November 5, 2019

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).\(^1\) PrEP is a once-daily anti-retroviral medication that when taken regularly prevents acquisition of HIV.\(^2\) 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 infections. 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.\(^3\)\(^4\)

The Administration’s recently announced plan to reduce new HIV infections by 90 percent by 2030 includes increasing PrEP utilization as a core pillar of the initiative.\(^5\) Full implementation of the

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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.

**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. 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. To increase access to PrEP in keeping with the Administration’s initiative to end new HIV infections, 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 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. 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. 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.

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9See, e.g., California Senate Bill 159 (2019), enacted in October 2019.


11Long-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.
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 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.¹² Significantly, the Phase III DISCOVER trial demonstrated that Descovy is non-inferior to the TDF-based regimen, Truvada, for PrEP.¹³ 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.”¹⁴

By the time the USPSTF recommendation goes into effect, there will be multiple forms of PrEP available, including a generic option. 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.¹⁵ Insurance plans should be required to follow clinical guidelines for PrEP laid out by the CDC.¹⁶ 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.

**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. These services must be covered without cost sharing. Existing sub-regulatory guidance on similar 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

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¹² The likelihood of renal and bone adverse events as a result of Truvada are not able to be ascertained before treatment.


¹⁵ ACA §§2713, 4106

part of a colonoscopy"). At a minimum, the following should be provided without cost sharing when prescribing PrEP, and regulators should clarify this in sub-regulatory guidance.

<table>
<thead>
<tr>
<th>Service</th>
<th>Interval</th>
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<tbody>
<tr>
<td>Clinical visit (with a primary care provider, infectious disease specialist, pharmacist, or public health clinic)</td>
<td>At PrEP initiation and every three months</td>
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<tr>
<td>HIV test</td>
<td>At PrEP initiation and every three months</td>
</tr>
<tr>
<td>Pregnancy testing of all cisgender women and transgender men with reproductive potential</td>
<td>At PrEP initiation and every three months</td>
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<tr>
<td>Hepatitis B test</td>
<td>At PrEP initiation and every three months</td>
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<tr>
<td>Medication adverse event assessment, adherence counseling, and behavioral risk reduction support</td>
<td>At PrEP initiation and every three months</td>
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<tr>
<td>Bacterial STI tests, including three-site extragenital testing for chlamydia and gonorrhea</td>
<td>Every three months</td>
</tr>
<tr>
<td>Renal functioning test</td>
<td>At PrEP initiation and every three months</td>
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**Insurance Plans Subject to ACA Preventive Services Requirements Should Be Encouraged to Implement PrEP Coverage and Cost Sharing Requirements for the 2020 Plan Year**

Sections 2713 and 4106 of the ACA require plans and Medicaid expansion programs to adopt the coverage and cost sharing provisions for USPSTF Grade A and B services in the plan year beginning no more than one year following the final recommendation. Since the PrEP recommendation was released in June of 2019, this means that for most private insurance plans and Medicaid expansion programs, the earliest effective date will be January 2021. However, given the overwhelming evidence that PrEP is both a highly effective and significantly underutilized prevention tool, coupled with federal and state efforts to dramatically scale up access to and utilization of PrEP, plans should be encouraged to implement the cost and coverage requirements of the USPSTF grade A recommendation for or during the 2020 plan year. State departments of insurance have already begun issuing guidance to this effect.18

Full implementation of the USPSTF recommendation for PrEP is critical to ending new HIV infections 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

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Respectfully submitted by:

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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
of Wisconsin | Bailey House, Inc. | Black AIDS Institute | Communities Advocating Emergency
AIDS Relief (CAEAR) | Community Access National Network (CANN) | Georgia AIDS Coalition |
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Rights Campaign | Legal Council for Health Justice | Michigan Positive Action Coalition |
Minnesota AIDS Project | National Alliance of State and Territorial AIDS Directors | National Health
Institute | Treatment Access Expansion Project | Treatment Action Group | Thrive Alabama