



Paying for Value:

Exploring Innovative Pricing Arrangements for Biopharmaceuticals

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Introduction

Over the past few decades, innovative medical technologies, including pharmaceuticals, biologics and devices, have been a driving force behind improved health outcomes. However, many argue that these same technologies have contributed to the dramatic rise in health care spending. In this dichotomy, manufacturers of health care products are confronted with ever-increasing costs to bring products to market, many of which are for smaller patient populations, while health care payers are under increasing pressure to rein in spending.

All of this comes at a time when the U.S. health care system has entered a new era of shrinking budgets and growing emphasis on value-based health care. As a result, manufacturers and payers have begun to reconsider how to price and pay for novel medical products, opening the door for innovative pricing arrangements in the U.S.

The need for stakeholders and policymakers alike to understand the implications of these financial arrangements is critical as the health system evolves. Exploration of these new payment models can help to ensure that manufacturers continue to develop innovative therapies and patients continue to access them in this new era of cost containment. As an independent multi-stakeholder group with expertise in analyzing the policy issues related to innovative drugs and devices, NEHI has launched an initiative to identify the benefits, risks and critical policy issues of expanded innovative pricing arrangements for health care products and technologies in the U.S. Information presented in this issue brief represent findings from an extensive literature review as well as expert interviews capturing the perspectives of stakeholders across the health care system.

What are Innovative Pricing Arrangements?

Innovative pricing arrangements, sometimes referred to as “alternative pricing” or “risk sharing” arrangements, were created to enable market access for drugs with positive evidence on a limited population. While innovative pricing arrangements are well established around the world, the U.S. health care system has less experience with these new payment models. They have been used extensively in Europe, typically as a compromise over market access, for drugs that would otherwise receive no approval for reimbursement. In the U.S, however, market access is generally not an issue. Once a therapy is approved by the Food and Drug Administration, very few are denied coverage, regardless of price. Thus innovative pricing arrangements have only been used sporadically in the U.S. over the past decade.

Innovative pricing arrangements generally fit into two categories: clinical outcome (or performance-based) schemes and financial-based schemes. The former include agreements where price, level or nature of reimbursement is tied to future measures of clinical or intermediate endpoints. The latter include agreements where financial limits are placed on therapies either per patient or per sales volume in order to control spending.

Generally, innovative pricing arrangements are agreed upon by manufacturers and payers in situations where there is a high-priced, novel therapy that is likely to have positive benefits for some and limited benefits for others, despite prior regulatory approval for safety and efficacy. It's difficult to predict who will positively benefit because predictive tools (such as diagnostics to identify subpopulations that will respond to the therapy) are unavailable or experience with the therapies is limited at the time of administration. Positive benefits may manifest in non-clinical benefits not often recognized in health care reimbursement such as improved productivity and quality of life. This additional value, in theory, should warrant additional reimbursement.

For these reasons, technology manufacturers and health care payers are increasingly interested in new ways to identify and reward innovations when they create measurable value for patients. This trend mirrors the overall movement towards value in health care happening in the U.S and has been in play internationally for some time, particularly in Europe, where health care technology assessment (HTA) programs set thresholds of cost effectiveness for market entry and reimbursement. In the U.S., payers and providers continue to place greater emphasis on value-based health care.

Although the U.S. has relatively little experience with innovative pricing arrangements, this brief identifies some high profile examples, along with the experience gained from the closely-related "coverage with evidence development" (CED) approach adopted by Medicare nearly 20 years ago. CED approaches offer conditional coverage, but require additional collection of patient data for products with uncertain clinical or cost effectiveness. Once sufficient evidence has been collected, reimbursement policies are often revisited. This approach is not a true innovative pricing scheme, as it does not require a novel approach to payment between the manufacturer and payer; rather, it solely requires data collection to enhance understanding of true clinical value.

Examples of Clinical Outcome or Performance-Based Agreements

Many of the best known examples of innovative pricing arrangements come from the United Kingdom, the most prominent being for Velcade, a treatment for multiple myeloma. In 2006, manufacturer Johnson & Johnson agreed to reimburse the National Health Service (NHS) for cases in which the drug was determined not to be clinically effective, measured by a reduction in blood protein levels by at least 50 percent (indicating tumor shrinkage). It is important to note that the arrangement was made after the therapy was denied full coverage by the NHS because the therapy did not meet the National Institute for Health and Clinical Excellence (NICE) cost effectiveness threshold.

