The Food and Drug Administration (FDA) has expanded the approval of Truvada (tenofovir disoproxil fumarate/emtricitabine) as pre-exposure prophylaxis (PrEP) against HIV to include adolescents.

Truvada was approved as an HIV prevention method in 2012 but only for individuals age 18 and older. The new approval expands this indication to include adults and adolescents at risk for HIV who weigh at least 35 kilograms (77 pounds).

The new approval was based on the ATN113 study, which enrolled 67 high-risk adolescents ages 15 to 17.

During the 48-week study, the participants made monthly clinic visits for the first three months and then switched to visiting only every three months. Although the participants’ overall level of adherence to the daily Truvada regimen was promising during the initial three months, it dropped off dramatically once the study protocol switched to less frequent clinic visits. This phenomenon led researchers to conclude that adolescents may need monthly monitoring to do well on PrEP.

The side effects of Truvada as PrEP among these adolescents were comparable to those observed in adult studies. The most common side effects were headache, abdominal pain and weight loss. Four of the participants experienced a decrease in bone mineral density, including three who experienced a modest decrease and one who had a greater than 4 percent decline in total bone mineral density by week 24 of the study.

“Study ATN113 has demonstrated that Truvada for PrEP is a well-tolerated prevention option for adolescents who are vulnerable to HIV,” said Sybil Hosek, PhD, clinical psychologist at the Cook County Health and Hospital System’s Stroger Hospital in Chicago and lead investigator of the study, in a press release from Gilead Sciences, which manufactures Truvada. “In addition to traditional risk-reduction strategies, health care providers and community advocates are now equipped with another tool to help address the incidence of HIV in younger at-risk populations.”

To read the Gilead press release, click here.