Switching to Dovato Linked to Less Weight Gain

Most people who switched to either Dovato or Biktarvy maintained viral suppression at two years.

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People who switched from more complex regimens to ViiV Healthcare's Dovato (dolutegravir/lamivudine) or Gilead Sciences' Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) were about equally likely to maintain viral suppression, but those randomized to Dovato gained less weight, according to study results presented at the European AIDS Conference (EACS 2025).

Modern antiretroviral regimens are safe and effective, so the choice of which to use often comes down to convenience and tolerability. People who are still on older combinations that require more pills, contain boosting agents (ritonavir or cobicistat) or have cumulative toxicities may be able to switch to simpler and more tolerable regimens.

One factor to consider is weight gain. Research on weight gain among people on HIV treatment have yielded mixed results. Some studies have found that regimens containing potent integrase inhibitors or tenofovir alafenamide (TAF), especially together, may lead to more weight gain. The older tenofovir disoproxil fumarate (TDF) formulation tends to suppress weight and lower cholesterol and triglyceride levels, so switching away from TDF loses this protective effect.

"For people living with HIV, achieving and maintaining viral suppression remains the cornerstone of effective treatment. However, HIV treatment options have now advanced to where we can also look to other health metrics to help define success," ViiV chief medical officer Jean van Wyk, MBChB," said in a news release.

The Phase IV PASO DOBLE study (NCT04884139), which enrolled more than 550 adults living with HIV in Spain, is the largest head-to-head randomized clinical trial comparing Dovato versus Biktarvy as a switch option for people with viral suppression. At the start of the study, participants were on regimens that could be optimized, for example, multi-tablet regimens or those containing boosters. The median age was 50, and they had been on HIV treatment for a median of 11 years.

As reported at the 2024 International AIDS Conference and in The Lancet HIV, just six people (2.0%) randomly assigned to switch to Dovato and two people (1.4%) assigned to Biktarvy had a viral load of 50 or higher at 48 weeks, showing that Dovato was statistically noninferior.

At EACS, Esteban Martínez, PhD, of Hospital Clinic Barcelona, reported that, with an additional year of follow-up, Dovato and Biktarvy were still about equally likely to maintain viral suppression at 96 weeks. In the Dovato group, 0.4% had a viral load of 50 or higher, compared with 1.1% in the Biktarvy group—not a statistically significant difference. No drug resistance was detected in either group.

What's more, Dovato was associated with significantly less weight gain and fewer drug-related adverse events, Martínez noted. People assigned to Dovato gained a mean 0.84 kilograms (about 1.9 pounds) through 96 weeks, compared with 2.35 kg (about 5.2 pounds) for those assigned to Biktarvy; 20.1% versus 34.8%, respectively, experienced a weight increase greater than 5%. As expected, people whose previous regimen included TDF were more likely to gain weight when they switched.

Looking at overall side effects, 7.6% of Dovato recipients experienced drug-related adverse events—mostly mild to moderate—versus 13.4% of those on Biktarvy. Two people taking Dovato and four people taking Biktarvy discontinued treatment due to adverse events, mainly neuropsychiatric symptoms.

"This 96-week data from PASO DOBLE underscores a favorable profile for Dovato, particularly regarding weight gain, which is an important consideration for virologically suppressed adults [who] may be on treatment for decades," Martínez said in the ViiV news release. "Longer-term data for a two-drug regimen is crucial for health care providers and people living with HIV as they work together to make informed treatment decisions, considering long-term health management beyond just viral suppression."

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