

## ACCESS TO HEPATITIS C CURES FOR MEDICAID PATIENTS

By Robert Gish, MD



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For most of history, hepatitis C has been incurable after the development of chronic infection. Doctors could offer symptomatic treatment or, for rare patients, curative therapy with a toxic combination of interferon and other medications, but their care options were limited.

In 2013, the first all-oral hepatitis C cure arrived on the market. This form of treatment, known as direct-acting antivirals, is more than 90 percent curative. Now, it's not only possible to cure those with hepatitis C; it may be possible to eliminate the disease altogether from our community. Researchers at Yale University estimate that boosting the number of hepatitis C patients treated by a multiple of four could almost eliminate hepatitis C from the population of non-drug injecting Americans in less than 10 years.<sup>1</sup>

But hepatitis C cures aren't as available as they could be. The initial cure was very expensive, and the population of infected patients who need treatment is estimated as high as 5 million.<sup>2</sup> Thus, many insurance plans, including Medicaid in some states, have implemented steps to limit coverage and to control immediate costs—without a consideration of the long-term costs of caring for the hepatitis C patients in our community. One way of limiting coverage is rationing treatment and covering the cost of a cure only for patients with advanced liver fibrosis.<sup>3</sup> Patients in earlier stages, including many who could be cured before suffering liver damage, may be denied treatment.

New direct-acting antiviral treatments for hepatitis C can cure patients and could nearly eradicate the disease

Due to the high cost of treatment, some state Medicaid systems limit access to only the sickest patients

Market competition has increased Medicaid rebates and brought down the price of hepatitis C cures significantly

The Centers for Medicare and Medicaid Services issued a November 2015 notice reminding state Medicaid systems of their legal obligation to patients and of the non-discrimination provisions of the Affordable Care Act

States such as Connecticut have demonstrated how to expand access even within budget constraints, while the Ryan White AIDS Program offers a precedent for federal policymakers on treating a large patient population suffering from a chronic and infectious condition

Aware that Medicaid care rationing could be construed as discrimination, the Centers for Medicare and Medicaid Services (CMS) took action. In November 2015, CMS issued a notice to state Medicaid systems advising them of their legal responsibility to patients with hepatitis C. The notice encourages states to improve access to treatment, and it highlights the market-driven pricing dip that allows for more patients in more states to receive the curative treatment they need.<sup>4</sup>

## CMS' DIRECTION FOR STATES

The Center for Medicare and Medicaid Services' notice – called “Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs” – reminds state Medicaid officials of several key points regarding coverage and patient access.<sup>7</sup>

### States Must Cover “Effective” and “Medically Necessary” Treatments

State Medicaid officials must work to ensure patients have access to the expanding number of “effective, clinically appropriate and medically necessary” hepatitis C treatments. In its notice, CMS points out that the drugs covered in an approved state plan must be available to individuals who are enrolled in Medicaid managed care programs.

States may, of course, impose reasonable restrictions. They aren't required to cover off-label uses of medication, for example, or drugs that haven't been proven to work.

### Price is a Challenge, but Not a Rationale to Discriminate

CMS encourages states to use all available tools to lower prices on hepatitis C cures. For example, CMS notes that “States have the option to include these drugs in the managed care contracts and capitation rates or to ‘carve out’ the drugs used in the treatment of chronic HCV infections from managed care contracts.” In that case, the states could provide access to these drugs through “fee-for-service” programs, or by making other arrangements.<sup>8</sup>

But, CMS warns, states may be breaking the law if they're unfairly restricting access to hepatitis C

## THE RYAN WHITE HIV/AIDS PROGRAM: A PRECEDENT FOR LARGE-SCALE TREATMENT CHALLENGES

In many ways, the challenges posed by treating hepatitis C mirror a national health care challenge of past decades: HIV/AIDS.

In the early days of dealing with AIDS, the federal government faced a growing and desperate patient population. In 1990, Congress passed the Ryan White CARE Act.<sup>5</sup> Today, the federal government teams with states, cities and private organizations to deliver care to more than half a million people who otherwise might not be able to afford AIDS treatment. In Fiscal Year 2014, the Ryan White HIV/AIDS Program received more than \$2.3 billion in federal funding.<sup>6</sup>

The parallels between AIDS in the late 1980s and hepatitis C today are striking:

- There are millions of patients suffering from hepatitis C, and many are too poor to afford expert medical care.
- AIDS was difficult or impossible to cure. Patients could aim only to slow the progression of the disease.
- The earliest AIDS treatments were expensive, making them difficult for most to afford.
- AIDS patients were often discriminated against, with their lifestyle blamed for their condition.

