Ombitasvir-Paritaprevir-Ritonavir *(Technivie)*

Drug Summary

Based on data from the PEARL-1 study, the ombitasvir-paritaprevir-ritonavir, given with ribavirin, is an effective all-oral regimen for treatment-naive and treatment-experienced patients with genotype 4 HCV who do not have cirrhosis. At this time, the ombitasvir-paritaprevir-ritonavir regimen should only be used at this time for patients with genotype 4 HCV without cirrhosis; dasabuvir is not included in this regimen since it does not have activity against HCV genotype 4. The effectiveness of ombitasvir-paritaprevir-ritonavir in patients with genotype 4 HCV and cirrhosis is not known. Clinicians need to distinguish the ombitasvir-paritaprevir-ritonavir fixed dose medication *(Technivie)* from the closely related ombitasvir-paritaprevir-ritonavir plus dasabuvir *(Viekira Pak)*; the key difference between these two is the absence of medication dasabuvir in the *Technivie* preparation.

Class and Mechanism

Ombitasvir is a NS5A inhibitor with potent pangenotypic picomolar antiviral activity and paritaprevir is an inhibitor of the NS3/4A serine protease. Ritonavir is a potent inhibitor of CYP3A4 enzymes and is used as a pharmacologic booster for paritaprevir—it significantly increases peak and trough paritaprevir plasma concentrations, as well as the area under the curve of paritaprevir. Ritonavir was originally developed and FDA-approved as an HIV protease inhibitor; it does not have activity against HCV.

Manufacturer for United States

*Technivie* (TEK-ni-vee) is a fixed-dose combination ombitasvir-paritaprevir-ritonavir *(Figure 1 and Figure 2)*. It is manufactured by AbbVie. The closely related combination ombitasvir-paritaprevir-ritonavir plus dasabuvir *(Viekira Pak)* is also manufactured by AbbVie.
Cost and Medication Access

The wholesale acquisition cost (WAC) for a 12-week course of ombitasvir-paritaprevir-ritonavir is $76,653, which corresponds to a cost per day of $912. There are no patient assistance programs listed by AbbVie for ombitasvir-paritaprevir-ritonavir.

Adverse Effects

On October 22, 2015 the United States FDA issued a Drug Safety Warning that treatment with ombitasvir-paritaprevir-ritonavir (Technive) can cause serious liver injury, mostly in patients with underlying advanced liver disease. In most of the reported cases, the liver injury occurred within 1 to 4 weeks of starting treatment. In clinical trials, approximately 1% of persons receiving ombitasvir-paritaprevir-ritonavir developed increases in alanine aminotransferase levels (ALT) to greater than 5 times the upper limit of normal. Because of this potential adverse effect, patients should have hepatic laboratory testing during the first 4 weeks after starting therapy, with further monitoring thereafter as clinically indicated. Among the 135 patients with genotype 4 HCV treated with ombitasvir-paritaprevir-ritonavir, none developed serum ALT levels greater than 5 times the upper limit of normal. The most common adverse effects observed in the PEARL-1 trial for patients receiving ombitasvir-paritaprevir-ritonavir without ribavirin were asthenia (25%), nausea (9%), and fatigue (7%).

Key Drug Interactions

For complete information on ombitasvir-paritaprevir-ritonavir-related drug interactions, see the Drug Interactions section in the Ombitasvir-Paritaprevir-Ritonavir (Technivie) Prescribing Information.