Monthly Injectable Cabenuva Approved

Injectable cabotegravir and rilpivirine are approved for people with viral suppression who would prefer monthly injections to daily pills.

March 29, 2021 By Heather Boerner

How's this for a shot in the arm—er, butt? In January, the Food and Drug Administration (FDA) approved the monthly injectable antiretroviral regimen Cabenuva to replace daily pills for maintenance of viral suppression. The United States now joins Canada and Europe in approving the first complete long-acting injectable treatment for HIV.

Cabenuva combines 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 FDA approved the shots for people with a long-term undetectable viral load, no history of treatment failure and no known or suspected resistance to either cabotegravir or rilpivirine.

Approval was based on positive results from the Phase III ATLAS and FLAIR trials, which found that monthly Cabenuva injections maintained viral suppression as well as standard daily oral regimens. What's more, the ATLAS-2M study showed that once-monthly and every-other-month injections are equally effective, with 94% of people in both groups maintaining viral suppression. For now, the FDA has approved only the once-monthly schedule, but ViiV Healthcare has requested approval for the every-other-month regimen.

Before switching to the shots, there will be pills—at least at the beginning. The FDA also approved a tablet version of cabotegravir, called Vocabria, which people switching to Cabenuva will need to take along with Edurant for a month to ensure that the new combination agrees with them. After that, they will receive two injections in the buttocks administered by a health care provider once a month. Vocabria and Edurant pills may also be used as a complete short-term regimen—for example, if someone has to miss a planned Cabenuva injection appointment.

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