



Twice-Yearly PrEP Works Well for Gay Men

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November 11, 2024 By [Liz Highleyman](#)

Lenacapavir, Gilead Sciences' twice-yearly HIV capsid inhibitor, was highly effective as pre-exposure prophylaxis (PrEP) in a second large study, according to data presented at the HIV Research for Prevention Conference in Lima, Peru.

The PURPOSE 2 trial enrolled more than 3,000 gay and bisexual men and gender-diverse people in the United States and six other countries. They were randomly assigned to receive either lenacapavir injections every six months or Truvada (tenofovir disoproxil fumarate/emtricitabine) pills once daily.

There were two new HIV diagnoses among the 2,180 participants in the lenacapavir group and nine cases among the 1,087 people assigned to Truvada. Lenacapavir reduced the risk of HIV acquisition by 96% compared with the background incidence rate and 89% more than daily Truvada. Lenacapavir was generally well tolerated, and no new safety concerns were identified. Some participants developed injection site reactions or nodules, but less than 1% stopped PrEP for this reason.

"These data reinforce that twice-yearly lenacapavir could be a highly effective and potentially game-changing HIV prevention choice that we have long hoped for in our efforts to end the HIV epidemic," says Colleen Kelley, MD, MPH, of Emory University.

But this promise can only be realized if lenacapavir PrEP is available to those who need it most. Gilead plans to submit the new results—along with data from the PURPOSE 1 trial, which showed that lenacapavir PrEP was 100% effective for young cisgender women in Africa—to the Food and Drug Administration by the end of the year, anticipating approval in 2025. Responding to pressure from advocates and global health leaders, Gilead recently announced that it will work with six pharmaceutical manufacturers to produce and sell generic versions of lenacapavir for PrEP in more than 100 resource-limited countries.

