CDC Recommends Twice-Yearly PrEP

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In June, the Food and Drug Administration approved twice-yearly lenacapavir injections—brand name Yeztugo—for HIV pre-exposure prophylaxis (PrEP). The Centers for Disease Control and Prevention (CDC) has now added a recommendation for lenacapavir PrEP, published in the September 18 edition of Morbidity and Mortality Weekly Report.

Lenacapavir, Gilead Sciences' first-in-class HIV capsid inhibitor, dramatically reduced the risk of HIV acquisition in two large Phase III trials. PURPOSE 1 showed that the twice-yearly injections were 100% effective for young cisgender women in Africa, while PURPOSE 2 found that lenacapavir PrEP reduced the risk of HIV acquisition by 96% among gay and bisexual men and gender-diverse people in the United States and six other countries.

Health officials, clinicians and advocates are hopeful that lenacapavir could finally help turn the tide of the HIV epidemic, but long-acting PrEP can only fulfill its potential if it is available to those who need it most. The drug's high cost—$28,218 per year in the United States—is a barrier to access, but the CDC recommendation could encourage broader insurance coverage. Cheap generic versions of the daily PrEP pill Truvada (tenofovir disoproxil fumarate/emtricitabine) are widely available, and some insurers may ask people to try the less expensive option first.

The day the CDC released its recommendation, advocates urged CVS Health to reverse its decision to hold off on covering lenacapavir PrEP. And some have gone further. "America needs a federally funded National PrEP Program that fills in the gaps in access for un- and underinsured populations and builds a pathway toward access to innovations in PrEP for everyone," says PrEP4All's Jeremiah Johnson.
