



Biktarvy Granted New Indication for HIV Treatment

The single-tablet regimen may now be prescribed for previously treated people without viral suppression.

August 4, 2025 By [Liz Highleyman](#)

On July 30, the Food and Drug Administration (FDA) approved a new indication for [Biktarvy](#) for people who previously received antiretroviral treatment but currently do not have an undetectable viral load, as long as they have no known or suspected resistance to the drugs in the combination pill.

Biktarvy, from Gilead Sciences, is a once-daily single-tablet regimen containing the integrase inhibitor bictegravir and two nucleoside/nucleotide reverse transcriptase inhibitors, tenofovir alafenamide (TAF) and emtricitabine.

“This expanded indication can now help healthcare providers more confidently support an even broader range of people with HIV, including people with HIV who are not virologically suppressed and are restarting HIV treatment,” Paul Sax, MD, of Brigham and Women’s Hospital, said in a [Gilead news release](#).

Many people with HIV struggle with [adherence](#), interrupt treatment at some point, see a rise in their viral load and need to restart treatment without viral suppression. Clinical trials of new antiretrovirals typically enroll either people starting treatment for the first time or those switching from another regimen with viral suppression. Like Biktarvy, they are therefore initially indicated for those new to treatment or currently on a suppressive regimen, and there are limited FDA-approved options for those looking to restart treatment with detectable virus.

The added indication for Biktarvy is supported by the strength of evidence from studies of previously untreated people that demonstrated rapid and durable viral suppression, long-term safety and tolerability and a high barrier to resistance, according to Gilead.

It is estimated that only two thirds of people with HIV have viral suppression at any point in time. Uncontrolled HIV can lead to disease progression and [drug resistance](#), and studies suggest that around 80% of new HIV transmissions are attributable to gaps in care when the virus is not fully suppressed. People with a sustained viral suppression, in contrast, do not transmit the virus during

sex ([Undetectable Equals Untransmittable](#), or U=U).

“For people with HIV who have stopped treatment or fallen out of care and are not virally suppressed, re-engagement and restarting treatment are crucial for preventing the spread of the virus and supporting individual long-term outcomes,” said Sax.

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