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

The fixed dose combination ombitasvir-paritaprevir-ritonavir (Technivie) 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 (Technivie) 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.
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AGATE-II

This phase 3, open-label, partly randomized trial enrolled treatment-naive or treatment-experienced adults with HCV genotype 4 infection, including 100 participants with cirrhosis and 60 without cirrhosis. The study was conducted at five academic and hepatology centers in Egypt. Participants without cirrhosis received 12 weeks ombitasvir-paritaprevir-ritonavir plus weight-based ribavirin. Patients with compensated cirrhosis were randomized to receive ombitasvir-paritaprevir-ritonavir for 12 weeks or 24 weeks. Overall, including both treatment-naive and treatment-experienced patients, more than 90% of patients achieved an SVR 12 (94% in those without cirrhosis; 97% in those with cirrhosis treated with 12 weeks; and 93% in those with cirrhosis treated with 24 weeks).

PEARL-I

In the phase 2b PEARL-I study, patients with chronic genotype 4 HCV infection, without cirrhosis, were treated with a 12-week course of ombitasvir plus paritaprevir plus ritonavir, with or without ribavirin. The study was a multicenter trial conducted in Europe, Turkey, and the United States. The enrollment included treatment-naive and treatment-experienced patients. The treatment-naive patients were randomized to receive a regimen with or without ribavirin, whereas all treatment-experienced patients received a regimen that included ribavirin. Note the regimen used in this trial did not include dasabuvir since it does not have activity against genotype 4 HCV. For the treatment-naive patients, 40 (91%) of 44 achieved an SVR12 with the regimen ombitasvir plus paritaprevir plus ritonavir; 42 (100%) of 42 of the treatment-naive patients achieved an SVR with ombitasvir plus paritaprevir plus ritonavir and ribavirin. Among the treatment-experienced patients, 49 (100%) of 49 patients achieved an SVR12 with ombitasvir plus paritaprevir plus ritonavir and ribavirin. This regimen was well-tolerated and there were few treatment discontinuations.

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References

Figures

Figure 1 Monthly Supply Carton

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.
**Figure 2 1 Week Supply Carton**

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.
Figure 3 Daily-Dose Pack

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.

The most up to date version of this content may be obtained from: https://www.hepatitisc.uw.edu/page/treatment/drugs/ombitasvir-paritaprevir-ritonavir