Cabenuva Now Approved for Every-Other-Month Dosing

Using the new dosing schedule, injectable cabotegravir and rilpivirine can be administered just six times a year.

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On February 1, the Food and Drug Administration (FDA) approved an every-other-month dosing schedule for Cabenuva, the first complete long-acting HIV treatment regimen that does not involve daily pills. Cabenuva, from ViiV Healthcare, was initially approved in January 2021 as a once-monthly regimen. The new schedule means some people will be able to take their HIV treatment just six times a year.

Cabenuva consists of an extended-release formulation of the integrase inhibitor cabotegravir plus an injectable version of Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine. It is indicated as maintenance therapy for adults living with HIV who have an undetectable viral load (less than 50) on their current antiretroviral regimen, no history of treatment failure and no known or suspected viral resistance to either cabotegravir or rilpivirine.

People who wish to switch to Cabenuva should first take cabotegravir and rilpivirine pills (sold as Edurant and Vocabria, respectively) for a month to ensure that the combination is well tolerated. After that, they will receive two injections in the buttocks administered by a health care provider either once a month or once every other month.

The Phase III ATLAS study, which enrolled more than 600 HIV-positive participants with viral suppression on their current oral regimen, showed that 93% of those who switched to Cabenuva maintained an undetectable viral load at 48 weeks, as did 96% of those who stayed on their oral regimen. The FLAIR trial showed that Cabenuva was also highly effective for people starting antiretroviral therapy for the first time.

A follow-up study, ATLAS-2M, showed that monthly and every-other-month dosing of the injectables are equally effective. The trial included 654 participants with an undetectable load who switched from a daily oral regimen and 391 people who rolled over from the monthly Cabenuva arm of the original ATLAS trial. They were randomly assigned to receive Cabenuva every four weeks or every eight weeks.

At 48 weeks, 94% of participants in both groups maintained viral suppression; 1.0% of people in

the once-monthly Cabenuva group and 1.7% in the every-other-month group had a viral load above 50. Further results, presented at last year's Conference on Retroviruses and Opportunistic Infections, showed that 91% of people in the every-other-month group and 90% in the once-monthly group still had an undetectable viral load at 96 weeks.

Just 1% of study participants—two in the once-monthly group and nine in the every-other month group—experienced confirmed virological failure, defined as two consecutive viral load measurements above 200. Most were found to have viral mutations associated with resistance to rilpivirine or integrase inhibitors. Nonetheless, all but one regained viral suppression when they switched to another regimen.

However, other research presented at the conference suggests that sticking to the dosing schedule is especially important for those on the every-other-month regimen. Pharmacological modeling studies showed delaying cabotegravir or rilpivirine injections by up to one week should have little impact, but longer delays could be a problem. People who need to miss an injection visit—for example, because they are traveling—can use Vocabria and Edurant pills as a "bridging" strategy.

Cabenuva is safe and generally well tolerated. The most common side effect is injection site reactions such as pain, redness or swelling, which are usually mild to moderate and resolve within a few days. Other adverse reactions may include fever, fatigue, headache, muscle pain, nausea, sleep disorders, dizziness and rash. In ATLAS-2M, rates of serious adverse events and discontinuation due to adverse events were low and comparable in the once-monthly and every-other-month groups.

Most participants in the original ATLAS study who switched from an oral regimen said they preferred monthly Cabenuva injections over daily pills. Reasons included greater convenience, not having to think about HIV and its treatment every day and not having pill bottles that could reveal their HIV status. The every-other-month schedule cuts the frequency of injections in half, which will improve convenience for patients and relieve pressure on providers. But Cabenuva recipients will still need to visit a clinic more often than they do now for routine viral load monitoring.

"Many people living with HIV face challenges with daily therapies and are interested in alternative dosing options," ATLAS-2M principal investigator Turner Overton, MD, of the University of Alabama at Birmingham, said in a ViiV press release. "In clinical trials, approximately 9 out of every 10 trial participants preferred long-acting cabotegravir and rilpivirine dosed every two months compared to daily oral cabotegravir and rilpivirine taken as the oral lead-in per trial protocol. This preference data highlights the meaningful impact long-acting regimens can have on the treatment experience for the HIV community."

Injectable cabotegravir alone, sold under the brand name Apretude, was recently approved for HIV pre-exposure prophylaxis (PrEP). Studies showed that injections given every other month were even more effective than daily Truvada (tenofovir disoproxil fumarate/emtricitabine) pills, both for cisgender men and trans women who have sex with men and for cisgender women.

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