

QUICK TAKE

THE USPSTF PrEP RECOMMENDATION

PRE-EXPOSURE PROPHYLAXIS (PrEP) IS A CRITICAL COMPONENT OF COMPREHENSIVE HIV PREVENTION.

First approved by the Food and Drug Administration (FDA) in 2012, PrEP involves HIV negative persons at risk of HIV infection taking antiretroviral medication to prevent infection. When taken as directed, PrEP can reduce the risk of HIV acquisition through sex by up to 99%. Ensuring stable and affordable access to PrEP for people at higher risk of HIV infection is critical to the Administration's **Ending the HIV Epidemic (EHE) Initiative** that is seeking to reduce the number of new HIV infections by 90% by 2030. To date, however, only about one in six people in the United States who could benefit from PrEP are using it.

THE USPSTF PrEP RECOMMENDATION CAN HELP TO INCREASE PrEP USE

WHAT IS THE USPSTF?

The **United States Preventive Services Task Force (USPSTF)** is an independent panel of national experts authorized by Congress and appointed by the Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services (HHS).

The task force reviews the scientific literature and makes evidence-based recommendations for the use of clinical preventive services such as screenings, counseling services, and preventive medications.

WHAT DID THE USPSTF CONCLUDE?

The USPSTF “found convincing evidence that PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use.”

The USPSTF concluded “with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial.”

WHY THE PrEP RECOMMENDATION MATTERS

Too few people in need of PrEP are receiving it due to both provider and patient barriers. These include lack of information regarding the evidence supporting PrEP's effectiveness and safety, as well as information on side-effects. Health insurance utilization management policies, including prior authorization and cost-sharing, have impeded access to PrEP. The requirement to cover PrEP without cost-sharing, coupled with the recognition of strong evidence for its safety and effectiveness, could reduce barriers to PrEP delivery and access.

CRITICAL STAKEHOLDER ACTIONS TO SUPPORT EFFECTIVE IMPLEMENTATION

FEDERAL AGENCIES

The **Centers for Medicare and Medicaid Services (CMS)** should **publish frequently asked questions (FAQs) outlining standards for comprehensive PrEP services**. This entails the Center for Consumer Information and Insurance Oversight (CCIIO) and the Center for Medicaid and State Operations (CMSO) working collaboratively with partner agencies within HHS, and the Departments of Labor and Treasury. FAQs should state that PrEP care includes (at frequencies consistent with federal clinical standards) laboratory monitoring, HIV testing, STI screening and treatment, and services to facilitate adherence and persistence of PrEP use. CMS also should clarify coverage for different PrEP formulations as they become available to ensure that individuals are able to access the PrEP medication that is clinically appropriate for them with no cost-sharing.

HEALTH PLANS

Health plans have a responsibility to deliver high-quality medically necessary covered services. PrEP is an effective intervention when it is implemented consistent with federal guidelines. **Health plans should not deploy prior authorization to restrict access to PrEP. While other utilization management approaches may be used to ensure clinical appropriateness, such policies should seek to minimize the burden on providers and patients and facilitate timely access for those with an indication for PrEP.** Health plans also should assess the number and demographics of enrollees with an indication for PrEP and establish performance targets for increasing adherent and persistent PrEP use. These data should be shared with health departments and the public.

HEALTH DEPARTMENTS AND INSURANCE REGULATORS

Health departments and insurance regulators are critical resources for stakeholder education and ensuring compliance with the PrEP standard of care. **Health departments should produce regularly updated data dashboards to show how many people are using PrEP, for how long, by race/ethnicity, gender, and risk group.** Health departments that currently provide PrEP co-pay assistance should redirect such assistance to expand education and navigation services. **Insurance regulators should issue guidance and/or regulations clarifying insurers coverage obligations (e.g. Colorado and New York), establish programs to assist people to resolve barriers to PrEP, and collect data on the frequency and patterns of access barriers.**

PROVIDERS AND COMMUNITIES

Health care providers and community members are essential voices to increase uptake of PrEP. **Providers and community members should monitor health plans to ensure compliance with the requirement to cover PrEP without cost-sharing.** They also should conduct outreach to health plans about PrEP and the USPSTF recommendation, and urge the adoption of multiple models of PrEP delivery that reduce the burden of PrEP care for users and providers. These include telehealth and home delivery models, same-day PrEP initiation, express PrEP visits, and task-shifting from doctors to nurses and pharmacists.

