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THE EMERGING PRICING SHOCK IN THE TREATMENT FOR HEPATITIS C

By Rebecca Owen

n the past few months there have been headlines in the press about the expected increase in the costs of treating hepatitis C due to a new, effective, and very expensive therapy.

The rhetoric is quite hot:

\$1,000 per Day Medication Enrages Express-Scripts

How Much Should Hepatitis C Treatment Cost?

Lawmakers Attack Cost of New Hepatitis Drug

The press has raised questions about pricing and which patients should receive treatment, and, certainly, they have expressed concern about the burden of this new treatment regimen under any proposed scenario. Here is a brief outline of the topic.

Hepatitis is the general term for an inflammatory condition of the liver, usually caused by a virus, although drugs, alcohol use and certain medical conditions are also causes. The most common forms of viral hepatitis are A, B and C. Hepatitis A is often associated with food contamination and is highly contagious, resulting in outbreaks that often make the evening news. Hepatitis B is usually spread through blood or body fluids, and, often, healthy adults have only mild symptoms and recover without treatment, although the symptoms can persist for life. Vaccinations for these two forms of hepatitis are usually on the list of recommendations for anyone planning adventure travel.

This article is concerned with the care and treatment of hepatitis C. A person can have hepatitis C for years with no debility, although, at the onset, there may be symptoms like nausea, fatigue or a low fever, any of which may be attributed to a number of other, more benign, causes. However, the disease does not lie dormant, but continues to damage the liver until the situation becomes critical enough to demand attention. About 75 to 85 percent of people who contract the disease de-



velop chronic hepatitis C, which can lead to liver failure and liver cancer. Hepatitis C is usually spread through contact with infected blood. Contaminated needles, including those used to make tattoos or piercings, are the most common means of transmission—and only one point of contact is sufficient to infect someone. Since donated blood was not tested for hepatitis C, as it is now, until 1992, people who received a blood transfusion prior to that time are at risk. There is no vaccine for hepatitis C.

Hepatitis C virus (HCV) is surprisingly prevalent—it is the most common chronic viral disease in the United States and the leading cause of liver cancer and liver transplants. The CDC estimates that 3.2 million people have chronic HCV in the United States, with some other estimates even higher—up to 5 million. The rates of infection were highest in the 1970s and 1980s, and infection is highest among baby boomers; however, the CDC reports that approximately 1 out of 3 people between the ages of 18 and 30 who inject drugs have the virus. Prison inmates have a high infection rate due to a number of risk factors.

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Medical facilities that rigorously use standard precautions and infection control are considered to pose no risk of transmission.

Historically, chronic hepatitis C has been treated using a combination of drugs, with patients living for many months, and even years, taking regimens determined by the genotype of the virus. These treatments have been shown to be effective for 50 to 80 percent of patients. However, the length of treatment, coupled with side effects, meant that a large portion of patients did not stay the course. A breakthrough drug combination has shortened the treatment time to just 12 weeks, and it shows a response in 90 to 95 percent of the patients who have one of the most common and difficult HCV genotypes. (For readers who are interested in more detail about treatments and comparisons, here is a link to an excellent clinical lecture on the topic: http://www.youtube.com/ *watch?v=e6-GcFxzdb4&feature=youtu.be.*)

The health implications are breathtaking, but so is the cost. One of the drugs—sofosbuvir, known by the name Sovaldi-is widely quoted as costing \$84,000 per three-month treatment. Even offsetting the cost of the older, less efficacious, treatment and the costs of unchecked liver disease, this breakthrough treatment has the potential to demolish Medicaid budgets, shock unwitting self-funded plans, and erode pricing margins for insurers. In a presentation to the California Technology Assessment Forum (CTAF) on March 10 of this year, the impact to California large group premiums was estimated at 14.1 percent. The cost of Sovaldi is being discussed in rating meetings, both public and private, and the implications are being discussed heatedly-including the comparison to costs in India (\$2,000 for six months) and to projected costs in Europe, which are falling somewhere between the U.S. and Indian costs.

Since it is unlikely that budgets can stretch to treat every person with the virus, there are policies being crafted to "decide how to decide" who is going to be allowed to receive Sovaldi-based treatment. The Veterans Administration has released a detailed algorithm (http://www.hepatitis.va.gov/pdf/2014hcv.pdf). Several states have released a prior authorization methodology (e.g., Texas http://www.hhsc.state.tx.us/news/meetings/2014/DUR/0410/6e.pdf), and insurance companies are forming their policies. Some companies are asking doctors to delay prescribing the regimen to patients who can wait. Frequently, the criteria are focused on restricting the treatment to persons with advanced liver disease, such as cirrhosis. CTAF estimated that if only patients with advanced liver disease are treated, the impact to costs would fall from the initial 14.1 percent projection to 4.7 percent.

For those managed care companies who accepted capitation rates for 2014 before the impact of Sovaldi was comprehended, the situation is more critical. Medicare and Medicaid plans have a larger portion of their population with HCV than commercial plans, especially in those states with expansion populations, and there is no room in the rates to absorb these additional costs. These companies are asking states to consider carving out the costs of HCV treatment from the rates or increasing reimbursements to cover the shortfall. States are carefully weighing their options, which include deciding questions of who will be covered as well as considering whether there is any room to ask for drug pricing concessions for public payers.

One of the hardest parts about writing an article on an emerging issue such as this is the speed with which the landscape is changing on the topic, but, within this rapidly changing landscape, there are some certainties to consider. The treatment is effective, and it certainly will save lives. The treatment is expensive and there are not enough resources to immediately cover the cost for all 4 million people with the virus. Finally, there are some very hard decisions to be made, and not everyone will be comfortable with the proposed solutions.