IN BRIEF

Technivie for HCV Genotype 4 Infection

The FDA has approved Technivie (Abbvie), a fixed-dose combination of the direct-acting antiviral agents ombitasvir and paritaprevir and the pharmacokinetic enhancer ritonavir, for oral treatment of chronic hepatitis C virus (HCV) genotype 4 infection in patients without cirrhosis. It is indicated for use in combination with ribavirin. Ombitasvir/paritaprevir/ritonavir copackaged with dasabuvir, an HCV RNA polymerase inhibitor that has little activity against HCV genotype 4, is approved as Viekira Pak for treatment of HCV genotype 1 infection.1

HCV genotype 4 is uncommon in the US and Canada. It is the most prevalent strain of HCV in Central sub-Saharan Africa, North Africa, and the Middle East.2 Technivie plus ribavirin was the first all-oral treatment approved for treatment of HCV genotype 4. Ledipasvir/sofosbuvir (Harvoni)3 was also recently approved for this indication; it does not require coadministration with ribavirin and can be used in patients with or without cirrhosis. Its use for this and other new indications will be reviewed in a future issue.

FDA approval of Technivie was based on an open-label trial (PEARL-I) in 86 treatment-naive and 49 treatment-experienced non-cirrhotic patients with HCV genotype 4 infection. Treatment-naive patients were randomized to receive Technivie with or without ribavirin for 12 weeks; all treatment-experienced patients received the combination plus ribavirin for 12 weeks. The rate of sustained virologic response 12 weeks after stopping treatment (SVR12), the primary endpoint, was 91% (40/44) in treatment-naive patients not receiving ribavirin and was 100% in both treatment-naive (42/42) and treatment-experienced (49/49) patients receiving the combination plus ribavirin.4

Adverse effects observed with Technivie in the clinical trial included asthenia, fatigue, nausea, insomnia, pruritus, and skin reactions. Like Viekira Pak, Technivie has been associated with serious, sometimes fatal cases of hepatic decompensation and is contraindicated in patients with moderate to severe (Child-Pugh B/C) hepatic impairment.5 It is also contraindicated in patients taking ethinyl estradiol (because of a risk of ALT elevation), CYP3A4 inducers such as rifampin, or certain sensitive CYP3A4 substrates such as midazolam or simvastatin.6

Each Technivie tablet contains 12.5 mg of ombitasvir, 75 mg of paritaprevir, and 50 mg of ritonavir. The recommended dosage is two tablets taken once daily in the morning with a meal for 12 weeks. Ribavirin should be coadministered with Technivie at a daily dose of 1000 mg in patients weighing <75 kg or 1200 mg in those weighing ≥75 kg. Use of Technivie alone may be considered in treatment-naive patients who cannot take or tolerate ribavirin. A 12-week supply of Technivie costs $76,653.7

1. A 4-drug combination (Viekira Pak) for hepatitis C. Med Lett Drugs Ther 2015; 57:15.
3. A combination of ledipasvir plus sofosbuvir (Harvoni) for hepatitis C. Med Lett Drugs Ther 2014; 56:11.
7. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer’s published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. November 5, 2015. Reprinted with permission by First Databank, Inc. All rights reserved. ©2015 www.fdbhealth.com/policies/drug-pricing-policy.