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FDA OKs Merck hepatitis C drug, adding to patient choices

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Patients with hepatitis C have yet another advanced treatment option, as the Food on Drug Administration on Thursday approved a new once-a-day pill developed by drugmaker Merck.

The FDA said Merck can begin marketing Zepatier for patients with two of the subtypes the liver-destroying virus, types 1 and 4. The combination pill includes the medications elbasvir and grazoprevir, which attack the virus in two different ways.

Merck & Co. said the price will be $54,600 for a 12-week treatment regimen. Insurers will likely still demand some discounts on that price.

The approval is good news for patients, because the growing competition should crimp the sky-high prices for hepatitis C drugs, and the additional option means there's one that will work for nearly every subgroup of people with hepatitis C.

Roughly 3 million Americans and millions more in other countries have the blood-borne virus, which doesn't produce symptoms—jaundice, fluid accumulation in the abdomen, bleeding and infections—until significant damage has been done. Many develop liver cancer or cirrhosis and require a liver transplant, but die before a match is available.

There are six genetic subtypes of the hepatitis C virus, and the five drugs now approved in the U.S. generally only treat some of those. Patients with both hepatitis C and HIV or another serious condition are

particularly difficult to treat, as are those who already have severe liver or kidney damage. Some of the drugs target those patient groups; Merck's is approved for patients with cirrhosis, for example.

The five hepatitis C treatments all can cure 90 percent of patients or better in three months or less. By comparison, the prior generation of treatments took a year, barely cured half of patients and required both daily pills and frequent shots of immune-system stimulator interferon. That caused awful flu-like side effects many patients could not tolerate.

Merck's Zepatier was approved for treating patients with hepatitis C genotype 1, the most common type in the U.S., and gentopye 4, one of the least common. It was tested in a total of 1,373 patients, with or without liver cirrhosis.

Twelve weeks after treatment ended, 94 percent to 97 percent of those with genotype 1, and 97 percent to 100 percent of those with genotype 4, had no virus detectable in their blood, suggesting they'd been cured, according to the FDA.

The drug's side effects include fatigue, headache, nausea and problems with liver function.

The increasing competition will help insurers and other payers win bigger discounts from all the makers of hepatitis C drugs. That includes market leader Gilead Sciences Inc., which makes Harvoni and Sovaldi; AbbVie Inc., which makes Viekira Pak; Bristol-Myers Squibb Co., which makes Daklinza, and Merck.

Harvoni carries a list price of $94,000 for one course of treatment, but insurers have been getting discounts of about 45 percent off that to include the drug on their formulary of covered medicines. It's far and away the market leader.

Merck said the list price for Zepatier is in the range of what it believes are the net prices competitors are getting from payers.

Also on Thursday, Bristol-Myers said the European Union approved sales there for Daklinza, which won U.S. approval in 2004.