TAG

The goal of hepatitis C virus (HCV) treatment is a cure (when there is no HCV in a person's bloodstream at least 12 weeks after treatment is finished).

What is Viekira XR? Viekira XR is a combination of hepatitis C virus–fighting drugs (paritaprevir/ritonavir/ombitasvir and dasabuvir) that block different steps of the virus life cycle. In the United States, Viekira XR is approved for people with hepatitis C genotype 1 who are over 18 years old. Viekira XR was previously approved and prescribed as a twice a day formula known as Viekira Pak. XR contains the same drugs, in the same amounts, as Viekira Pak, now in a once daily package.

**What is Technivie**? Technivie is a combination of paritaprevir/ritonavir and ombitasvir. Technivie is approved for people over 18 years of age who have hepatitis C genotype 4 without cirrhosis.

**How is Viekira XR used?** Viekira XR is taken once daily, with food, for 12 or 24 weeks. Viekira XR comes in a box of 4 (weekly) cartons of daily-dose packs with three beige tablets in each pack. The tablets should be swallowed whole (they should not be split, chewed or crushed). Some people will need to take another drug, called **ribavirin (RBV)**, twice daily when taking Viekira XR.

**How is Technivie used?** Technivie is taken once daily, with food, for 12 weeks. Technivie comes in a box of 28 dailydose packs with two pink tablets. Both pink tablets are taken in the morning. It should be used with another drug, called **ribavirin (RBV)**, which is taken twice daily. Using Technivie by itself can be considered for people who cannot take RBV if they are being treated for the first time.

It is important to make sure that you have gotten the right treatment (with or without RBV) for the recommended length of time (12 or 24 weeks).

## Viekira XR and Technivie with Cure Rates\*

Genotype 1a (including mixed or unknown subtypes), never treated or treatment-experienced, no cirrhosis	+ Cirrhosis
Viekira XR + RBV, 12 weeks: 94% to 97%**	Viekira XR + RBV, 24 weeks: <b>95%</b> Viekira XR + RBV, 12 weeks: <b>89%</b> (consider 12 weeks of treatment according to HCV treatment history)
Genotype 1b, never treated or treatment-experienced, no cirrhosis	+ Cirrhosis
Viekira XR, 12 weeks: 100%	Viekira XR, 12 weeks: 99%
Genotype 4, never treated, no cirrhosis	+ Cirrhosis
Technivie + RBV, 12 weeks: 100% (90.9% without RBV)	N/A
Genotype 4, treatment-experienced, no cirrhosis	+ Cirrhosis
Technivie + RBV, 12 weeks: 100%	N/A

\*Cure rates in clinical trials are higher than in real life since the people in them are usually healthier and get extra monitoring and support. \*\*Cure rates are from clinical trials of the components of Viekira XR (administered as Viekira Pak).

The most important thing a person can do to be cured is not to miss taking doses of HCV treatment—called **adherence**. Adherence lowers the risk for drug resistance.

**What is drug resistance?** Each day, HCV makes billions of copies of itself. Some of these copies are not the same as the original virus. They may have changes (called *mutations*) that can stop hepatitis C drugs from working. If people miss doses of their treatment, the virus gets a chance to reproduce—and some of these copies can be resistant to HCV treatment. Some people have drug resistance even though they have never been on hepatitis C treatment—but many can be cured anyway.

Most people who are not cured have resistance to one or more of the HCV drugs they've taken. Resistance to certain hepatitis C drugs can disappear within months. But resistance to other drugs can last for years and might prevent re-treatment from working.

**Viekira XR or Technivie and age, gender, and race/ethnicity**: In clinical trials, cure rates did not differ by age (over 65 vs. under 65). Cure rates were the same for women and men. There is not much information about how well Viekira XR or Technivie work by race or ethnicity because most people in the trials were white. But researchers noticed two things: adding RBV to Viekira XR increased cure rates for African Americans with HCV genotype 1a (100% vs. 84%), and people with a common genetic factor among African Americans (called the IL28B TT genotype) were less likely to be cured by Viekira XR (see TAG's Hepatitis C and the IL28B Gene fact sheet).

**Side effects from Viekira XR and Technivie: Talk with your health care provider about possible side effects and how they will be managed.** In clinical trials, the most common side effects from Viekira XR or Technivie were nausea, itching, and insomnia. People taking RBV also experienced fatigue, weakness, rash, and other skin reactions (see TAG's **RBV** fact sheet for more information). Most of these side effects were mild.

