January 29, 2016

Zepatier Approved for Hepatitis C

On Jan. 28, 2016, Merck received approval from the U.S. Food and Drug Administration (FDA) for Zepatier™ (elbasvir / grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection. Recommended dosing of Zepatier is one tablet once-daily, with or without ribavirin (RBV), for 12 or 16 weeks. Zepatier is expected to be in pharmacies by Feb. 19, 2016. It will be available through open distribution. Full prescribing information can be found at: http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf

At a Glance

- **Brand (Generic) Name:** Zepatier™ (elbasvir / grazoprevir)
- **Manufacturer:** Merck
- **Date Approved:** Jan. 28, 2016
- **Indication:** Treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin
- **Dosage Forms Available:** Fixed-dose combination tablets containing 50mg of elbasvir and 100mg of grazoprevir
- **Launch Date:** Zepatier is expected to be in pharmacies by Feb. 19, 2016.
- **Estimated Annual Cost:** The 12-week regimen will have a list price of $54,600.
- **Specialty Status:** Zepatier will be added to Express Scripts’ specialty drug list.
- Zepatier contains elbasvir, an NS5A inhibitor and grazoprevir, a second-generation protease inhibitor.
- In April 2015, Merck received a breakthrough therapy designation for Zepatier for the treatment of patients with HCV GT4 infection and for patients with HCV GT1 infection with end stage renal disease (ESRD) on hemodialysis. HCV GT4 infection accounts for about 6% of cases. Approximately 10% to 15% of patients with HCV have ESRD.
- Zepatier will compete with other all-oral combination products on the market for hepatitis C. Gilead’s Harvoni® (ledipasvir / sofosbuvir) is approved for patients with HCV GT1, 4, 5 and 6 infection, AbbVie’s Viekira Pak™ (ombitasvir / paritaprevir / ritonavir; dasabuvir) is approved for patients with HCV GT1 infection and AbbVie’s Technivie™ (ombitasvir / paritaprevir / ritonavir) is approved for patients with HCV GT4 infection without cirrhosis. In addition, Sovaldi® (sofosbuvir – Gilead) is approved for use with other agents to treat patients with HCV GT1, 2, 3 and 4 infection.
- The first pan-genotypic regimen, Gilead’s sofosbuvir / velpatasvir, is expected to be approved by June 28, 2016, for patients with HCV GT1-6 infection.
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