



PrEP for HIV Prevention

Access, Treatment, and Emerging Policy Considerations

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PrEP (pre-exposure prophylaxis) for HIV prevention is a medication regimen that is highly effective for preventing HIV transmission from sex or injection drug use. Studies show that daily PrEP adherence is 99% effective in preventing HIV infection. While millions of Americans at higher risk for HIV infection could benefit from PrEP, and expanding PrEP use is a central pillar of the federal Ending the HIV Epidemic initiative, current utilization rates are much lower than needed to produce population-level public health benefits. As the federal government takes steps to increase PrEP availability and as more formulations become available, state and federal policymakers should keep in mind recent policy developments and emerging considerations.

Treatment

The CDC released the first clinical guidelines for PrEP in 2014, with an update in 2017.¹ Current guidelines recommend:

- Identifying patients at high risk of HIV infection, including men who have sex with men at high risk, partners of people living with HIV (or serodiscordant couples), and people who inject drugs.
- Confirming a negative HIV test, normal renal function and no contraindicated medicines before beginning treatment.
- Follow-up visits every three months for HIV and STD screening and adherence counseling, and twice-yearly renal function assessment.

Current and potential PrEP medication options include:

- **Truvada** (Gilead) was approved in 2012 for PrEP and will go off-patent in 2020.
- **Descovy** (Gilead) was approved in 2019 for PrEP for cisgender² men and transgender women; a post-marketing study is planned by the manufacturer to evaluate the drug in cisgender women and adolescents over the next five years.
- **Generic** formulation of Truvada manufactured by Teva is currently planned for a September 2020 U.S. launch;³ European generics are currently manufactured by Teva, Mylan, and Sandoz.
- **Alternate delivery mechanisms** such as injectable formulations and implants have not yet come to market but are moving through the research pipeline.

Access

Strategies to expand access to PrEP include expanding coverage of the drug and associated medical and wraparound services as well as lowering the price of PrEP medication.

Uptake remains a challenge:

- Only 10% of Americans who could benefit from PrEP have ever received a prescription.
- Early data on PrEP use reflects disparities in prescriptions among indicated groups, with higher proportions of prescriptions among white men who have sex with men compared to black and Latinx men who have sex with men, transgender people, black women, people who inject drugs, and LGBTQ youth.⁴

Private insurance coverage will improve due to U.S. Preventive Services Task Force “A” grade:

- In 2019, USPSTF gave PrEP a grade A recommendation, its highest recommendation, for PrEP as a preventive intervention for patients at high risk of HIV infection.

¹ <https://www.cdc.gov/hiv/guidelines/preventing.html>

² Cisgender refers to an individual whose matches the sex that they were assigned at birth.

³ <https://www.nbcnews.com/feature/nbc-out/generic-hiv-prevention-drug-coming-2020-gilead-says-n1003391>

⁴ https://oneill.law.georgetown.edu/wp-content/uploads/Big-Ideas_PrEP-Scale-up_August-2019.pdf

- The Affordable Care Act requires private insurance to cover “A” or “B” rated preventive services without cost-sharing. Full implementation of PrEP coverage and cost sharing provisions for most plans will take effect in January 2021.

The federal “Ending the HIV Epidemic” initiative will facilitate PrEP access by:

- Distributing Gilead’s donation of Truvada and Descovy for up to 200,000 patients per year. To qualify, patients must lack health insurance for outpatient prescription drugs, have a valid, on-label prescription, and test negative for HIV.
- Expanding access to PrEP among community health center patients who have an indication.

High prices still put PrEP out of reach for many Americans:

- Truvada’s U.S. list price ranges from \$1,600 to \$2,000 per month.
- In Europe, where generic formulations have already reached the market, PrEP medication costs from \$15 per month in Belgium to \$130 per month in Switzerland.
- When a generic formulation is released in the US in late 2020, PrEP could become more affordable.
- A wide range of studies in countries with generic PrEP have shown evidence of cost-effectiveness and cost savings.⁵

Emerging Policy Considerations

Achieving the promise of the USPSTF “A” recommendation by:

- Fully implementing the recommendation by ensuring that services available without cost-sharing include CDC-recommended STD screening, lab monitoring and adherence counseling.
- Ensuring that the recommendation applies to all current and future FDA-approved products for PrEP for HIV as recommended in the CDC PrEP guidelines.

Increasing access through:

- Robust support for public coverage programs and clinics, including Medicaid expansion, opt-in Medicaid prevention benefit,⁶ and Community Health Centers.
- Public education and outreach in recognition that many of people who could benefit most from PrEP have limited engagement with the health system or have not been counseled about PrEP.
- Educational campaigns targeted to clinicians and other healthcare professionals.
- Reaching people who inject drugs by connecting education and interventions with syringe services programs and substance use disorder treatment facilities.
- Reaching women, who are currently underrepresented in PrEP prescriptions for indicated populations, through Title X and federal family planning programs.

Evaluating innovative care models, including:

- Strategies to improve PrEP treatment adherence and retention
- “On-demand” non-daily dosing strategies, which are being piloted in New York City and San Francisco
- Allowing certified pharmacists to dispense limited quantities of PrEP without a physician’s prescription but with a referral to primary care provider, which is now legal in California

PrEP Resources

[Prelocator.org](#) includes search features to find PrEP providers that serve uninsured patients and those with programs with access assistance.

[Locator.hiv.gov](#) provides listings of services providers for PrEP, as well as HIV and STI testing, Ryan White-funded care programs, community health centers, substance use and mental health services, family planning programs, and housing assistance.

Patient assistance programs: The National Alliance of State & Territorial AIDS Directors (NASTAD)’s comprehensive list of programs run by certain states and private entities can be found at [nastad.org/prepcost-resources/prep-assistance-programs](https://www.nastad.org/prepcost-resources/prep-assistance-programs).

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5855998/>

⁶ <https://www.kff.org/medicaid/issue-brief/coverage-of-preventive-services-for-adults-in-medicaid/>