FDA OKs PrEP for Adolescents

PrEP is officially approved for adults and adolescents at risk for HIV who weigh at least 77 pounds.

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The Food and Drug Administration has expanded the approval of Truvada (tenofovir disoproxil fumarate/emtricitabine) as pre-exposure prophylaxis (PrEP) against HIV to include adolescents as opposed to just those over 18. This means PrEP is now officially approved for adults and adolescents at risk for HIV who weigh at least 77 pounds.

The new approval was based on a 48-week study that enrolled 67 high-risk adolescents ages 15 to 17. Although the participants' overall level of adherence to the daily Truvada regimen was promising during the initial three months, when the adoloscents made monthly clinic visits, adherence dropped off dramatically once the study protocol switched to requiring visits only every three months, as is standard for a PrEP prescription. This phenomenon led researchers to conclude that adolescents may need monthly monitoring to do well on PrEP.

The side effects of Truvada as PrEP among these adolescents were comparable to those observed in adult studies.

"Our hope is that this new adolescent indication [for Truvada] addresses a few of the many barriers that people experience when trying to access PrEP," says Sybil Hosek, PhD, a clinical psychologist at the Cook County Health and Hospital System's Stroger Hospital in Chicago and lead investigator of the study. "The indication should provide prescribers with increased confidence that this prevention product is safe and well tolerated by youth and thus no longer needs to be provided off-label."

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