There have been several prominent clinical outcome based agreements in the U.S. as well. In 2009, Merck and Cigna entered into an arrangement in which two of Merck's type-2 diabetes medications would receive preferential placement on the Cigna formulary. In return, Merck provided a discount to Cigna for any patient taking any oral diabetes medications who demonstrated improved blood sugar levels and medication adherence. Further discounts were triggered if Cigna showed that the medications had been taken as prescribed. This scheme is

unique in that the manufacturer provided the incentive to the payer regardless of what diabetes medication was taken and that the incentives were tied to improved outcomes. After one year, patients who were enrolled in the program (regardless of prescribed drug) exhibited a 5 percent improvement in blood sugar levels and a 4.5 percent increase in compliance with blood sugar lab testing.

In 2008, Proctor & Gamble, Sanofi-Aventis and Health Alliance agreed to a slightly different approach for the osteoporosis therapy Actonel. The arrangement arose due to doubts that Actonel could prevent non-spinal fractures. Consequently, the manufacturer agreed to reimburse the payer for the cost of the treatment of any non-spinal fracture that a patient on the medication suffered up to a ceiling, rather than reimbursement for the cost of their drug. By alleviating the payer's efficacy concerns, the manufacturers were able to reach more patients. Initial results were positive, as the incidence of non-spinal fractures was consistent with clinical trial data and Proctor & Gamble's reimbursement to Health Alliance was 79 percent below the predefined limit established in the deal. While critics of the agreement are skeptical, the deal generated significant publicity for the therapy.

As these examples attest, manufacturers and payers have been interested in clinical outcome-based agreements for quite sometime; however, the terms of the agreement vary from case to case. In just these few examples, clinical measures ranged from biomarkers to clinical outcomes and included both measurement of success and failure.

Examples of Financial-Based Agreements

Rather than linking reimbursement to clinical outcomes, others have set financial limits on novel therapies. One such agreement in the United Kingdom was for Lucentis, a treatment for macular degeneration. In this arrangement formed in 2008, NHS agreed to cover up to 14 treatments, the length of treatment estimated to achieve full benefit for most patients, after which manufacturer Novartis would pay for any additional treatments required. Like Velcade, Lucentis did not meet the NICE cost effectiveness threshold and was initially only approved for one-fifth of patients.

Another form of financial-based agreement placed a global spending limit for Enbrel, a rheumatoid arthritis treatment. In 2003, Wyeth Pharmaceuticals and the Australian government agreed only to cover Enbrel up to a fixed global amount, after which Wyeth would not be reimbursed for the use of Enbrel. Like many agreements in the United Kingdom, this one only came to fruition after Enbrel was deemed non-cost effective according to Australian standards.

Examples of Coverage with Evidence Development Agreements

Coverage with evidence development (CED) schemes have been used by many health care stakeholders to enhance understanding of clinical and cost effectiveness and to inform reimbursement moving forward.

In 2007, manufacturer Genomic Health struck a deal with United Healthcare for the Oncotype DX Test, a genetic test used to identify breast cancer patients who will respond to chemotherapy. Under the arrangement, United Healthcare agreed to reimburse the list price of the test for 18 months while results were tracked and clinical effectiveness was verified. If women were still receiving chemotherapy without a test suggesting it would be valuable for them, United Healthcare would seek to negotiate a lower price as the test was not having the intended effect on

actual medical practice.¹ In another example, Actelion Pharmaceuticals agreed to fund a tracking system to measure progress of patients on Tracleer, a pulmonary hypertension medication, while the Australian government agreed to pay full cost for those patients whom the medication benefited. In 2008, the drug was approved by the Pharmaceutical Benefits Advisory Committee as a cost effective therapy for pulmonary arterial hypertension and it's likely that the body of evidence gathered from the drug registry supported this decision.²

In the U.S., Medicare first applied the CED concept in 1995 and later formalized the CMS Coverage with Evidence Development Program in 2006 with the notion that additional data collection would enhance coverage decisions and clinical practice. The goal of the program is threefold: to generate utilization and effectiveness data so Medicare can document appropriate use; to consider future coverage changes; and to generate an evidence base for providers.

Benefits of Innovative Pricing Arrangements

Some analysts argue that innovative pricing arrangements have the potential to both provide value and contain costs. Among them:

Supporting Access to Innovative Technologies

Payers have become increasingly pressured to control spending while continuing to reimburse cutting-edge treatments and technologies. In cases where clinical performance data are unclear, innovative pricing arrangements allow the payer to reimburse novel therapies where they may not have otherwise. These arrangements minimize a payer's downside risk by creating clear financial boundaries.

