Avoiding the Tragedy of the Commons in Health Care

Policy Options for Covering High-Cost Cures

Soeren Mattke, Hangsheng Liu, Emily Hoch, and Andrew W. Mulcahy

Recent advances in drug development make curing chronic and deadly conditions a distinct possibility. A headline-grabbing example is Gilead Sciences Inc.'s 2013 introduction of Sovaldi,¹ a new treatment that can cure 90 percent of patients with chronic hepatitis C virus infection.² Less visible but equally remarkable are gene therapy treatments in development for selected hereditary disorders and cancers; such developments include treatments for lung cancer³ and the correction of the p53 tumor suppressor gene, among others.⁴

These and other new curative drugs shatter the usual pricing paradigm. Treating a chronic disease used to mean lifelong treatment and, thus, a large number of pills per patient. Manufacturers had the opportunity to generate substantial revenue, even if the price per pill was low. Curative treatments, however, imply a finite number of units per patient and a shorter treatment course. To get to comparable revenue streams, manufacturers set unit prices for these treatments at very high levels—if the value generated by the

drug permits. For example, Sovaldi's list price is \$1,000 per pill. Yet even at this eye-popping price, many payers do not consider the drug poor value for money, as the required 12-week, \$84,000 treatment course can rid many patients of a costly and often deadly disease.⁵ Even the United Kingdom's National Health Service, which relies on cost-effectiveness studies as one input into decisions on using new drugs, decided to cover the drug, albeit after negotiating a discounted price from the manufacturer.^{6,7}

The high up-front cost of those cures creates a challenge for health systems with multiple and competing payers (such as in Germany and the United States) and systems in which coverage decisions are made by subnational jurisdictions (such as in Sweden and Canada), because patients may switch insurers or jurisdictions. Previously, lifelong treatment to stabilize patients with chronic disease meant continuous payments for their care. But now consider a health plan member that has undergone a successful treatment course with Sovaldi. From the day the member is cured,

her expected medical cost reverts to the population average, and she turns from a “bad risk” into a desirable customer for a health plan. If a patient can switch to a competitor immediately after receiving the treatment, a health plan may hesitate to pay for the treatment in the first place. In this hypothetical, an insurance company might be tempted to cover high-cost cures very restrictively both to scare away patients with those diseases and to woo patients whose cure has already been paid for by a competitor. Or, as another example, private insurers might hesitate to generously cover high-cost cures typically used by older adults in the hope that those members will age into Medicare coverage before undergoing treatment.

This phenomenon is a *free-rider problem*, in which one party benefits from an activity paid by others. Of course, a health plan could not legally deny coverage of high-cost cures outright, but an insurer could employ marketing strategies and administrative hurdles to discourage eligible patients from enrolling. Delaying access is a viable strategy for insurers to steer expensive patients to competitors. Indeed, there is empirical evidence for such behavior

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in insuring people with the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS).⁸

Besides the obvious problem of depriving patients of access to clinically appropriate and life-saving drugs, use of such obstacles to deter enrollment by those in need of high-cost cures could unravel the market for those cures. Insurers that maintained coverage could become subject to adverse selection by patients in need of high-cost cures. This selection would drive up their premiums and could ultimately price them out of the market. Pharmaceutical companies might then stop investing in the development of curative drugs, because limited coverage decreases expected returns on investment.

In this Perspective, we discuss the free-rider problem that may result from the availability of high-cost cures and present a framework to analyze policy options as a remedy. Solving this policy problem is of some urgency as more and more curative treatments reach the market. Advances in new, likely expensive, treatments will be fueled by such initiatives as the 21st Century Cures Act, which intends to remove various barriers to the discovery, development, and delivery of new life-saving cures.⁹

The Tragedy of the Commons

A multipayer health system risks experiencing what Garrett Hardin termed “the tragedy of the commons.”¹⁰ Acting in its own commercial interest, each health plan could restrict access to pricey cures and collectively deprive patients of their benefit. But if insurers act in a coordinated fashion, the free-rider problem could be addressed and an overall better outcome achieved.

