Biktarvy Is a Safe and Effective Option During Pregnancy

Recent data confirm that the single-pill regimen maintains viral suppression during the second and third trimesters.

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The Biktarvy single-tablet regimen is safe and well tolerated during pregnancy, maintains viral suppression during the second and third trimesters and postpartum, and protects babies from vertical transmission, according to updated label information approved by the Food and Drug Administration (FDA).

This update makes Biktarvy the only second-generation integrase inhibitor with in-label clinical trial data and FDA approval for virologically suppressed adults who are pregnant, according to a Gilead Sciences news release.

“This label update marks an important milestone for Biktarvy, reinforcing its efficacy profile for pregnant people with HIV, an often understudied and most vulnerable community in clinical research,” said Jared Baeten, MD, PhD, Gilead’s vice president of HIV clinical development. “Not only is Biktarvy an alternative regimen for use in pregnancy, but people of childbearing potential can also remain on Biktarvy if they become pregnant.”

In general, pregnant people living with HIV and those who wish to become pregnant can use many of the same commonly used antiretroviral regimens as people who are not pregnant. But newer regimens have limited data on their safety and effectiveness during pregnancy, including their effects on fetal development and outcomes for babies after birth.

Biktarvy is a single once-daily pill containing the integrase inhibitor bictegravir, tenofovir alafenamide and emtricitabine. Multiple studies have shown that it is safe and effective for non-pregnant people who are either starting HIV treatment for the first time or switching from another regimen with an undetectable viral load and no resistance to bictegravir or tenofovir.

The Department of Health and Human Services perinatal guidelines list Biktarvy as an alternative first-line regimen for people who are pregnant or trying to conceive and recommend that people who are already on Biktarvy with viral suppression when they become pregnant should stay on it.

The preferred first-line regimens during pregnancy are the integrase inhibitor dolutegravir or the boosted protease inhibitor darunavir/ritonavir, each with a dual NRTI backbone of either abacavir/lamivudine, tenofovir alafenamide/emtricitabine or tenofovir disoproxil fumarate/emtricitabine. Dolutegravir, which is more widely available worldwide and has been more extensively studied during pregnancy, is also favored by the World Health Organization, now that potential concerns about birth defects have been resolved. The U.S. guidelines recommend against the injectable regimen Cabenuva (long-acting cabotegravir and rilpivirine) due to a lack of data and note that there is inadequate data for single-tablet regimens that contain only two drugs.

The updated Biktarvy label includes additional data from Study 5310, which evaluated its pharmacokinetics, safety and efficacy in HIV-positive people in their second or third trimester of pregnancy who had viral suppression on another regimen and no known resistance to the component drugs. The study found that plasma drug levels were lower during pregnancy compared to postpartum. However, all 32 participants who completed the study maintained viral suppression during pregnancy, at the time of delivery—an important consideration for preventing mother-to-child HIV transmission—and through 18 weeks postpartum. What's more, all 29 newborns had undetectable HIV when tested at birth and four to eight weeks later. Side effects were similar to those seen in non-pregnant individuals and the study did not identify any new safety or tolerability concerns.

Click here for full updated prescribing information for Biktarvy.

Click here for more news about HIV treatment.
