Long-Acting Cabenuva Injections Now Approved for Teens

The long-acting regimen will enable some adolescents to take their HIV treatment just six times a year.

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The Food and Drug Administration (FDA) has extended the indication for Cabenuva (injectable cabotegravir plus rilpivirine) to include adolescents ages 12 and up. This will enable eligible young people living with HIV to take antiretroviral therapy just six or 12 times per year.

Daily antiretroviral pills are highly effective, but some people find long-acting injections more convenient, which could lead to better adherence. This could be especially important for adolescents, as some studies have found that this group struggles with adherence.

Cabenuva consists of an extended-release formulation of ViiV Healthcare's integrase inhibitor cabotegravir plus an injectable version of Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine. It is indicated as maintenance therapy for adults and adolescents weighing at least 77 pounds (35 kilograms) who have achieved viral suppression (a viral load below 50 copies) on daily oral antiretroviral therapy and who have no history of treatment failure and no known or suspected resistance to either drug.

The FDA initially approved Cabenuva as a once-monthly regimen for adults in January 2021. An every-other-month schedule was added in February 2022. Last week, the federal agency authorized a new dosing regimen that allows people to start the injections directly without taking cabotegravir and rilpivirine pills for a month; the oral lead-in period is now optional. (Injectable cabotegravir alone for pre-exposure prophylaxis, sold as Apretude, was initially approved in December 2021 for both adults and adolescents.)

The ATLAS study showed that people who switched from a standard oral regimen to monthly Cabenuva injections were about equally likely to maintain viral suppression as those who stayed on daily pills (93% and 96%, respectively). The ATLAS-2M study showed that those who received the injections every eight weeks were as likely to maintain an undetectable viral load as those who did so every four weeks. The FLAIR trial found that Cabenuva is also effective for people starting HIV treatment for the first time. Interim data from an ongoing study called MOCHA (More Options for Children and Adolescents) showed that drug levels and safety profiles in adolescents similar to those of adults.

Cabenuva is safe and generally well tolerated. The most common side effect is injection site reactions, such as pain, redness or swelling. These are usually mild to moderate and last a median of three days. Other adverse events, including fever, fatigue, headache, muscle pain, nausea, sleep disorders, dizziness and rash, are uncommon. Few people taking Cabenuva in clinical trials experienced serious adverse events or stopped treatment due to side effects.

Studies of adults found that participants reported greater satisfaction with Cabenuva compared with daily oral treatment. Reasons for preferring the injections include not having to think about HIV treatment every day and not having pill bottles that could reveal HIV status—advantages that will also benefit teens. The drawback is that the regimen requires visiting a health care provider for injections in the buttocks every month or every two months; Cabenuva cannot be self-administered.

“Adolescents living with HIV and their caregivers face notable treatment challenges with daily oral HIV therapy, including the stress and difficulties of taking medication every day,” ViiV’s Lynn Baxter said in a press release. “With today’s approval for Cabenuva, we are bringing this younger population a first-of-its-kind HIV treatment that is dosed as few as six times a year and removes the need for daily oral therapy altogether.”

Click here for updated prescribing information for Cabenuva.
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