

Injectable Cabenuva Can Now Be Started Without Oral Lead-In

People can now start Cabenuva injections directly without first taking cabotegravir and rilpivirine pills for a month.

March 25, 2022 By [Liz Highleyman](#)

The Food and Drug Administration (FDA) has approved a new streamlined dosing process for [Cabenuva \(injectable cabotegravir plus rilpivirine\)](#) that does not require an oral lead-in period, which involves taking cabotegravir and rilpivirine pills for a month prior to injections. The oral lead-in is now optional.

[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 who have achieved viral suppression 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 in January 2021. An [every-other-month schedule was added](#) in February 2022. Results from the [ATLAS-2M study](#) showed that people who received the injections every eight weeks were as likely to maintain viral suppression as those who received them every four weeks.

Both of those approvals included a four-week oral lead-in period using cabotegravir and rilpivirine pills to ensure that the regimen was well tolerated before switching to long-acting injections.

But clinical trials and early real-world use have shown that Cabenuva is safe and well tolerated. The most common side effect is injection site reactions, such as pain, redness or hard swelling (induration). Severe adverse events are rare.

[Results from the FLAIR trial showed](#) that the frequency of adverse events was similar for people who switched directly from a standard oral regimen to monthly Cabenuva injections and those who first took four weeks of cabotegravir and rilpivirine pills.

The latest update gives people living with HIV and their doctors more options: They can choose whether to receive Cabenuva injections every month (12 times a year) or every other month (six times a year), and they can opt to start with an oral lead-in period or not. ([Injectable cabotegravir](#)

[alone for pre-exposure prophylaxis](#), sold as Apretude, can also be started with or without an oral lead-in.)

“Since launching Cabenuva, we have been keenly focused on optimizing the user experience for both people living with HIV and healthcare providers,” ViiV’s Lynn Baxter said in a [press release](#). “Today’s label update for the optional oral lead-in provides a streamlined initiation process for the regimen by allowing people to start directly on long-acting injections and underscores ViiV Healthcare’s ongoing commitment to providing innovative treatment options that address the evolving needs of the HIV community.”

Click here for [updated prescribing information for Cabenuva](#).

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