Case 1: Costly drug for Hepatitis C

Y. W. is a 57-year-old patient with Hepatitis C, genotype 1, contracted 30 years ago before the blood supply was screened for the virus. She is otherwise healthy and takes no other medications. She was diagnosed several years ago, when she was screened due to symptoms including nausea, fatigue, and body aches. In 2010, she attempted treatment with Interferon and Ribavirin, for which she was a “non-responder,” meaning she did not clear the virus from her system. Given that she has chronic Hep C infection, she is at risk for long-term complications of cirrhosis (up to 20% of Hep C patients) and liver cancer. Since 2010, she has had routine monitoring coordinated by her PCP and hepatologist, and there has been no evidence that her liver disease has progressed.

She recently heard and read about a new, very effective, well-tolerated treatment for Hepatitis C. She scheduled an appointment with her doctor to request treatment with the new drug, Harvoni (sofosbuvir-ledipasvir). She was told that the drug has much improved response rates (about 90%) compared to the older interferon-based therapy that she has tried in the past, and its side effect profile is low. However, because it is so expensive, she was informed that many insurance companies (including hers) cover the drug only for patients with advanced liver disease, who are at risk for more immediate complications from their Hepatitis C. She underwent further evaluation including a liver biopsy to see if she qualifies. Her liver biopsy shows grade 1 inflammation, stage F1 fibrosis (range of fibrosis is F0 – F4). Her insurance mandates stage F3 fibrosis before approving the use of Harvoni.

She is very frustrated and desperately wants the drug to clear her HCV once and for all. There is no way she can afford the out-of-pocket cost for the drug, which would be more than $90,000 for the complete treatment, one pill daily for 12 weeks.

Questions:
1. Why is Harvoni so expensive?
2. What would the cost be to provide the drug to all patients with HCV who could benefit from it? Is this cost-effective given the alternative of no or less-effective treatment?
3. What alternatives does the pt have to get the drug?
4. What do you think of the insurance company’s approach to covering the drug?
5. Explore the perspective of the drug company producing the drug, the patient and the insurer.
6. How does access to the drug vary in different areas and internationally, and why does it vary?
7. Should clinicians take cost into account when discussing and determining treatment plans with their patients?
8. Should medical societies and disease associations take cost into consideration when making clinical practice guideline recommendations?
9. Compare this to other examples of allocating scarce resources in the United States.