COMMENTARY

The Challenge of Paying for Cost-Effective Cures

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ABSTRACT

In this article, we consider the problem of financing highly effective and cost-effective prescription drugs within a value-based pricing system. Precisely because these drugs are highly effective, their value-based prices may be quite expensive; and moreover, the value-based price of a cure ought to be set high enough to create incentives for innovation, otherwise these beneficial therapies may be underdeveloped. However, in our fragmented health insurance system, where patients move frequently between payers, these payers generally lack the incentives to pay value-based prices for cures because they cannot ensure that they will reap the long-term economic benefits. Therefore, we argue that there is a need for mechanisms to spread the burden of financing of cures across payers to maximize patient access and the public good. We suggest that risk adjustment, reinsurance, and risk corridors are familiar policy options that merit consideration to address the problem and create incentives for value-based pricing.

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The pricing of prescription drugs has recently received considerable attention—and rightly so. This scrutiny follows widely publicized decisions by drug manufacturers to charge exorbitant amounts for their products; seemingly excessive drug prices, however, are not all created equal. Rather, the legal, regulatory, and market structures enabling high prices may differ from product to product—and likewise, the policy challenges posed by high drug prices may differ. Paying for the subset of expensive but highly effective cures poses particularly difficult challenges, including the lack of incentives for health plans to cover these expensive treatments.

Not All High Drug Prices Are Equal

Many high prices are a result of market power from patent protection, regulatory exclusivity, the usual healthcare market forces in the United States, or some combination thereof. These high prices may come about through steep mark-ups. For example, Turing Pharmaceuticals abruptly raised the price of pyrimethamine—a decades-old drug lacking competing products—from $13.50 to $750 per pill, shortly after acquiring the product. And Mylan has been scrutinized for increasing the price of a 2-pack of EpiPens from $100 in 2007 to over $600 in 2016 before the expected arrival of a generic. In other instances, manufacturers have steadily—and more gradually—raised prices for newer brand name drugs that they developed. As one example, Novartis increased the price of its cancer treatment, imatinib, from approximately $30,000 per year in 2001 to $92,000 per year in 2012. For all of these therapies, policies primarily aim to reduce prices through introducing competition or price controls.[1]

In a small subset of cases, however, highly effective and novel therapeutics are introduced on the market with seemingly astronomical, but also arguably cost-effective, initial prices. The clearest example may be sofosbuvir-based drugs, hailed as cures for hepatitis C virus (HCV) infection and priced by Gilead Sciences, Inc, at roughly $1000 per pill, or $84,000 for a 12-week course of therapy.[2] However, sofosbuvir-based drugs are not the only prod-

ucts that may pose this problem; for instance, novel biologic therapeutics, such as gene and stem cell therapies, may one day offer cures for previously untreatable conditions, and similarly, may come with exorbitant—yet possibly cost-effective—price tags.[3]

TAKEAWAY POINTS

Exorbitant prescription drug prices are rightly being scrutinized, and several promising proposals to lower prices have been advanced. For the small subset of prescription drugs that are cost-effective cures, however, the policy challenge is not simply to lower prices.

- Prices of these extremely effective therapies ought to be value based and high enough to incentivize development.
- Even value-based prices may be too expensive for private payers that cannot realize long-term economic benefits of cost-effective cures because of patient churn.
- Despite their flaws, the "3Rs"— risk adjustment, reinsurance, and risk corridors—are familiar policy options that merit consideration to address this problem.

Policy Challenges for Expensive, Cost-Effective Cures

For this subset of novel therapeutics that are cost-effective cures, the policy challenge is not simply to lower the drugs' prices. Prices of such therapies ought to be high enough to create incentives for innovation, and if set too low, beneficial therapies may be underdeveloped or undersupplied. Instead, the policy challenge is to ensure that payers have the incentives and resources to finance the therapies. In the United States, achieving this goal is particularly challenging because patients rarely stay with the same payer for more than a few months or years. Because of this churn within the fragmented health insurance system, payers are not likely to realize the long-term economic benefits of cost-effective cures.[4]

To be clear, regardless of the reasons for high drug prices, the growth of overall spending on therapeutic products in the last decade—and the resulting strain on governmental, private payers', and patients' budgets—is deeply troubling.[5] As a result, numerous reforms to address drug affordability have been advanced. At the state level, legislation has been proposed that would require drug manufacturers to make transparent the costs of drug development, cap prices for public payers in a state, or permit the importation of cheaper foreign drugs.[6] Other proposals advocate for change at the federal level, such as the federal government using its "march-in" rights under the Bayh-Dole Act or negotiating for better drug prices for Medicare.[1]

Among the numerous reforms to address drug affordability in the United States that have been proposed, a particularly promising one is to move to a value-based pricing system. In such a system, a drug's price is based on its cost-effectiveness, calculated by the relative cost per unit of benefit—whether measured in quality-adjusted life-years (QALYs), future healthcare costs avoided, budgetary impact, or other metrics.[7] The underlying goal is to ensure that the drug's price is commensurate with its health benefits. Value-based pricing would help reduce drug prices where costs appear unwarranted by their relative benefits.

