

Issue Brief

Cost-Based and Value-Based Principles for COVID-19 Drug Pricing

by Emily Gu and Justin Oh



Gilead Sciences, Inc., а Foster City, California based biopharmaceutical company, developed remdesivir, or Veklury®, as a treatment for Hepatitis C in 2009.1 The drug failed to demonstrate efficacy against Hepatitis C and was later repurposed as a treatment for the Ebola epidemic in West Africa. Now, remdesivir has been repurposed once again, and was authorized for use under an Emergency Use Authorization (EUA) by the FDA as an antiviral treatment for COVID-19.² Candidates for remdesivir treatment are patients hospitalized for moderate-to-severe COVID-19, and previous evidence indicates that treatment has led to clinical benefits such as shortened time to recovery in adults.³ As the pandemic continues, the potential advantages and limitations of remdesivir have stimulated discussion over appropriate pricing.

Policy Debate

There is a policy debate over two major principles that guide drug pricing. The dominant framework is value-based pricing, where the drug is priced based on existing alternatives and adjusted to consider incremental clinical benefits. However, the Institute for Clinical and Economic Review (ICER), a leader in developing price benchmarks for novel pharmaceuticals, proposed a new version of cost-based pricing (also known as costrecovery) as an alternative framework last year. These cost-based principles link the appropriate price of a new drug to the investments by firms in research and development (R&D) and manufacturing. In its model, ICER distinguishes R&D investments financed by the government from those financed by the pharmaceutical firms themselves; the role of these publicly financed investments in subsequent drug pricing is still a matter of debate.

This issue brief will compare cost-based pricing (CBP) and value-based pricing (VBP), and illustrate them using remdesivir as a guide. We will assess the actual price for remdesivir, announced by its manufacturer, in light of these two benchmarks

Principles of CBP and VBP

The prices charged by the pharmaceutical industry must balance the social needs for both affordability and R&D investment. Much of the R&D expense is borne by taxpayers through NIH grants, rather than the manufacturer and its investors.⁴ Due to the huge social and economic costs of the COVID-19 pandemic, any effective treatment or vaccine would have a large social value and hence a potentially high VBP, yet much of the R&D is financed by the taxpayer, leading to a potentially low CBP.



Cost-Based Pricing	
Estimate 1: Minimal marginal cost only	\$5 - \$600
Estimate 2: Minimal marginal cost and 2020 projected manufacturer R&D costs	\$1,005 - \$1,600
Revised Estimate 2 ⁺	\$1,255 - \$1,850
Value-Based Pricing	
Assume No Mortality Benefit (Base case)*	\$2,470
Assume Mortality Benefit	\$3,980 - \$4,140

Figure 1. ICER Remdesivir Pricing (Per Course of Treatment).⁵

† Revised per Refinitiv remdesivir sales forecast.

* Dexamethasone was included in the standard of care for hospitalized patients

requiring supplemental oxygen via noninvasive or invasive mechanisms.

Cost-based pricing sets prices at a level that ensures innovators are returned an amount that covers for the costs of drug development and production. This methodology considers three major components: marginal costs of production for each subsequent treatment course, R&D costs paid via the manufacturer, and R&D costs paid by the government. Under a CBP model, private companies developing vaccines and treatments are rewarded with patent rights, and the government and/or private insurers set a price ceiling after examining the cost of development and production.⁵

Value-based pricing establishes a recommended price ceiling for drug treatments using costeffectiveness analysis. This analysis is based on the added clinical benefit to patients and society, comparing them to the added price charged. Value-based prices do not reflect the costs necessary to bring the new product to market, either in terms of R&D or of production (manufacturing and distribution).⁵

CBP and VBP Applied to Remdesivir

ICER has played a significant role in assessing remdesivir pricing. In November 2020, ICER proposed an analysis outlining two cost-based estimates: 1) price per treatment course that covers the minimal costs of production of the treatment; and 2) price per treatment course that covers the minimal costs of production plus the projected short-term spending by the manufacturer for clinical research.⁵ The first cost-based price is the simplest, and results in an acceptable price range of \$5-\$600.



To determine the projected short-term spending outlined in estimate 2, we referred to public statements by Gilead Sciences outlining forecasted R&D costs of \$1 billion, including all clinical research related to remdesivir in 2020.⁶ Based on other statements from Gilead, ICER assumed that approximately 1 million treatment courses of remdesivir would be sold in 2020.⁷ This results in projected short-term spending of \$1,000, which must be included in the costbased price. Estimate 2 yields a pricing range of \$1,005-\$1,600.

In mid-October worldwide 2020 sales of remsdesivir were predicted to reach \$2.5 billion.⁸ As current treatments are \$3,120 a course, this suggests that only around 800,000 treatment courses would be sold in 2020 and that ICER was overly optimistic about its use. Abiding by Gilead's manufacturing cost projection and ICER's CBP principles, the true projected short-term spending for remdesivir should instead be \$1,250 for each treatment course.