The Ryan White program helps reach the neediest sufferers with quality care. A similar approach would benefit hepatitis C sufferers without bankrupting Medicaid.

## CONNECTICUT: HOW ONE STATE EXPANDED COVERAGE

In Connecticut, the state will cover treatment for any Medicaid patient with hepatitis C, regardless of liver function. That means doctors can help people in the earliest stages of the disease.

To make this approach possible, medical professionals worked closely with state officials to:

1. **Delay potential lawsuits.** Healthcare providers believed they had the law on their side. But rather than pursuing immediate legal action, they first asked for a meeting with the state's top health care officials.
2. **Incorporate clinician expertise.** The professionals writing the state regulations didn't have the expertise to solve this problem. For example, the top state official was a pediatrician who admittedly wasn't an expert on hepatitis C treatment. Knowledgeable providers stepped up to share their guidance.
3. **Expand the pool of treaters.** Under Connecticut's new guidelines, any prescribing caregiver can now treat hepatitis C patients. The pool is no longer limited to liver experts, making it easier for patients to get care.
4. **Take incremental steps.** The advocates recognized Medicaid would be unlikely to pay for all hepatitis C treatment. So they asked for an interim measure, treatment of Stage 3 and 4 patients, as well as patients with HIV or other co-morbid conditions such as diabetes and cryoglobulinemia (found in over 70% of all patients with HCV). Coverage started there, then expanded.<sup>12</sup>

treatments “by imposing conditions for coverage that may unreasonably restrict access to these drugs.”<sup>9</sup>

### Competition Among Treatments is Driving Down Prices

CMS also notes that, because of rising rebates and competition among new drugs entering the market, the cost of curing hepatitis C is already plunging. “This competition may enhance the ability of states to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices...thereby reducing costs. CMS encourages states to take advantage of such opportunities,” the notice explains.<sup>10</sup>

## IMPROVING ACCESS TO CURES

As states consider how to implement CMS' notice, they must keep in mind the long-term benefits and cost savings associated with curing hepatitis C. While upfront costs are high, curing rather than simply mitigating hepatitis C has the effect of saving money in the long run. Treating patients before they suffer complete liver breakdown could reduce incidents of cirrhosis, death, liver transplant and liver cancer.<sup>11</sup>

Furthermore, market forces are already bringing down costs. Several new drugs are on the market or coming to the market, and competition among pharmaceutical companies should allow prices to tumble still further. And as more insurance plans, including Medicaid, cover treatment, they're putting pressure on drug makers to offer larger rebates and lower prices. These factors help make the existing courses of treatment less expensive, opening the door for Medicaid systems to expand access to a broader group of hepatitis C patients.

## CONCLUSIONS

State Medicaid programs exist to ensure that needy patients can access medical care. As CMS' November 2015 notice makes clear, that legal responsibility extends to hepatitis C patients who would benefit from curative treatments.

As states consider how to make good on their obligations to hepatitis C patients, they might look to Connecticut, where health care providers have worked with state officials to design programs that expand access to hepatitis C cures. They might also find reassurance in market forces that have and continue to drive down prices for curative treatments.

At the federal level, lawmakers should encourage sharing best practices among states. Policymakers can also look to past successes, including AIDS treatment, in considering how to address the challenges associated with hepatitis C treatment.

Improved access for Medicaid patients will help keep treatment decisions within the context of the physician-patient relationship, where they belong. The availability of curative treatment will also allow physicians to comply with their professional ethics requirements and fulfill their medical oath to help patients.

Moreover, the combined power of administrators and medical providers can expand access to hepatitis C treatment without breaking the bank. Greater access to treatment is the wiser, cost-efficient alternative to the legal entanglements that could result from discriminatory policies. It's also the ethical option for Medicaid systems, which represent the only health care coverage option for many hepatitis C patients.

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