Nevertheless, even if value-based pricing and the other reforms are adopted, cures and highly effective therapies may continue to pose significant financing challenges. Their value-based prices may continue to be very expensive precisely because they are so beneficial.[8] Again, sofosbuvir-based therapies for HCV infection provide an instructive example. These drugs offer sustained virologic response rates greater than 95% in most patients—meaning they are highly effective—and are associated with a shorter duration of treatment and fewer adverse effects than previous HCV treatments.[2] Because of the clear benefits of sofosbuvir-based treatments, they have been found to be cost-effective for a majority of patients even at their current prices.[2] Furthermore, therapies that treat serious conditions and are more effective and safer than existing treatments—similar to sofosbuvir-based products—are precisely the kind of novel therapies that we want to encourage, and prices should reflect that.

The value-based prices of highly effective therapies may thus be unaffordable for many individuals without financing mechanisms that spread the cost across large populations. In this way, financing cures is no different than financing other types of important, but expensive, types of healthcare, such as open-heart surgery. In the United States, the basic mechanism to spread the financial cost of expensive healthcare services and therapies is insurance. However, private health insurers are not built to account for the long-term cost-effectiveness of a given therapy because patients frequently move between payers. Payers that bear the high short-term costs of a cost-effective cure, therefore, will rarely realize the long-term economic benefits. This inability to capture the financial benefits dampens payers' incentives to pay even the value-based price of cures.[9] To the contrary, health insurers may try to avoid costly patients by structuring drug formularies to dissuade such patients from choosing the plan, thereby engaging in the type of health-based discrimination the Affordable Care Act (ACA) was designed to prevent.[10]

The benefits of cost-effective cures are "public goods"—in other words, the payer that bears the cost cannot exclude others from realizing the economic benefits of the cure because of churn in the US insurance market.[4] The challenge is how to privately finance the public good of high-priced cures. In the absence of a considered solution, the de facto response is for governmental and private payers to limit access to the therapy in a type of rationing based on severity of illness and ability to pay. Perversely, rationing such therapies may result in avoidable excess morbidity, mortality, and healthcare spending that is distributed unevenly, and perhaps unjustly. To realize the hopes for highly effective, novel therapies in the United States, it is therefore critical to explore policy options for spreading the cost of cures.

This policy challenge also arises in other contexts in which the risks of high-cost patients must be spread across disparate payers—and risk adjustment, reinsurance, and risk corridors (the "3Rs") are actuarial solutions to this problem. Under a risk adjustment program, all payers pay into a fund that will compensate those payers that incur unusually high costs. Reinsurance is an insurance policy that insurers buy to protect against excess financial risk. Risk corridors limit both downside risk of losses and excess profits for health plans. The 3Rs have been used in the ACA and Medicare Part D, to protect insurers against adverse selection and consumers against destabilization of the insurance market and discriminatory health insurance practices.[11]

A similar program could be implemented for the high costs associated with paying for cost-effective cures in private health plans. Incentives for value-based pricing could be incorporated into the program by limiting program coverage to those therapies that are both highly cost-effective and priced using value-based methodologies. Although the ACA's 3Rs have faced significant political and legal challenges, and the fate of the ACA is uncertain, these programs have had some success in Medicare Part D to stabilize drug plan premiums and insurer participation, and should be considered.[12] Despite their limits, they are familiar models that can help address the challenges for financing cost-effective cures. Other policies to address the disjunction between the immediate expenses and delayed benefits of high-cost cures, such as credits or financial transfers from future payers, remain theoretical but also should be explored further.[4]

Conclusions

Because the value-based price for cost-effective cures may be high, new drugs and biologics that hold the promise of cures may pose challenges for a value-based pricing system—even if currently proposed reforms are enacted. In the fragmented health insurance system, where patients move frequently between plans, payers lack incentives to pay even value-based prices for cures because they will not reap the long-term benefits. However, if prices drop below value-based thresholds, incentives for innovation will diminish. We, therefore, need to explore mechanisms to spread the burden of financing of cures to maximize patient access and the public good. Value-based pricing is essential, but without interventions to spread the cost of cures, beneficial and cost-effective therapies may still be undersupplied and out of reach for many patients. ■

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