Liver enzyme levels may increase while taking Viekira XR or Technivie. Your health care provider should check your liver with blood tests during the first four weeks of treatment—and afterward as needed.

**Do Viekira XR and Technivie work for HIV-positive people?** Yes, but Viekira XR or Technivie should not be used by coinfected people unless they are also being treated for HIV. This is because one of the drugs in Viekira XR and Technivie can cause resistance to some HIV drugs. In a clinical trial of 63 people with HIV and hepatitis C genotype 1, 93.5% were cured after 12 weeks of Viekira Pak plus RBV. Technivie has not been studied in people coinfected with HIV and hepatitis C genotype 4.

Viekira XR or Technivie can be used with these HIV drugs: Isentress or Reyataz (300 mg), which should be taken in the morning, without ritonavir (Norvir), plus Truvada or Viread with Epivir or Emtriva.

Viekira XR or Technivie and other medications: Viekira XR or Technivie should not be used with certain drugs. Combining medications can increase or lower drug levels (called *drug-drug interactions*). Increasing drug levels can make side effects from each drug worse. If drug levels get too low, a drug can stop working, putting a person at risk for drug resistance or not being cured. Talk with your health care provider about starting or stopping any medications, supplements, or herbal remedies.

Some drugs should be switched, stopped, or avoided while using Viekira XR or Technivie. More information is available in the prescribing information for Viekira XR and Technivie (http://www.rxabbvie.com/pdf/viekiraxr\_pi.pdf and http://www.rxabbvie.com/htm/technivie/technivie pi.htm) and at: www.hep-druginteractions.org.

**Viekira XR or Technivie and hormonal contraception (birth control):** Viekira XR and Technivie cannot be used with medications containing ethinyl estradiol (women can use progestin-only birth control). Medications containing ethinyl estradiol can be restarted two weeks after stopping Viekira XR or Technivie.

**Viekira XR or Technivie during pregnancy, nursing, and in children:** It is not known whether Viekira XR or Technivie cause harm to unborn babies. If you are pregnant or planning pregnancy, talk with your health care provider about the risks and benefits of HCV treatment. It is not known whether Viekira XR or Technivie pass into breast milk.

Viekira XR and Technivie have not been studied in children and are not approved for people under 18 years old.

Ribavirin causes birth defects and miscarriage. Ribavirin should not be used by pregnant women or by male partners of pregnant women. Ribavirin stays in a person's body for months. Women and their male partners should avoid pregnancy for six months *after* they have stopped taking ribavirin. Using two forms of birth control to prevent pregnancy while taking ribavirin—and for six months afterward—is recommended. Nursing during treatment with ribavirin is not recommended. There is a ribavirin pregnancy registry at: http://www.ribavirinpregnancyregistry.com.

Storing Viekira XR: Keep Viekira XR or Technivie at room temperature (below 86°F).

**Viekira XR or Technivie in people with kidney disease:** Viekira XR or Technivie can be used by people with mild or moderate kidney disease. People with severe kidney disease should consult with a specialist before using Viekira XR or Technivie. They have not been studied in people on dialysis.

**Viekira XR or Technivie in people with cirrhosis:** Hepatitis C treatment guidelines recommend that people with serious liver damage (Child-Pugh Class B or C cirrhosis) be treated by a specialist. Technivie has not been studied in people with HCV genotype 4 and cirrhosis. Viekira XR and Technivie should *not* be used in people with Child-Pugh Class B or Class C cirrhosis.

Access to Viekira XR and Technivie may be restricted by public and private payers. The criteria differ by type of coverage and the state it is issued in. ProCeed is AbbVie's Viekira XR patient assistance program. ProCeed may help people with private insurance with copayments. Uninsured people may be eligible for free medication through proCeed.

Information about pro<u>C</u>eed is available by phone at 1.844.2PROCEED (1.844.277.6233), Monday through Friday between 8:00 a.m. and 5:00 p.m. (Eastern Time), or online at: https://www.viekira.com/patient-support/financial-resources.

Information about the Technivie patient assistance program is also available by phone at 1.844.2PROCEED (1.844.277.6233), Monday through Friday between 8:00 a.m. and 5:00 p.m. (Eastern Time.

This fact sheet is current as of January 2017. Always check for updated information.