COMPONENTS OF PrEP CARE

PrEP involves more than taking medication. Essential components of PrEP care include:

- Regular provider visits
- HIV testing
- Safety monitoring of side-effects and monitoring of kidney function
- Medication adherence and risk reduction counseling
- Availability of condoms
- Screening, diagnosis, and treatment of sexually transmitted infections (STIs) at least every 3 months. For gay and bisexual men and other men who have sex with men (MSM), such screenings should screen at 3 sites of potential infection (mouth, urethra, and rectum).

In 2019, following a review of the scientific evidence, the United States Preventive Services Task Force (USPSTF) issued a final recommendation and gave PrEP its strongest rating, an A. This recommendation has the potential to increase access to PrEP and signals to providers the importance of offering PrEP to patients. Pursuant to the Affordable Care Act (ACA), most private health plans and all Medicaid-expansion programs must cover USPSTF-recommended services free of charge, when clinically indicated. State Medicaid programs also can extend this coverage to all non-expansion Medicaid beneficiaries. This policy goes into effect when a health plan's next plan year begins on or after June 11, 2020. For most plans, this means January 2021. Additional federal guidance is needed on several elements of how this USPSTF recommendation should be interpreted by health plans to maximize PrEP access and utilization.

While the USPSTF evaluated the single PrEP agent that had been approved by the FDA at the time of its review, the task force's final recommendation calls for "clinicians to offer PrEP with effective antiretroviral therapy," apparently anticipating coverage of additional products. Since that time, another product has been approved, and both generic products and several new PrEP long-acting formulations and modalities are expected to be approved in the near future. It will be important for federal regulators to offer guidance now on coverage to avoid confusion and minimize barriers to PrEP as science evolves and as new agents become available.

CREATING A LEVEL PLAYING FIELD FOR HEALTH PLANS

There is a long history of health plans deploying strategies to deter enrollment of individuals with costly health needs, such as using restrictive drug coverage policies as a way to avoid enrolling costly people with HIV. Moreover, the financial incentives are not fully aligned to reward health plans for being proactive at achieving critical public health objectives. Before the USPSTF recommendation comes into force, the federal government should issue binding guidance that clarifies that the non-medication components of PrEP care (as described above) must be covered without cost-sharing as part of the USPSTF recommendation and that standardizes coverage of PrEP medications to ensure comprehensive coverage and prevent plans from using drug coverage policies to deter enrollment of PrEP users. Models for such clarifying guidance associated with USPSTF recommendations include FAQs issued by CCIIO around polyp removal during colonoscopies, BRCA testing, and coverage of contraceptive methods.

TO LEARN MORE

The USPSTF's Final Recommendation Statement for PrEP is available at bit.ly/uspstfprep.

Read our Big Ideas brief, *Achieving Sufficient Scale of PrEP Use Is Critical to Ending the HIV Epidemic*, August 2019, at the link below.

For implementation considerations from the HIV Health Care Access Work Group of the Federal AIDS Policy Partnership (FAPP), see their November 2019 letter, available at bit.ly/fappuspstfprep.

For clinical practice guidelines, see the US Public Health Service/CDC Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update, available at bit.ly/cdc2017prepguidelines.

As part of the EHE Initiative, the Administration has launched **Ready, Set, PrEP**, a nationwide program to provide access to PrEP for people who do not have health care coverage. People can enroll or get more information at GetYourPrEP.com or toll-free at 855-447-8410.

IMPLEMENTATION OF THE USPSTF RECOMMENDATION MUST ENSURE ACCESS TO COMPREHENSIVE PrEP SERVICES AND REQUIRE COVERAGE WITHOUT COST-SHARING OF NEW PrEP REGIMENS AS THEY RECEIVE FDA APPROVAL.