Biktarvy Is Now An Option for Younger Children

The Food and Drug Administration approved the single-pill treatment for children weighing at least 30 pounds.

October 27, 2021 By Heather Boerner

Biktarvy, a once-daily combination pill containing bictegravir, tenofovir alafenamide and emtricitabine, has become one of the most popular HIV treatment regimens since it was approved for adults in 2018 and for children who weigh 25 kilograms (55 pounds) in 2019. Now, the Food and Drug Administration (FDA) has approved it for younger children.

The FDA approved the indication on October 18; it applies to children who weigh between 14 and 25 kg—or about 30 to 55 pounds. The small once-daily pill contains lower doses of the three medications for children's lower weight. The FDA approved the pill both for children new to treatment and those who already have an undetectable viral load on their current antiretroviral regimen.

The approval is based on a single arm study of 22 children, 91% of whom maintained an undetectable viral load after 24 weeks on the new pill. The study reported no new adverse events or abnormalities, making the treatment as safe for children as it is for adults.

The approval means that all people living with HIV who weigh at least 14 kg will now have access to a version of Biktarvy, if it's right for them.

"As children living with HIV will be on therapy for the foreseeable future and from such a young age, there are a number of factors I weigh as a clinician when prescribing the right HIV treatment option to my pediatric patients," Carina Rodriguez, MD, pediatric infectious disease chief at the University of South Florida Morsani College of Medicine, said in a Gilead Sciences press release. "Finding an efficacious treatment option is paramount, but tolerability and safety are keys to ensuring treatment success."

Click here to more news about children living with HIV and the 2021 pediatric HIV guidelines.

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