



IDSE Infectious Disease SPECIAL EDITION



SEPTEMBER 1, 2023

USPSTF Gives 'A' Rating to All 3 Approved PrEP Medications, but Access Challenges Remain

By Gina Shaw

The U.S. Preventive Services Task Force (USPSTF) issued updated recommendations for HIV prophylaxis classifying all three currently available pre-exposure prophylaxis (PrEP) medications as grade A recommendations.



The previous recommendations, issued in 2019, gave a grade A recommendation to the daily oral agent tenofovir disoproxil fumarate with emtricitabine (Truvada, Gilead). The new recommendations also include the daily oral drug tenofovir alafenamide with emtricitabine (Descovy, Gilead) and the long-acting injectable cabotegravir (Apretude, ViiV Healthcare), both of which were approved since the publication of the 2019 USPSTF document.

"The USPSTF concludes with high certainty that there is a substantial net benefit from the use of effective antiretroviral therapy to reduce the risk of acquisition of HIV in persons at increased risk of acquiring HIV," the recommendation said ([JAMA](#) 2023;330[8]:746-763).

This move is anticipated to increase access to PrEP, as most private insurance plans are required to cover "A" and "B" recommended preventive services without a copay. The Affordable Care Act also requires PrEP to be free under almost all health insurance plans.

"This is something that we in the HIV community have been wanting since the new PrEP drugs were approved, particularly because we know that the injectable form of PrEP is superior to oral therapy, particularly with regard to adherence," said

Melissa Badowski, PharmD, a clinical associate professor in the section of infectious diseases pharmacotherapy at the University of Illinois-Chicago College of Pharmacy, and the founding chair of the American College of Clinical Pharmacy HIV Practice and Research Network.

A panel of the task force led by Roger Chou, MD, a professor of medicine and of medical informatics and clinical epidemiology at the Oregon Health & Science University, in Portland, reviewed 20 randomized clinical trials with 36,543 participants and 12 studies of diagnostic accuracy with 5,544,500 participants to update the recommendations. They noted that 11 trials in the 2019 review found that oral PrEP was associated with a reduced risk for HIV infection versus placebo or no PrEP, with greater efficacy seen in association with higher adherence. In addition, one new trial in men who have sex with men (MSM) showed oral tenofovir alafenamide-emtricitabine was noninferior to tenofovir disoproxil fumarate-emtricitabine (TDF/FTC). Long-acting injectable cabotegravir was associated with a reduced risk for HIV infection compared with oral TDF/FTC in two new trials.

The recommendations also call for clinicians to recommend PrEP to the following high-risk groups:

- anyone who has a sexual partner with HIV;
- those who have had a bacterial sexually transmitted infection within the past six months, such as syphilis, gonorrhea or Chlamydia for MSM and transgender women, and gonorrhea and syphilis for heterosexual people;
- those who do not use condoms or use them inconsistently; and
- anyone who injects drugs or has a sexual partner who injects drugs.

"These recommendations are very important, as access to PrEP has been disappointing and uptake overall has been very low, particularly in communities that are most affected by HIV," said Jonathan Appelbaum, MD, the chair of the Department of Clinical Sciences, and Laurie L. Dozier Jr., MD, the education director and professor of internal medicine at Florida State University College of Medicine, in Tallahassee.

Although new diagnoses of HIV in the United States declined by 8% between 2017 and 2021, due in part to the availability of PrEP, racial, ethnic and regional disparities in PrEP use persist. In an editorial accompanying the recommendations, authors from the Division of Infectious Diseases at Emory University School of Medicine noted that although young Black, Latino, gay, bisexual, and other adolescents and MSM living in the Southern states experience the highest burden of new HIV diagnoses in the nation, PrEP coverage in each of these demographic categories is lower than the national average of 30%. "For example, Black and Latino gay and bisexual men accounted for 37% and 30% of new HIV diagnoses, respectively, among MSM in 2021, but only 11% and 21% of Black and Latino PrEP-eligible individuals were prescribed PrEP, compared with 78% of their White counterparts," they wrote ([JAMA Intern Med](https://doi.org/10.1001/jamainternmed.2023.3929) 2023 Aug 22. doi:10.1001/jamainternmed.2023.3929).

"Part of the issue is that a lot of primary care providers still don't feel at ease prescribing PrEP," Dr. Appelbaum said. "Infectious disease and HIV clinicians have been comfortable using these drugs for years, but general practitioners are not as familiar and comfortable with them. We need to do a lot more outreach and education for front-line providers of healthcare, including emergency departments and urgent care centers as well as sexually transmitted disease clinics."

"The guidelines offer a standardized evidence-based approach to HIV prevention, which is critical for ensuring that high-quality care is uniformly available, regardless of location or healthcare provider," said Tam Phan, PharmD, an assistant professor of clinical pharmacy in the Titus Family Department of Clinical Pharmacy at the University of Southern California's Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, in Los Angeles. "The guidance also recognizes the importance of support mechanisms for those taking PrEP, such as

regular checkups and educational resources, which can improve adherence rates and, consequently, the drug's effectiveness. By updating language to be more inclusive and non-stigmatizing, the USPSTF shows a commitment to ethical considerations in healthcare and addressing various health disparities we see with HIV."

For the long-acting injectable cabotegravir, infrastructure is also important, Dr. Badowski said.

"Clinical staff have to be trained to administer these injectables, and you have to have a monitoring system to ensure that patients return for their injections every two months, so that no one falls through the cracks."

Despite the USPSTF recommendations, access and coverage for PrEP is also threatened by litigation. In September 2022, U.S. District Judge Reed O'Connor of Texas ruled in favor of the plaintiffs, a group of Christian business owners claiming that federal requirements that private insurance policies cover PrEP violated their religious freedoms, in *Braidwood Management v. Becerra*. In a subsequent ruling issued in March 2023, Mr. O'Connor blocked enforcement for zero-cost preventive services recommended by the USPSTF—such as tobacco cessation, PrEP, and screenings for anxiety, hypertension, and hepatitis B and C—but in June, the U.S. Court of Appeals for the 5th Circuit approved an agreement between the parties that largely stayed the ruling while the case proceeds through the court system.

If the lower court's ruling is allowed to stand, it would be a blow to the progress that has been made in controlling HIV, argued a team of medical, public health and legal experts from Yale University, The University of Texas and the University of Alabama at Birmingham in a report released in February 2023 (<https://law.yale.edu/yls-today/news/report-challenges-court-decision-prep-and-public-health>).

They calculated that if the ruling is upheld, HIV infections could be expected to result in at least 2,083 new HIV infections—up from a base of 28,200 infections—over the following year. "If the Braidwood court blocks the national PrEP Mandate, the result will be new HIV transmissions, with attendant harm to the health and quality of life of people who are at risk for HIV throughout the United States, as well as individuals in their social networks," the authors concluded, adding that these harms would be disproportionately (or primarily) inflicted on minority communities and those who are economically disadvantaged.

"USPSTF's new recommendation, if it is allowed to prevail in governing insurance coverage, will minimize cost barriers, but we will still have issues of access and stigma to deal with," Dr. Appelbaum said.

Dr. Appelbaum reported that he serves on an advisory board for ViiV Healthcare. Drs. Badowski and Phan reported no relevant financial disclosures.

Related Articles

Long-Acting
Injectable
More
Effective
Than Daily
PrEP for
Women



Breaking the
Barriers To
PrEP Use



Bringing
Equity to
PrEP Use in
the United
States

