The 2015 Treatment Landscape for Genotype 1 of Hepatitis C

Groundbreaking new hep C treatments have been approved for people with genotype 1 of the virus. Insurers are striking coverage deals with the major pharma players. What does this mean for people seeking treatment?

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The fast-changing field of hepatitis C virus (HCV) treatment has shifted into yet another exciting phase, with the recent arrival of two highly effective cures for the estimated 70 percent of Americans who have genotype 1 of the virus. (On the whole, genotypes 2 through 4 must still rely on the crop of drugs approved a year ago. But advances in research should change that soon.)

“For genotype 1, we’re pretty much ready for primetime,” says Daniel Fierer, MD, an associate professor of medicine and infectious disease specialist at Mount Sinai Hospital in New York City. “I’m in favor of treating people at all levels of fibrosis. Anybody who comes into my office and wants to be treated, I think that’s appropriate.”

But the question remains as to whether HCV-positive Americans, in particular those without major liver damage, can secure insurance coverage for these expensive new medications.

Gilead Sciences and AbbVie, the two major pharmaceutical players at this stage in the hep C treatment game, have each locked in exclusive deals with insurers in order to grab chunks of the lucrative market.

Pharmacy benefit manager Express Scripts announced in December that it will only reimburse for AbbVie’s combination therapy Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir), which was approved in December for people with genotype 1, including those with cirrhosis. As a part of the deal, AbbVie granted Express Scripts an undisclosed discount on Viekira Pak’s list price of $83,319 for 12 weeks of treatment.

Then, in early January, news came down that Gilead had struck deals with both the insurer Anthem and CVS Health, which has a pharmacy benefit management wing. Anthem will prioritize Gilead’s Harvoni (ledipasvir/sofosbuvir) for coverage of genotype 1 treatment, while CVS will exclusively cover Harvoni and Gilead’s Sovaldi (sofosbuvir) for all genotypes.

It is unclear whether Gilead offered a discount to CVS. According to Anthem's statement with regards to its own deal, "We were able to achieve a very competitive rate and a freeze on retail pricing for 2015."

Harvoni was approved in October 2014, just for genotype 1, and costs $63,000 for eight weeks or $94,500 for 12 weeks of treatment. Sovaldi, approved in December 2013, has an $84,000 price tag for the same duration.

The next to jump into the fray has been the pharmacy benefit manager Prime Therapeutics, which will cover both Harvoni and Viekira Pak, and has negotiated a "substantial reduction" in the price for both therapies.

Physicians and patient advocates have expressed concern that Express Scripts' deal with AbbVie reduces choice in ways that may pose a burden on people seeking a cure. In Phase III clinical trials including people with genotype 1, Harvoni demonstrated cure rates of 94 to 99 percent, while Viekira Pak's cure range was essentially the same, at 95 to 100 percent. (Still, the relative benefits of the two regimens have not been studied in a head-to-head clinical trial.) But while Harvoni is only one pill, once a day, Viekira Pak treatment involves taking two doses of one pill once a day and one dose of another pill twice a day. Also, people with genotype 1a, as well as those with cirrhosis or who have had a liver transplant, must take ribavirin with Viekira Pak. Ribavirin can cause troublesome side effects, such as anemia, and cannot be taken by pregnant women.

Another major benefit of Harvoni over Viekira Pak is that an estimated 45 percent of people with genotype 1 of hep C will only need to take Harvoni for eight weeks instead of 12. This includes people who fit three criteria: They do not have cirrhosis, are on their first cure attempt, and have a baseline viral load below 6 million. The standard treatment length for Viekira Pak is 12 weeks, although some of those who have genotype 1a and cirrhosis, as well as liver transplantees, must take the regimen for 24 weeks. That same extended treatment time is advised for people taking Harvoni who have been treated before and who have cirrhosis.

Barry Bernstein, MD, vice president of infectious disease development at AbbVie, is concerned that press reports about Viekira Pak's various downsides when compared with Harvoni are leaving the false impression that AbbVie's offering is clinically inferior. He underlines the fact that, even with the extra pill burden and perhaps the addition of ribavirin, Viekira Pak's actual cure rates were still near perfect in clinical trials, and comparable to Harvoni's.

"The proof is in the pudding for these regimens," Bernstein says. "It's how patients do."

A considerable upside of the AbbVie-Express Scripts deal is that the pharmacy benefit manager has pledged to cover all people with genotype 1, not just those with advanced liver disease. Many insurers, both public and private, have placed restrictions on coverage for those seeking hep C treatment who have minimal liver damage.

"Given the restrictions we've seen placed on Harvoni, the AbbVie-Express Scripts deal is mostly a

good thing, as it will result in more people getting access to treatment and cure," argues Michael Ninburg, executive director of the Hepatitis Education Project in Seattle. "My hope is that for someone for whom the AbbVie regimen is not ideal, for example someone who is coinfected with HIV and on an antiretroviral regimen that is contraindicated with AbbVie's, Express Scripts would provide Harvoni."

Indeed, another drawback of Viekira Pak is that a smaller selection of HIV antiretrovirals have been certified as safe to take with the hep C therapy, while a more robust number can be safely combined with Harvoni.

"I change my patients' ARVs if absolutely necessary, but it is much better to not have to make such a change in such important medication," says Mount Sinai's Daniel Fierer.

In order to gain access to Harvoni for his coinfected patients who have Express Scripts as a pharmacy benefit manager, Fierer is preparing for more of the same battles with insurance companies that have become such a headache for him since Sovaldi hit the scene.

"I'm distressed that treatment is being denied to many patients because they are not sick from their HCV, and that we can't treat patients before they get sick—prevention being worth a pound of cure, if you will," Fierer says. "The complex paperwork—different for every insurer—the hoops to jump through, the multiple denials and letters for each patient: These make for an almost impossible burden on my office."

Referring to the process of choosing which regimen to prescribe for hep C treatment, James Burton, MD, medical director of liver transplantation at the University of Colorado Hospital in Aurora, says, "Obviously, it's not going to be dictated by what's convenient, by what's preferred by the provider, but by what's covered by insurance."

Fierer recalls saying to multiple insurance agents, "I'm supposed to be in seeing patients right now. My job is to see patients, not to argue with you and say, 'Now I doubly can't treat patients. Now that you're denying care to patients and I was just unable to see two people because of your obstinacy on this.'"

In a hostile insurance climate, physicians who seek to prescribe the other major option for those who have genotype 1, Janssen's Olysio (simeprevir) and Sovaldi for 12 weeks, may run into a wall. When studied among people with genotype 1 in the Phase II COSMOS trial, 12 weeks of the regimen showed a 95 percent cure rate among those without cirrhosis. Twenty-four weeks of treatment for participants with cirrhosis—as the FDA now recommends for HCV-positive people with that level of liver disease—had a cure rate of 100 percent. However, the therapy costs just over $150,000 for 12 weeks and $300,000 for 24 weeks.

Not all clinicians are in quite the reimbursement doldrums that Fierer and Burton report, however. Andrew H. Talal, MD, MPH, a professor of medicine and hepatologist at State University of New York at Buffalo, says he for one is having a relatively breezy experience with insurance companies

when it comes to hep C treatment approvals, even for people with minimal liver damage.

“We haven’t had that much trouble,” Talal says. “We do have some denials, but we generally appeal them.”

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