



FDA Approves Idvynso Combination Pill

The Food and Drug Administration approved Merck's once-daily single-tablet regimen containing doravirine and islatravir.

June 29, 2026 By [Liz Highleyman](#)

On April 21, the Food and Drug Administration approved Idvynso—Merck's once-daily single-tablet regimen containing doravirine and islatravir—as a switch option for people currently on HIV treatment with an undetectable viral load. Doravirine (sold alone as Pifeltro) is a next-generation non-nucleoside reverse transcriptase inhibitor with a high barrier to resistance, while islatravir is a first-in-class nucleoside reverse transcriptase translocation inhibitor. The combination pill is the first two-drug antiretroviral regimen without an integrase inhibitor or tenofovir.

Idvynso is approved for adults on stable antiretroviral therapy with a viral load below 50 who have no history of virological treatment failure and no known doravirine resistance mutations. The recommended dose is one tablet once daily with or without food.

Late-stage clinical trials showed that Idvynso maintains viral suppression when people switch from a standard daily oral antiretroviral regimen. As reported at the Conference on Retroviruses and Opportunistic Infections in February, people with undetectable virus who switched to Idvynso from either Biktarvy (bictegravir/tenofovir alafenamide/-emtricitabine) or various other two- or three-drug oral regimens were as likely to maintain an undetectable viral load as those who stayed on their existing combination. Idvynso also shows promise as a first-line treatment option.

Idvynso was safe and generally well tolerated. Study participants did not experience decreases in their white blood cell counts, which were seen in prior studies testing higher doses of islatravir. Unlike tenofovir, neither doravirine nor islatravir is active against hepatitis B virus.

“People aging with HIV face additional health challenges, including managing multiple chronic conditions and medications at the same time,” says Carl Baloney Jr., president and CEO of AIDS United. “It is essential that management of HIV considers these factors in addition to virologic suppression when choosing an HIV treatment regimen.”

