



The HIV+Hepatitis Policy Institute submitted the following comments to the Women’s Preventive Services Initiative recommending that HIV preexposure prophylaxis (PrEP) be included for all women at risk of HIV as part of sexually transmitted infection counseling and as part of the Well-Woman Preventive visits, as they update HRSA’s recommended preventive services for women.

### **2021 Counseling for STIs**

The HIV+Hepatitis Policy Institute recommends that HIV preexposure prophylaxis (PrEP) be included as part of the 2021 Counseling for Sexually Transmitted Infections (STI) Recommendations. The CDC’s *Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, 2020*, states that STD care in primary care settings should include: “PrEP for HIV prevention and nPEP of HIV risk assessment, education, and referral or link to HIV care.” Only 7% of women who could benefit from PrEP were prescribed PrEP in 2018. While HIV diagnoses among women have declined in recent years, approximately 7,000 women received an HIV diagnosis in the United States in 2019. The current USPSTF recommendation for PrEP was released in 2019 (providing a Grade A recommendation for PrEP “with effective antiretroviral therapy to persons who are at high risk of HIV acquisition”).<sup>1</sup>

PrEP is a unique preventive intervention both because of its safety and efficacy as well as the rapidity at which innovative PrEP products are coming to market. There is currently one approved PrEP drug for women (Truvada)<sup>2</sup> and the FDA is expected to approve an injectable form of PrEP (long-acting cabotegravir) soon<sup>3</sup>. A recent study showed the long-acting injectable to be superior for cisgender women in sub-Saharan Africa.<sup>4</sup> At the core of the federal *Ending the HIV Epidemic* initiative is an ambitious goal to drastically reduce new HIV transmission by 90 percent by 2030. Increasing the uptake of PrEP is a key component to ending HIV in the United States.

PrEP is both an incredibly effective and woefully underutilized prevention intervention in the U.S. PrEP is over 90 percent effective at preventing sexual transmission of HIV and over 70 percent effective at preventing HIV transmission among people who inject drugs.<sup>5</sup> At the same time only ~20 percent of people indicated for PrEP have actually been prescribed PrEP.<sup>6</sup> Ensuring PrEP education and prescriptions, when appropriate, during STI counseling is a critical opportunity to increase PrEP knowledge and uptake for sexually-active women.

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<sup>1</sup> USPSTF, Final Recommendation Statement, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 2019) available at [https://www.uspreventiveservicestaskforce.org/home/getfilebytoken/poDYcagnw7SqKNNbrFt\\_CV](https://www.uspreventiveservicestaskforce.org/home/getfilebytoken/poDYcagnw7SqKNNbrFt_CV).

<sup>2</sup> <https://www.fda.gov/files/science%20&%20research/published/HIV-PrEP-drug-can-be-part-of-strategy-to-prevent-infection-in-at-risk-adolescents.pdf>.

<sup>3</sup> ViiV Healthcare, ViiV Healthcare receives FDA Breakthrough Therapy Designation for investigational, long-acting cabotegravir for HIV prevention, November 17, 2020, available at <https://viiVhealthcare.com/en-us/us-news/us-articles/2020/viiV-healthcare-receives-fda-breakthrough-therapy-designation-for-investigational-long-acting-cabotegravir/>.

<sup>4</sup> <https://www.hptn.org/research/studies/hptn084>.

<sup>5</sup> CDC, PrEP Effectiveness, available at <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html>.

<sup>6</sup> Harris NS, Satcher Johnson A, Huang YA, et al. Vital Signs: Status of Human Immunodeficiency Virus Testing, Viral Suppression, and HIV Preexposure Prophylaxis — United States, 2013–2018. *Morbidity and Mortality Weekly*

### Well-Women Preventive Visits

The HIV+Hepatitis Policy Institute recommends that HIV preexposure prophylaxis (PrEP) be included as a routine part of the 2021 Well-Woman Preventive Visits Recommendations for all women at risk of HIV. The current USPSTF recommendation for PrEP was released in 2019 (providing a Grade A recommendation for PrEP “with effective antiretroviral therapy to persons who are at high risk of HIV acquisition”).<sup>1</sup> Only 7% of women who could benefit from PrEP were prescribed PrEP in 2018. While HIV diagnoses among women have declined in recent years, approximately 7,000 women received an HIV diagnosis in the United States in 2019.

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<sup>1</sup> USPSTF, Final Recommendation Statement, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 2019) available at [https://www.uspreventiveservicestaskforce.org/home/getfilebytoken/poDYcagnw7SqKNNbrFt\\_CV](https://www.uspreventiveservicestaskforce.org/home/getfilebytoken/poDYcagnw7SqKNNbrFt_CV).

<sup>2</sup> <https://www.fda.gov/files/science%20&%20research/published/HIV-PrEP-drug-can-be-part-of-strategy-to-prevent-infection-in-at-risk-adolescents.pdf>.

<sup>3</sup> ViiV Healthcare, ViiV Healthcare receives FDA Breakthrough Therapy Designation for investigational, long-acting cabotegravir for HIV prevention, November 17, 2020, available at <https://viihealthcare.com/en-us/us-news/us-articles/2020/viiv-healthcare-receives-fda-breakthrough-therapy-designation-for-investigational-long-acting-cabotegravir/>.

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<sup>5</sup> CDC, PrEP Effectiveness, available at <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html>.

<sup>6</sup> Harris NS, Satcher Johnson A, Huang YA, et al. Vital Signs: Status of Human Immunodeficiency Virus Testing, Viral Suppression, and HIV Preexposure Prophylaxis — United States, 2013–2018. *Morbidity and Mortality Weekly Report: Recommendations and Reports*. 2019;68(48):1117- 1123.

[https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm?s\\_cid=mm6848e1\\_w](https://www.cdc.gov/mmwr/volumes/68/wr/mm6848e1.htm?s_cid=mm6848e1_w).