

FDA OKs Gilead's Descovy, a Safer Version of Truvada, for HIV Treatment Only (Not for PrEP)

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The U.S. Food and Drug Administration (FDA) has approved Gilead Sciences' fixed-dose combination tablet [Descovy](#) (emtricitabine/tenofovir alafenamide, or TAF) for the treatment of HIV. The tablet, which is an updated take on Truvada (tenofovir disoproxil fumarate, or TDF/emtricitabine) that includes a new, safer version of tenofovir, is not approved as pre-exposure prophylaxis (PrEP).

Descovy has been approved for use in combination with other antiretrovirals (ARVs) to treat HIV in adults and adolescents 12 years of age and older.

Research into Descovy for use as PrEP is only in its earliest stages, and it is not clear at this time if the tablet would be as effective as Truvada at preventing acquisition of the virus among HIV-negative individuals. Researchers estimate that many years of clinical trials are yet required before Descovy could be approved as PrEP.

[Research has shown](#) that TAF is [safer for the bones and kidneys](#) than TDF. Because TAF more efficiently targets cells, a dose one tenth that of TDF is required, and 90 percent less drug winds up in the bloodstream, where it may cause harm.

Descovy has a boxed warning regarding the risks of lactic acidosis and severe hepatomegaly with steatosis, as well as posttreatment acute exacerbation of hepatitis B virus (HBV).

The FDA's approval of Descovy was based on 48-week data from two Phase III studies, called Studies 104 and 111, in which a Descovy-based regimen, given as Genvoya (elvitegravir/cobicistat/emtricitabine/TAF), proved non-inferior to (essentially meaning it suppressed HIV as well as) a Truvada-based regimen, given as Stribild (elvitegravir/cobicistat/emtricitabine/TDF) among people treated for HIV for the first time. Tests of kidney and bone health found that the Descovy-based regimen was preferable to the Truvada-based treatment with regard to those safety measures.

The new tablet's approval is also based on a Phase III study, Study 109, in which individuals with a fully suppressed viral load thanks to Truvada-based treatment were switched to a Descovy-based

treatment, given as Genvoya. Again, the Descovy-based therapy proved non-inferior and safer for the bones and kidneys.

Further Phase III studies that supported Descovy's approval tested switching virally suppressed individuals with mild to moderate kidney impairment to Genvoya and also starting people on Genvoya as their first ARV regimen.

Lastly, studies have shown that Descovy leads to the same drug levels of TAF and Emtriva (emtricitabine) in the blood as Genvoya.

To read the full prescribing information about Descovy, including important safety warnings, [click here](#).

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