Two factors determine whether a free-rider problem might emerge. First, the up-front investment must be high enough to have a meaningful financial impact on a payer. To illustrate,

antibiotics cure infections with a limited number of doses, but we do not expect health plans to selectively seek patients who have recently overcome a bout of sinusitis. Second, the condition in question must be common enough to warrant attention. Cures for extremely rare disorders might be very expensive, but their small number of eligible patients makes them a rounding error in the overall budgets.

Second, the longer it takes for the benefit to materialize, the more incentives insurers have to avoid patients that need the cure. If a therapy requires a large up-front investment but the savings materialize within a typical insurance contract period (i.e., one year), a health plan incurs no adverse financial consequences from covering it. But the longer it takes for the cure to translate into lower health care costs—for example, the projected ten years for hepatitis C treatments¹¹—the stronger the incentive for insurers to avoid patients in need of it or to seek patients who have been successfully treated.

Managing the Commons

Researchers and advocates for access to care have discussed several options to address the possible free-rider problem, including alignment of incentives at the patient level, coordination among payers, and government intervention.

Patient-Level Options

Multiyear insurance. As described earlier, the free-rider problem will emerge only if the benefits of a cure take longer to materialize than the typical one-year insurance contract period. At the moment, average tenure in commercial health plans is about three years, leaving little time for the benefits from treatment to accrue.^{12,13}

The Affordable Care Act's changes to health insurance—including guaranteed issue, community rating, and exclusion of preexisting conditions from coverage decisions—may have the unintended consequence of shortening the average tenure, allowing members to switch plans more freely. Insurers might be particularly tempted to deter individuals close to age 65 from enrolling, because they will migrate into Medicare, which would then reap the benefits of any expensive therapies paid by the commercial insurer.¹⁴ As we have argued in an earlier blog post, multiyear insurance policies can realign the distorted incentives.¹⁵

Credit markets. Others have proposed to shift the responsibility to patients who could either pay directly with cash or, if they could not afford the cost, borrow funds through credit markets to fund the treatment.¹⁶ The cost of the treatment would be amortized over a long period and patients could pay back the loan just like paying back a mortgage. Some patients already bear a significant share of the cost for specialty drugs through cost-sharing. The credit market approach exposes patients to even more financial risk.

Payer Coordination

Health currency. In another option to address the free-rider problem, the residual value of a cure could be transferred between insurers through a *health currency*, which represents the residual value of the treatment benefit.¹⁷ When a patient switches to a new insurer, the new insurer would, in essence, purchase the benefit and reimburse the remaining dollar value to the previous insurer.

Cure fund. Under this proposed idea, payers would prospectively contribute funds to a pool, from which treatments on a preapproved list of cures would be paid. Each member of the pool would contribute in proportion to the number of plan members.

Ideally, all public and private payers would participate in this pool, but the model would be viable if a large enough number of payers joined.

Reinsurance. Scott Gottlieb and Tanisha Carino have proposed using reinsurance models to cover selected high-cost cures.¹⁸ Payers would contribute to this reinsurance pool based on their expected exposure and be reimbursed for the cost of actual cases. Reinsurance combines properties of multiyear policies (because the risk pool can be maintained over multiple years) and the cure fund (which is, in essence, a reinsurance model).

Government Interventions

Patent buyout. Among government intervention options, the government could purchase the patent covering a high-cost cure to compensate the manufacturer for its research and development investment, plus a markup.¹⁹ Payment for each patient would then be based on the marginal production cost.

We argue that two properties affect which policy options are suitable for a given cure. The first property is time to break even: How long does it take until enough value is accumulated to recoup the initial investment in the cure? The second is severability: To what extent is the cost of a cure separable from the cost of overall treatment and management of a disease?

