Dovato Approved as Switch Regimen

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The Food and Drug Administration has expanded its approval of ViiV Healthcare's two-drug antiretroviral regimen Dovato (dolutegravir/lamivudine) to include people with a fully suppressed viral load who switch from a different HIV regimen. Previously, the regimen was approved only for those starting HIV treatment for the first time.

The expanded approval was based on the findings of a Phase III study that enrolled people who had maintained an undetectable viral load for six months on a regimen of at least three antiretrovirals that included the drug tenofovir alafenamide. Some of the participants were randomized to switch to Dovato while the others stayed on their original regimen.

A year later, the two study groups had similarly high rates of full viral suppression. The safety results for those who received Dovato were similar to those in previous studies of the two-drug tablet among those starting it as their first regimen.

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