ICER'S ALTERNATIVE PRICING MODELS: NEW THREATS TO BIOPHARMACEUTICAL'S PROFITABILITY AND INNOVATION

Heather Lee Whipple, Senior Vice President, Brand Market Access Insights, EVERSANA





- ICER's two models have presented a new view of "fair" pricing, providing evidence that advocates for substantially lower prices closely tied to manufacturing costs only
- The new cost recovery model for *remdesivir* is attractive to payers and has potential utility in other areas. This model is clearly a threat to biopharmaceutical companies and is a serious "watch-out"
- Payers believe that remdesivir should be priced at or lower than the traditional value-based price
- Payers are concerned about increased medical costs associated with the COVID-19 pandemic as well as the potential costs to pharmacy budget for treatment
- Although payers were favorable to ICER's modeling of remdesivir, there
 are still some who believe that ICER's methods need improvement



- An online survey was fielded in May 2019 to gather reactions on ICER's initial analysis to inform public debate of pricing for remdesivir (Gilead Sciences) and other future treatments of COVID-19
- Twenty medical directors and pharmacy directors from leading payers participated, representing approximately 100 million pharmacy lives

ICER's New Cost Recovery Model Takes on the Definition of "Fair" Pricing and Profits for Biopharmaceutical Companies

On May 1, 2020, the Institute for Clinical and Economic Review (ICER) released Alternative Pricing Models for remdesivir and Other Potential Treatments for COVID-19. This research was prepared by ICER in collaboration with Melanie D. Whittington, PhD and Jonathan D. Campbell, PhD (both from the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences). Highlighted cost-effectiveness model findings are based on lowest cost/QALY threshold.

ICER plans to request public comment and conduct peer-reviewed processes alongside updates to evidence sources in future iterations of this research.

The two models in this research are a deviation from ICER's traditional value assessment approach. The cost recovery model implies that biopharmaceutical companies should not profit from innovation in a time of worldwide pandemic. The question remains if ICER will apply this approach in subsequent reviews outside of the pandemic.

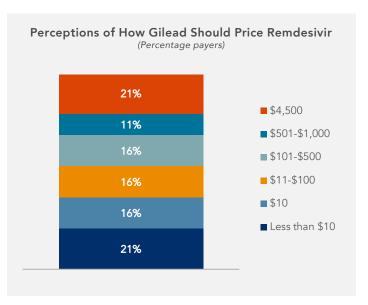
	Model 1: Cost Recovery	Model 2: Cost-Effectiveness Analysis
Objective	Set a price that compensates the manufacturer for the costs of production without additional profit	Estimate the cost-effectiveness and corresponding health-based price benchmarks of remdesivir versus standard of care
Inputs	Marginal cost of producing the drugResearch and development costsProfits	 Quality of life improvements Mortality benefits Benefits of fewer days in the ICU, on ventilation, and in hospital
Findings for Remdesivir	\$9.32 US for a 10-day course of treatment (rounded to \$10)	 \$4,460 US for a 5- or 10-day course of treatment (Base case of \$50,000/QALY)

Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.

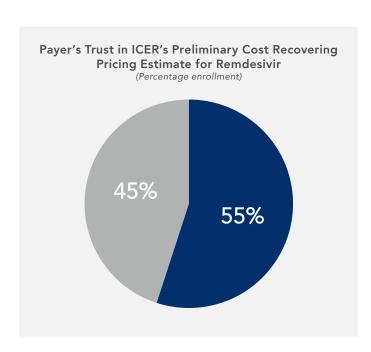


Majority of Payers Believe That Remdesivir Should be Priced at or Lower Than the Traditional Value-Based Price

ICER's initial analysis resulted in two very different suggested prices for *remdesivir*: \$9.32 or \$4,500 per 10-day treatment course. Payer executives are divided on their perception of what the true price of *remdesivir* should be; however, unsurprisingly, many fall somewhere between the two estimates provided by ICER.



n=19. Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.



N=20 payers representing 100 million commercial lives. Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.

Payers Split on Trust in ICER's Preliminary Cost Recovery Pricing Estimate for 10-Day Course of Remdesivir

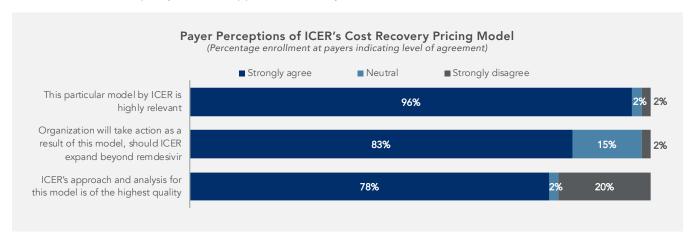
Nearly two-thirds (65%) of payers representing more than half of enrollment believe that ICER was able to accurately pinpoint the core costs associated with producing *remdesivir*. This is consistent with other Health Strategies Insights by EVERSANA's Evolution of Customer Views on ICER and Resulting Impact on Brand Access findings which indicate ICER's growing creditability with payers.

