FDA Approves Olysio-Sovaldi Hep C Combo

November 6, 2014

On November 5, the U.S. Food and Drug Administration granted approval of Olysio (simeprevir) and Sovaldi (sofosbuvir) to be used in combination for the treatment of genotype 1 of hepatitis C virus (HCV), Bloomberg News reports. Janssen's NS3/4A protease inhibitor Olysio and Gilead Sciences' nucleotide analog NS5B polymerase inhibitor Sovaldi were each approved at the end of 2013 and since then have often been prescribed together. (Although Sovaldi in combination with interferon and ribavirin has dominated the market.) But because Olysio and Sovaldi had not been approved as a combination therapy, clinicians have had to prescribe them off label. This approval removes that technicality and also allows Janssen to market the combination.

The FDA recommends 12 weeks of Olysio-Sovaldi for people without cirrhosis and 24 weeks of the combination therapy for those with cirrhosis.

About 70 percent of Americans with hep C have genotype 1.

"It's a very encouraging time for patients with chronic hepatitis as the advent of new direct-acting treatment combinations, like Olysio plus [Sovaldi], offer all-oral, interferon- and ribavirin-free treatment options," Eric Lawitz, MD, primary investigator for the COSMOS clinical study and a professor of medicine at the University of Texas Health Science Center, said in a release. "The availability of multiple treatment options is important to physicians and patients so optimal treatment decisions can be made, given the complexity of the disease and diversity of patient population."

Insurers are less inclined to be so enthusiastic about the Olysio-Sovaldi combination, thanks to its steep price. For a 12-week supply, Olysio costs $66,360 and Sovaldi has an $84,000 price tag, pushing the total cost to $150,360. A 24-week treatment would cost $300,720.

Janssen faces steep competition for the Olysio-Sovaldi regimen from Gilead's single-pill combination treatment, Harvoni (ledipasvir/sofosbuvir), which costs $94,500 for 12 weeks of therapy. Recommended treatment lengths for Harvoni are 8, 12 or 24 weeks, meaning that the price could run as low as $63,000. Physicians may consider eight weeks of Harvoni for those who do not have cirrhosis, who are treatment naive and who have a baseline viral load below 6 million. Twelve weeks of the combination tablet is recommended for those who do not have cirrhosis, regardless of previous treatment experience, and for treatment-naive people without cirrhosis.

Twenty-four weeks is recommended for treatment-experienced people with cirrhosis.

The Olysio-Sovaldi approval was based on data from the Phase II COSMOS trial, an open-label, randomized study that tested 12 or 24 weeks of the two drugs, with or without ribavirin, among people with genotype 1 of the virus, including treatment-experienced participants with compensated liver disease as well as treatment-naive participants. The FDA looked at two cohorts of the study: One included prior non-responders to therapy with no to moderate fibrosis; the other included treatment-naive participants and prior non-responders to interferon and ribavirin treatment who had advanced fibrosis or cirrhosis.

Ninety-five percent (20 out of 21 participants) of those with METAVIR fibrosis scores of F0 to F3 who took 12 weeks of Olysio-Sovaldi achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Eighty-six percent (6/7) of all participants who had cirrhosis and took the combination therapy for 12 weeks achieved an SVR12, and 100 percent (10/10) of those with cirrhosis who were treated for 24 weeks were cured.

Across the board, 93 percent (26/28) of participants cured after taking 12 weeks of treatment and 97 percent (30/21) achieved an SVR12 after 24 weeks of treatment.

To read the press release, click here.

To read the Bloomberg story, click here.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.poz.com/article/Olysio-Sovaldi-approval-26373-5345