ICER proposed alternative value-based prices for remdesivir using three thresholds: 1) \$50,000 per incremental quality-adjusted life year (QALY), and equal value of a life-year gained (evLYG); 2) \$100,000 per QALY and per evLYG; and 3) \$150,000 per QALY and per evLYG.⁵ These benchmarks assume remdesivir produces clinical benefits that extend and improve quality of life beyond the current standard of care. For the purposes of this issue brief, the first threshold is the most policy-relevant. Previous clinical research indicates that remdesivir has a net benefit in patients with moderate-to-severe COVID-19.³ In Figure 1, we outline pricing estimates in this patient population, for cases assuming mortality benefit and no mortality benefit. ICER determined the value-based pricing base case of remdesivir to be \$2,470, under the assumption of no mortality benefit associated with the treatment. Assuming mortality benefit, however, ICER found the valuebased pricing to be nearly double the base-case pricing at a range from \$3,980 to \$4,140.

CBP modeling offers advantages to government officials, patients, and innovators by not only increasing access to drugs but also building social capital for companies. The cost-based price of remdesivir is \$1,250 for each course of treatment, which is less than half the current price set by Gilead Sciences at \$3,120. Gilead Sciences also benefits from CBP through increased reputation, as a low pricing for remdesivir may be commended during a global pandemic.⁹

However, some disadvantages may arise with a CBP model. With nearly twelve years on the market, remdesivir has been repurposed three times before becoming a COVID-19 treatment. This draws to question whether R&D costs pre-COVID should be factored into the cost-based pricing of the treatment. CBP holds the potential to dampen investor enthusiasm for research in COVID-19 treatments now that remdesivir has been granted EUA and has some market share. VBP exhibits a different set of advantages. Prices set above cost-based minima drive increased private investments toward research that could lead to reliable and effective candidates. VBP incentivizes investments even in costly and potentially risky interventions by allowing private innovators to charge higher prices based on additional clinical benefits.⁹ VBP benefits consumers by generating a price ceiling that prevents the onset of unwanted excesses seen in the status quo (unrestricted pricing).

VBP is reliant on a cost-effectiveness analysis. This suggests a level of uncertainty in decisionmaking in the interpretation of clinical data, especially when data collection is in its early stages and continuing to evolve.⁵ Research throughout the COVID-19 pandemic has been everchanging, and the increased urgency for treatment implies that treatments will need to be priced even when data collection is ongoing. This introduces instability and potential fluctuation in any pricing recommendations. ICER has proposed that prices evolve alongside the presentation of clinical data; however, this idea is not well developed and will be undoubtedly complex.



Comparing CBP, VBP and Manufacturer Pricing for Remdesivir

Gilead Sciences has presented three tiers for the pricing of remdesivir: 1) governmental payers in the United States; 2) private insurers in the US and public payers in other wealthy nations; and 3) Low and Middle Income Countries (LMIC). We will focus on pricing for private insurers at \$520 per vial, or \$3,120 for a typical five-day treatment course.¹⁰ Gilead's benchmark price only abides by ICER's value-based pricing principles if the following assumptions hold: 1) Gilead's 5-day treatment course is used in contrast to ICER's 10 day treatment; 2) patients experience shorter time to recovery and a mortality benefit; and 3) dexamethasone is not included in the standard of care.¹¹ According to research published in the New England Journal of Medicine, as well as recommendations from the WHO, dexamethasone has been included in the standard of care for moderate-to-severe COVID-19 patients.¹² This alteration has already led to decreases in the ICER VBP benchmarks in contrast to previous iterations of ICER's remdesivir pricing analyses. Furthermore, recent studies report that remdesivir fails to show a mortality benefit and does not shorten the time to recovery in moderateto-severe COVID-19 patients.¹³ We will not rely on ICER's VBP benchmark that assumes mortality benefit in patients, as ongoing trials such as Solidarity provides clinical data indicative of remdesivir's lack of clinical benefits.14

Mounting evidence questions the mortality benefit of remdesivir, implying that an adjusted VBP benchmark would lead to a much lower valuation.

It is unsurprising that the VBP of remdesivir is much greater than the CBP. The manufacturer's price is much greater than CBP benchmarks. While Gilead's profit margins are a concern to some, others argue that this will incentivize others in the life sciences industry to take part in the search for a better treatment. We have postulated an intermediate pricing mechanism that may provide a compromising ground of benefits; however, this is an early idea that warrants further development.

Conclusion

The cost-based and value-based principles for COVID-19 drug pricing form different pricing benchmarks. We see that the cost-based and value-based prices for each treatment course of remdesivir are \$1,250 and \$2,470 (base case), respectively, which are both less than Gilead's price at \$3,120 per 5-day treatment course. In addition to assessing the future state of the COVID-19 pandemic, this work must take into further consideration the ever-changing development of COVID-19 treatments like remdesivir alongside the appropriate drug pricing framework.



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