Participants that did not agree either lacked confidence in ICER's methods, or nontraditional assumptions including:

- No research and development costs
- No profit to the biopharmaceutical company

Payers See Potential Utility in Cost-Recovery Modeling in Other Categories

Most payer executives find ICER's new cost recovery modeling, which represents an estimate based on peer-reviewed methods of calculating the minimum costs of product for a course of therapy, to be highly relevant and would use findings from this model in future access decisions should ICER expand use beyond *remdesivir*. However, some payers remain hesitant in the quality of ICER's approach and analysis for this model.



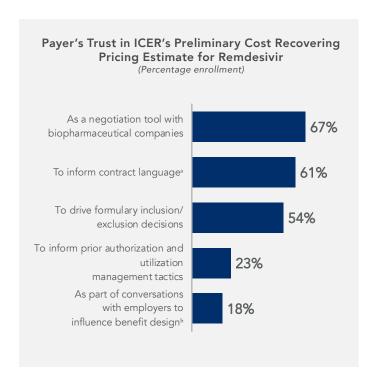
N=20 payers representing 100 million commercial lives. Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.

ICER's Cost Recovery Pricing Model Would Be Leveraged in Contract Negotiations and Language, Assuming Continued Use

Payers representing 67% of pharmacy lives would use results and findings from ICER's cost recovery pricing model in contract negotiations with biopharmaceutical companies, should the organization continue to evaluate drug costs with this model beyond just treatments for a global pandemic. This could upend how value is determined and could pose a threat to biopharmaceutical companies, especially those with older products under review.

These intentions are similar to payer response to ICER's Unsupported Price Increase Assessment released in late 2019; however, the true influence and role of ICER in these conversations and final contracts is still yet to come to fruition.

For more insights on payer reactions to ICER's Unsupported Price Increase Assessment, please refer to Health Strategies Insights by EVERSANA's market alert from December 2019. Read the full assessment here.

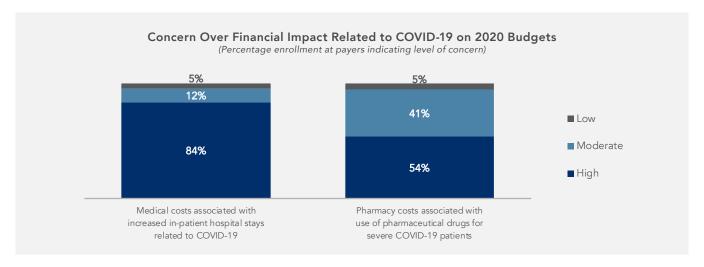


^ae.g., price protection; ^be.g., drive use to high deductible plans; N=20 payers representing 100 million commercial lives. Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.

Payers Are More Concerned with the Impact of COVID-19 on Medical Budgets, Pharmacy as Well, but to a Lesser Degree



As expected, payers are concerned by medical costs associated COVID-19, while pharmacy is also concerned about unplanned costs to treat the disease.



N=20 payers representing 100 million commercial lives. Source: Health Strategies Insights by EVERSANA, Health Technology Assessment, May 2020.

Implications for the Industry

- 1. ICER has leveraged the COVID-19 crisis as an opportunity to reshape how the industry looks at the value of biopharmaceutical drugs
 - Presenting two models serves to shift the value-based assumptions downward, providing attractive evidence to equip payers in negotiations with biopharmaceutical companies
- 2. ICER may evolve the cost-recovery approach to other categories and biopharmaceutical companies should be prepared to model this approach. In fact, proactive modeling will provide an optic into the impact this approach could have on profitability
 - Companies should be prepared to respond to increased challenges regarding cost transparency and profits
 - Companies should conduct scenario planning and risk assessments based on a potential shift to applying this model to non-pandemic response products. Developing an enterprise-wide response strategy and action plan will be key to minimizing the risks associated with this model
- 3. ICER's 2020 updates to the Value Assessment Framework include the practice of providing multiple scenarios and accepting data on biopharmaceutical company R&D costs
- **4.** Pharmacoeconomic modeling prior to submitting data to ICER is critical, and great consideration should be place on submitting in-confidence data
 - Biopharmaceutical companies should revisit payer profiles and account-based strategies given the disruption of COVID-19 and overall concern for medical and pharmacy budgets

ICER is an agile and evolving organization, and biopharmaceutical companies will need to execute and nurture an enterprise-based approach.