Tax coverage. Treatment cost could be removed from regular coverage, and the government could pay for selected high-cost cures directly using tax revenue. This approach has been used in the past to overcome obstacles to accessing new and expensive treatment options, such as Medicare coverage of end-stage renal disease or the Ryan White Act for the coverage of HIV/AIDS drugs (although these treatments are not curative).²⁰

Benefit mandates. Insurance regulators could step in and mandate coverage of high-cost cures, thereby avoiding a free-rider problem; however, this approach is of limited utility in practice. First, it would require microregulation of which drugs to cover, which coverage restrictions to permit, and what patient cost-sharing to accept. This process would almost certainly become politicized and be used as a tool to protect market share by entrenched companies. Second, in the United States, it would result in a patchwork of coverage, because different types of health plans are subject to different federal and state regulation.^{21,22}

A Framework to Inform Choices

In theory, all of these options are viable, but which can effectively solve the free-rider problem? Which works best in a given situation? At the outset, we reject any approach that pushes the financial burden onto patients through the credit market, because the very purpose of insurance is to protect against large but rare losses. We also reject benefit mandates because of their complexity, as described.

We argue that two properties affect which policy options are suitable for a given cure. The first property is time to break even: How long does it take until enough value (i.e., clinical benefit

and/or reduced cost) is accumulated to recoup the initial investment in the cure? The second is severability: To what extent is the cost of a cure separable from the cost of overall treatment and management of a disease? Severability is high for a drug that can cure a condition without any other treatment and low for a drug that is part of a complex treatment regimen.

Based on those two dimensions, Figure 1 displays a simple framework that can inform the choice of a policy solution (eliminating credit markets and benefit mandates). Irrespective of the time to realize value, reinsurance policies require a high degree of severability because such policies must be written to precisely define what they cover (i.e., one curative treatment, not including additional treatments). Multiyear policies can be used for all treatments for which value generation takes slightly longer than the usual one-year period of an insurance policy.

Because they cover a specific treatment, both a cure fund and a patent buyout require a higher degree of severability. In contrast, the health currency and tax coverage options can also be applied in situations where a high-cost cure needs to be delivered as part of a complex treatment regimen. Policy solutions that require government involvement (i.e., patent buyout and tax coverage) are better suited for cures that take decades rather than years for full value generation, because coordination between private-sector actors tends to be more difficult over very long time frames.

Case Studies

Direct-Acting Antiviral Drugs for Hepatitis C

A new generation of highly effective and well-tolerated drugs now allows for a cure of hepatitis C, a previously chronic infection with

Figure 1. A Framework for Selecting a Policy Solution

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high morbidity and mortality, in almost all patients. These drugs are referred to as *direct-acting antivirals* because they target the replication of the virus directly, as opposed to earlier treatments that stimulate the body’s immune system to attack the virus. As mentioned earlier, per-patient costs for these drugs are high, and time to break even is too long to make multiyear policies practical. To illustrate, based on overall medical cost, it takes about 5.4 years for a payer to recoup the investment in treatment with Sovaldi for a patient with compensated liver cirrhosis.²³ At the same time, eradicating the hepatitis C virus does not require treatment other than the antiviral drugs, meaning that severability is high and both a cure fund and reinsurance models would be viable.

Gene Therapy for Hemophilia

Hemophilia is a group of genetic disorders in which the body cannot synthesize blood-clotting factors. Patients must receive regular intravenous infusions of those factors to avoid severe bleeding complications. Because the disorder is caused by an isolated genetic defect, it is a logical target for gene therapy approaches to correct it.²⁴ Data from early-stage trials suggest that those treatments can partially restore the production of clotting factors, which would allow reducing or even avoiding infusions for a few years. This means that the period over which the value of treatment materializes is reasonably short, albeit longer than a year, so multiyear insurance policies could allow payers to realize the full benefit of the up-front investment.

RT100 for Congestive Heart Failure

Despite recent treatment advances, congestive heart failure remains a chronic condition with high treatment cost, particularly for hospital care. Average treatment costs in the United States have been estimated at \$32.4 billion per year as of 2015 and are projected to be \$77.7 billion by 2030.²⁵ Furthermore, costs increase as the disease progresses; more than 50 percent of the annual cost of heart failure care are related to hospitalization,²⁶ and 70 percent of all heart failure hospital admissions are associated with worsening chronic heart failure.²⁷ Recently announced data from a phase 2 trial of RT100, a gene therapy for heart failure, suggest that a single

dose of this drug can reverse the changes in cardiac structure and function that underlie heart failure.²⁸ If these findings are confirmed in larger trials, it would imply that the clinical and cost trajectories of patients with heart failure could be altered fundamentally with only one dose of the drug.

