Determination of risk for HIV and appropriateness of PrEP is a clinical decision, to be made by prescribers based on the clinical indications in the Centers for Disease Control and Prevention's (CDC) PrEP Clinical Practice Guideline.<sup>7</sup> Utilization management techniques that attempt to restrict access to PrEP using prior authorization or a similar process to screen public or private insurance beneficiaries for HIV risk factors perpetuate stigma and encourage plan designs that discriminate against LGBT individuals.<sup>8</sup> To increase access to PrEP in keeping with the Administration's initiative to end new HIV transmissions, regulators should explicitly prohibit use of prior authorization for PrEP as a way to identify individuals at high risk for HIV. Several state Medicaid programs have taken steps to limit or remove prior authorization for PrEP<sup>9</sup> and there are a number of state legislative bills that limit or prohibit use of prior authorization for PrEP in the individual and small group insurance markets.<sup>10</sup> Any proposed utilization management for PrEP should be reviewed by public health authorities and regulators in line with CDC guidelines and FDA indications to ensure it is clinically appropriate (for example, to ensure people can access TAF if they have, or are at risk for, bone or kidney issues as well as to identify other clinically recommended indications where a TAF-based regimen is necessary.)

## **The Dynamic Medication Landscape for PrEP Necessitates Additional Guidance to Ensure Access to New PrEP Formulations When They Become Available**

The PrEP pipeline is rapidly evolving.<sup>11,12</sup> There are currently two FDA-approved anti-retroviral (ARV) medications for PrEP. Truvada (tenofovir disoproxil fumarate and emtricitabine; TDF/FTC), made by Gilead Sciences, is a brand-name drug approved for PrEP in 2012. Generic versions of TDF/FTC are expected to be commercialized beginning in September 2020.

Descovy (emtricitabine/tenofovir alafenamide; F/TAF) – another brand-name product made by Gilead Sciences – was approved by the FDA for PrEP in October of 2019. Unlike Truvada and the

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<sup>7</sup>US Public Health Service. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update. A Clinical Practice Guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>.

<sup>8</sup> AIDS Foundation of Chicago, United Healthcare Discriminates against Vulnerable Populations by Denying PrEP Access (August 2017), available at, <https://www.aidschicago.org/page/news/all-news/united-health-care-discriminates-against-vulnerable-populations-by-denying-prep-access>. After advocacy claims that United's actions were discriminatory against LGBT individuals, United ended the practice.

<sup>9</sup> Naomi Seiler, Academy Health, Leveraging Financing and Coverage Benefits: Medicaid Strategies to Deliver PrEP Intervention Services (January 2019), available at [https://www.academyhealth.org/sites/default/files/leveragingfinancingcoveragemedicaidstrategiesprep\\_jan2019\\_0.pdf](https://www.academyhealth.org/sites/default/files/leveragingfinancingcoveragemedicaidstrategiesprep_jan2019_0.pdf).

<sup>10</sup> See, e.g., California [Senate Bill 159](#) (2019), enacted in October 2019.

<sup>11</sup> AVAC, The Future of ARV-Based Prevention and More (October 2018), available at [https://www.avac.org/sites/default/files/infographics/AR2018\\_The\\_Future\\_ARV\\_Based\\_Prevention.pdf](https://www.avac.org/sites/default/files/infographics/AR2018_The_Future_ARV_Based_Prevention.pdf).

<sup>12</sup> Long-acting injectable forms of PrEP are currently undergoing clinical trials and could be available in the next several years. Given that these products will utilize a different administration route, there are additional considerations for how the USPSTF recommendation will need to be updated.

pending generic options, Descovy contains tenofovir alafenamide, or TAF, instead of TDF. Descovy may be preferable for certain individuals, particularly those with kidney or bone disease and those who experience renal or bone adverse events while taking Truvada.<sup>13</sup> Significantly, the Phase III DISCOVER trial demonstrated that Descovy is non-inferior to the TDF-based regimen, Truvada, for PrEP.<sup>14</sup> The study focused on safety and efficacy outcomes among cisgender men. Because of a lack of clinical data on cisgender women, the FDA indication for Descovy as PrEP excludes “individuals at risk from receptive vaginal sex.”<sup>15</sup>

As the USPSTF cost-sharing and coverage requirements for PrEP go into effect, there will be multiple forms of PrEP available, including a generic option anticipated in September of 2020. Guidance is necessary from federal and state regulators to ensure that private insurance plans and Medicaid programs interpret the USPSTF guidelines in line with current science and clinical recommendations. Individuals must have access to the PrEP medication that is clinically appropriate for them – and to be consistent with the Affordable Care Act (ACA) preventive services requirements, that medication must be available with no cost sharing.<sup>16</sup> Insurance plans should be required to follow clinical guidelines for PrEP laid out by the CDC.<sup>17</sup> Though TDF-based regimens may be clinically appropriate for the majority of PrEP candidates, TAF-based regimens must be available with the same cost-sharing protections for individuals for whom it is indicated based on clinical judgment and grounded in clinical guidelines. This includes off-label use of Descovy in cisgender women in accordance with the CDC PrEP Guideline.

Full implementation of the USPSTF recommendation for PrEP is critical to ending new HIV transmissions in this country, and we appreciate the role that state and federal regulators will play in ensuring that the coverage and cost-sharing requirements are implemented and enforced. Please contact Amy Killelea with the National Alliance of State and Territorial AIDS Directors at [akillelea@nastad.org](mailto:akillelea@nastad.org), Phil Waters at [pwaters@law.harvard.edu](mailto:pwaters@law.harvard.edu) with the Center for Health Law and Policy Innovation, or Rachel Klein at [rklein@tmail.org](mailto:rklein@tmail.org) with The AIDS Institute if we can be of assistance.

Respectfully submitted by:

ADAP Educational Initiative | AIDS Alabama | AIDS Action Baltimore | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health AIDS Resource Center

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<sup>13</sup> The likelihood of renal and bone adverse events as a result of Truvada are not able to be ascertained before treatment.

<sup>14</sup> AVAC, DISCOVER Trial Fact Sheet, available at <https://www.avac.org/discover-trial-factsheet>.

<sup>15</sup> FDA, Supplemental Approval Letter, NDA 208215/S-012 (October 2, 2019), available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2019/208215Orig1s012ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/208215Orig1s012ltr.pdf).

<sup>16</sup> ACA §§2713, 4106

<sup>17</sup> US Public Health Service, Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline (2017), available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>.

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