Is Treating Hepatitis C Cost-Effective?

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The pace of progress in treating chronic Hepatitis C virus (HCV) infection in the last 3 years has been breathtaking. It now seems probable that the majority of those infected with HCV can be cured—even if they are co-infected with HIV. In fact, treatment no longer requires 12 months, or even 6 months of therapy, and soon-to-be gone are the days of weekly interferon injections as part of therapy.

In addition, an HCV cure looks very different than an HIV “cure.” Curing HIV requires a lifetime of combination antiretroviral therapy (cART) to restore and maintain immunologic health and suppression of the virus; at least currently, cART does not eradicate the virus. Stop the antiretrovirals, and HIV returns within weeks. HCV cure, on the other hand, truly seems to eradicate the virus, at least as far as we know at present.

However, the “cost” of a cure is expensive. Gilead Sciences, the manufacturer of sofosbuvir, has priced the cost of a 12-week course of treatment with that drug alone at around US$84,000. Add in the cost of ribavirin or other drugs used as part of a sofosbuvir-based combination regimen, and the cost per treatment course likely exceeds US$150,000. On the other hand, the cost of cART to treat HIV is in the range of US$30,000 – US$40,000 per year; after 40 years of treatment, antiretroviral costs will total around US$1.5 million (or 10 times that of a course of combination anti-HCV therapy). Nevertheless, many payors (eg, insurance companies) are balking at the high upfront cost of treating HCV infection, and some have implemented policies that require their insured to attempt less expensive interferon-based regimens first, or to contribute substantial sums out-of-pocket to cover much of the medication costs.

I have been critical in previous articles of “greedy” pharmaceutical companies, and, like most physicians, have spent many long hours on the phone with insurance companies advocating on behalf of patients. But the key issue now, moving forward, is whether these newer therapies for eradicating HCV are cost-effective. If they are, and if the data showing cost-effectiveness are substantial, then it should be easier to convince insurance companies that their policies should not be overly restrictive despite the high upfront costs of drugs like sofosbuvir. Fortunately, there have been quite a few articles written in the last 1 to 2 years that address the issue of cost-effectiveness of treating HCV infection. I’ll try to summarize the findings here.

Cost effectiveness? It's complicated

To start, the issue of cost-effectiveness is complicated. Too often, those who discuss this issue forget that there are substantial lifetime costs of not treating a particular condition. For instance, a recent study estimated that the lifetime costs of caring for an HCV-infected person, in the absence of attempting to eradicate the virus, was around US$24,000 per year.[1] This figure covered ambulatory visits, inpatient stays, etc. In addition, the more severe (advanced) the disease was, the greater were the annual costs, such that those with end-stage liver disease (ESLD) had costs of around US$60,000 per year. However, not everyone with chronic HCV infection will advance to ESLD; conversely, some will develop hepatocellular carcinoma, a condition associated with substantial costs of chemotherapy, liver transplantation, frequent hospitalizations, etc.

In other words, any cost-effectiveness estimate starts with a number of assumptions, such as the percentage of individuals in whom disease will advance, costs associated with treatment at different stages of disease severity, adherence rates, life expectancy, expected “cure” rates, medication costs, ambulatory and inpatient costs, and costs of laboratory and other diagnostic studies. In addition, cost effectiveness can be expressed in a number of different ways, including cost per cure, lifetime cost per infected person, and, most commonly, cost per quality-adjusted life year saved (QALY). In general, interventions that cost less than US$50,000 – US$100,000 per QALY are considered cost-effective. For instance, the cost of hemodialysis for those with end-stage kidney disease (ESKD) is around US$50,000 – US$60,000 per QALY, and the cost of cART is around

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US$30,000 per QALY. Coronary artery bypass grafting can cost over US$100,000 per QALY, and screening mammography, starting at a very early age (say, 35 – 40) can cost over US$350,000 per QALY. These examples are important to keep in mind, especially since insurance companies have been willing to pay for the treatments and associated costs for those diagnosed with these conditions, or for those following current screening/prevention guidelines.

**How much does cost-effective HCV treatment cost?**

So, what are the cost-effectiveness estimates for the various treatments for chronic HCV infection?

1. **First**, treatment with either the “gold-standard” 48-week regimen of pegylated-interferon plus ribavirin, or a strategy of starting with pegylated-interferon plus ribavirin and adding telaprevir if there is either no rapid virologic response or no sustained virologic response was cost-effective (US$27,700 and US$37,500 per QALY, respectively).²

2. On the other hand, the strategy of initiating triple therapy with telaprevir plus pegylated-interferon plus ribavirin came in at US$1,240,000 per QALY, decidedly not cost-effective.²

3. Using somewhat different assumptions, another group of investigators found that the incremental cost-effectiveness ratio (ICER) of adding boceprevir to a pegylated-interferon plus ribavirin-based regimen was between US$17,000 and US$55,000 per QALY, giving an overall cost-effectiveness figure of between US$21,000 and US$59,000 per QALY.³

4. Finally, a third set of investigators found that the incremental cost-effectiveness ratio (ICER) of adding boceprevir to a pegylated-interferon plus ribavirin-based regimen was between US$17,000 and US$55,000 per QALY, giving an overall cost-effectiveness figure of between US$21,000 and US$59,000 per QALY.³

Taken as a whole, these studies suggest that, under certain assumptions, treating chronic HCV infection with the newer, albeit more expensive, direct acting agent (DAA)-based regimens is a cost effective strategy. These results are likely due, in part, to the improved cure rates associated with the DAA-based regimens. Note, however, that cost-effectiveness studies typically do not address the question of “who should be treated” or “when should treatment be initiated.”

On the other hand, a very elegant recent study out of France did attempt to incorporate disease severity into their cost-effectiveness models.⁵ Specifically, the researchers found that for treatment-naïve HCV genotype 1-infected persons:

1. Treating those with fibrosis scores of F2 or greater with sofosbuvir plus pegylated interferon plus ribavirin came in at under US$60,000 per QALY.

2. Using the same regimen when the fibrosis score is F0 or F1 is not cost effective (cost > US$130,000 per QALY).

3. Waiting for newer, non-interferon-based therapies when the fibrosis score is F2 or greater, or treating now only when the fibrosis score is F4 and then immediately treating everyone else regardless of fibrosis score as soon as non-interferon-containing regimens are approved, is not cost effective (albeit highly dependent on the cost of newer therapies), with costs in the range of US$400,000 per QALY.

On the other hand, another study, using completely different assumptions and methods, found that treating all HCV genotype 1 chronic infections, without staging (fibrosis score), with a 12-week “all oral-based regimen,” came in at less than US$50,000 per QALY under a variety of assumptions.⁶

**Take Home Points**

For now, most guidelines suggest prioritizing therapy based on fibrosis score, treating the most advanced as soon as possible, and giving consideration to waiting for other therapies at very early stages of fibrosis. Regardless of the decision to treat now or defer treatment until later, it does seem that many of these regimens are cost effective and should not be withheld or made difficult to obtain by insurance companies and other payors.

**References:**


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