With potentially only one dose per patient required, the unit cost of RT100, and thus the up-front investment for a payer, is expected to be quite high, and it would take several years for the value of the treatment to amortize through a reduction in hospital admissions. At the same time, treatment of advanced heart failure requires a combination of drugs, implantable devices, and procedures. This combination of longer time to break even and limited severability suggests that a health currency might be a solution to transfer the residual value embedded in an RT100-treated patient from one insurer to the next.

HIV Eradication

Highly active antiretroviral treatment (HAART) has turned HIV infection from a deadly disease into a chronic condition, as the treatment can suppress proliferation of the virus. However, HAART cannot cure HIV because latent reservoirs in the body allow the virus to persist and proliferate again once HAART is stopped. A novel concept to eradicate HIV is to pharmacologically activate those latent reservoirs under the protection of HAART.²⁹ This treatment approach aims at stimulating latently infected cells

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to express the virus. Once the cells start producing the virus, the body’s immune system will recognize, attack, and kill those cells. In other words, the treatment triggers a fulminant proliferation of the virus in infected cells, while HAART protects new cells from infection. Several agents to activate dormant HIV are now in early-stage trials.

The short-term cost of this treatment strategy would be high because the activating drugs would have to be combined with broad HAART regimens tailored to the patient’s variant of the virus and, most likely, with supportive measures. The long-term benefit would be the avoidance of decades of HAART and other treatment for individual patients and of new infections for the population. This combination of limited severability and long time to break even suggests that tax coverage would be a suitable approach, especially in light of the public-health benefits of eradicating HIV.

Figure 2 summarizes where each case study falls in our framework for selection a policy solution.

Summary

Unprecedented breakthroughs in drug treatment over the past few years are offering new hopes for many patients. Particularly remarkable is that many of those drugs can cure conditions that used to require lifelong treatment—or can at least fundamentally change disease trajectories rather than merely control the progression of the disease. But this paradigm shift creates a challenge for payers’ budgets because spending on curative drugs is heavily front-loaded.

In an earlier work, we outlined how payers could use debt-financing approaches to spread the cost of such drugs over a longer

Figure 2. Case Studies for Considering Policy Solutions

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period and make spending more manageable.³⁰ Here, we addressed another problem with drugs that imply front-loaded payments: In health systems with multiple payers, patients might not remain with any one payer long enough for the payer to amortize the cost of investing in expensive cures, and this may lead to barriers to access. We discussed different policy options that permit alignment of incentives and prevent adverse selection for payers who make such advances easily accessible. These options can be combined with the debt finance model described earlier.

Implementing such financing models is far from easy. It requires the political will of public and private payers to collaborate in order to establish equitable mechanisms that distribute the cost and benefits fairly, as well as the foresight of working out the

technical details before free-rider concerns begin to interfere with patient access. Implementation requires sophisticated economic analyses of how breakthrough cures will affect medical spending over time and how those spending trajectories can be aligned with patient movement between payers. Health insurers have much to learn from the financial industry, where such complex products to distribute risk are well established, but the insurers should also take into account the risks of such products.³¹

As we have mentioned, drug manufacturers have an important role to play in keeping their products affordable and priced in pro-

portion to the health benefits that they deliver. With the proposed framework as a guide, manufacturers can integrate the expected financing model in their strategies for research and development investment and for commercialization. They could contribute to up-front financing of a transfer mechanism—for example, by capitalizing a cure fund—and support the economic analyses that are required to set it up. In the end, the success of such complex and innovative schemes is dependent on the collaboration and contribution of all stakeholders.

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About This Perspective

In this Perspective, Mattke and his colleagues discuss the risk that strategic behavior by health insurers could unravel the market for curative therapies for chronic diseases. Because the cost of these cures is front-loaded but the benefits accrue over time, insurers might attempt to delay treatment or avoid patients who require it, in the hope that they might change insurers. The authors discuss policy options to remedy this potential free-rider problem through alignment of incentives at the patient level, coordination among payers, and government intervention, and then present a framework to analyze these options.

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