People With HIV Are Highly Satisfied With Cabenuva

Injections given every month or every other month were preferred over daily pills.

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People with HIV who received long-acting Cabenuva preferred the monthly or bimonthly injections over their previous daily oral regimen, and those who tried both dosing schedules favored less frequent administration, according to study results published in Patient-Centered Outcomes Research.

In January 2021, the Food and Drug Administration (FDA) approved once-monthly Cabenuva, from ViiV Healthcare, as the first complete injectable antiretroviral regimen that does not require daily pills. The new treatment is approved for people with an undetectable viral load on their current therapy who wish to switch to a long-acting option.

Cabenuva consists of an extended-release formulation of the integrase inhibitor cabotegravir plus an injectable version of the non-nucleoside reverse transcriptase inhibitor rilpivirine (sold in pill form as Edurant). The injections must be administered by a health care provider, usually in the buttocks.

The Phase III ATLAS and FLAIR trials showed that people who switched from a daily oral treatment regimen to monthly Cabenuva were about equally likely to maintain viral suppression. The follow-up ATLAS-2M study showed that every-other-month administration works as well as monthly injections. So far, the FDA has approved only monthly administration, but ViiV has requested a bimonthly indication.

In prior studies, most participants said they preferred the long-acting regimen over daily pills, despite the possibility of injection site reactions (ISRs) and the need to see a provider more frequently than they would if they took daily pills and required only periodic viral load monitoring. 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 new results from ATLAS-2M confirm this finding. This trial included 645 people with an undetectable viral load who switched from a daily oral HIV regimen and 391 people who rolled over from the monthly Cabenuva arm of the original ATLAS trial. A majority (70%) were men, the

median age was 42 years and the median CD4 count exceeded 600.

The participants were randomly assigned to receive injections of 400 milligrams of cabotegravir and 600 mg of rilpivirine every four weeks or 600 mg of cabotegravir and 900 mg of rilpivirine every eight weeks, following an oral lead-in period using cabotegravir and rilpivirine pills.

William Spreen, PharmD, of ViiV, and colleagues analyzed patient-reported outcomes through 48 weeks. These included treatment satisfaction, treatment acceptance, acceptability of injection site reactions and reasons for switching to or continuing on the long-acting regimen.

People who switched directly from daily pills reported a large increase in treatment satisfaction in both the monthly and every-other-month arms, but the improvement was greater for those who received the injections every eight weeks. Among the 306 people who started on bimonthly injections, 300 (98%) said they preferred this regimen over daily pills.

People who were already receiving monthly Cabenuva in the earlier ATLAS trial reported high treatment satisfaction and acceptance at baseline. This was maintained over time, regardless of whether they continued to receive monthly injections every four weeks or were randomized to the every-eight-weeks arm. Among the 191 participants who switched from monthly to every-other-month administration, 94% preferred the less frequent dosing schedule, 3% preferred monthly dosing and 2% preferred daily pills.

Although injection site reactions, such as pain and swelling, were common, acceptance of these reactions improved over time. ISRs tend to decrease with continued use, and few participants discontinued Cabenuva for this reason. Although ISRs occurred more often per visit with the bimonthly regimen—which contains a higher volume of the drug—this was offset by less frequent dosing, resulting in similar acceptability of the local reactions regardless of the dosing regimen, the researchers noted.

“Both long-acting regimens provided high treatment satisfaction and acceptance, irrespective of prior [cabotegravir plus rilpivirine] exposure,” with most participants preferring the every-eight-weeks schedule over both the every-four-weeks regimen and their previous daily oral regimen, the study authors concluded.

“Patient satisfaction may contribute to individual improvements in adherence, which in turn translates to better management of HIV,” they wrote. “Increasing patient satisfaction is also vital to improving overall quality of life for people living with HIV-1, a metric of ever-increasing importance as the efficacy, tolerability and accessibility of HIV therapeutics continue to improve.”

Injectable cabotegravir alone every other month is also being studied for pre-exposure prophylaxis (PrEP). Researchers reported last year that cabotegravir injections were more effective for HIV prevention than daily oral Truvada (tenofovir disoproxil fumarate/emtricitabine) both for cisgender men and trans women who have sex with men in the HPTN 083 study and for cisgender women in the HPTN 084 study.

Click here for to read the study abstract.

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