Generating Overall Health Care Value

Some innovative products and technologies may reduce overall health care costs when used appropriately. This situation could manifest when products arrest disease progression that would otherwise lead to expensive treatment or when therapies significantly improve the health of an entire patient population.

Enhancing Understanding of Effectiveness

In theory, innovative pricing arrangements expedite the collection of clinical performance data in larger populations. Real world clinical data is needed to accurately ascertain true clinical and cost effectiveness as a drug's true effect on sub-populations is difficult to predict in a clinical trial. Only after a therapy has been on the market and tested in practice can true effectiveness be determined.

Risks of Innovative Pricing Arrangements

The expansion of these approaches poses significant challenges to the current business models of industry and payers alike, and will have major implications for all health care stakeholders. Among them:

¹ Pollack, A. (2007). Pricing Pills by Results, The New York Times; July 4, 2007, Retrieved from:

<http://www.nytimes.com/2007/07/14/business/14drugprice.html?pagewanted=all>, Last Accessed February 2012.

² Pugatch, M. et.al. (2010). Sharing the Burden: Could Risk-Sharing Change the Way We Pay For Healthcare? The Stockholm Network, Retrieved from: http://www.stockholm-network.org/downloads/publications/Sharing_the_Burden.pdf. Last Accessed: February 2012.

Supporting Access to Ineffective or Not Cost-Effective Technologies

Of course, there is some risk for payers, providers and patients in reimbursing treatments that may prove ineffective or not cost-effective in the real world. A payer's ability to restrict or withdraw coverage may be limited once a therapy is established in the market and providers and payers may be subject to additional risks of litigation for malpractice or denial of coverage, especially in situations where an established treatment is forgone.

Providers may have concerns about these arrangements influencing their care decisions. For example, providers may feel pressure to prescribe products with lower co-pays or added discounts rather than on the basis of clinical performance alone.³

Increasing Data Collection Burden

Additional data collection requires additional investment in data infrastructure. In the U.S., however, there has been growing public and private investment in health information technology in recent years.

Though the infrastructure may soon be in place, incentives for provider data collection are not. Providers' reimbursement rates are decreasing as their administrative burden is growing. Arrangements that require additional testing and documentation beyond standard practice routines may not be feasible under current forms of payment.

Confounding Clinical Performance

Questions around how to truly quantify performance in a real world setting remain unanswered. The relative time of treatment during disease progression and patient medication adherence may confound conclusions on a drug's effectiveness resulting in an imbalance in risk and reward between the payer and manufacturer.

Limiting Upside Potential for Manufacturers

There are potential consequences to limiting reimbursement when technologies first enter the market. It is difficult to accurately predict market size upon regulatory approval, as these arrangements are based on the manufacturer's and payer's perception of value, which may or may not be precise in a practical clinical setting. Limiting reimbursement potential upon market entry may hinder the manufacturer's ability to collect and reinvest unexpected profit into research and development.

Barriers to Expanded Use of Innovative Pricing Arrangements in the United States

Despite the many risks, many stakeholders believe the potential benefits of innovative pricing arrangements warrant further exploration. These arrangements exist only on a small scale in the U.S. due to critical barriers. Among them:

High Transaction Costs for All Parties

Each health care stakeholder faces additional upfront costs when implementing these novel arrangements. Negotiating these arrangements is a resource-intensive endeavor. Both

³ Carlson, J (2009). Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals, Journal of Managed Care Pharmacy, Vol. 15, No. 8 October 2009. Retrieved from: <http://www.amcp.org/data/jmcp/683-687.pdf>. Accessed November 2011.

manufacturers and payers need to invest in pre-negotiation forecasting and modeling and unlike payers, manufacturers are not in the risk-business and are generally less experienced when it comes to risk-sharing contracts.⁴ Further adding to transaction costs, manufacturers have to separately negotiate the terms of these arrangements with each payer in an environment where both parties tend to have deep seated distrust and very different perspectives on appropriate clinical outcomes and financial adjudication.⁵

Once a deal is complete, the arrangements often require significant investments in process design and maintenance. The data collection costs are high and resource-intensive. Manufacturers and payers will need to monitor and maintain data in the form of a patient registry. Manufacturers may find that the added cost to maintain a registry are more than the potential benefit and providers may encounter objections from patients if their premium dollars are supporting clinical research and not health care.⁶ The U.S. situation is in stark contrast with Europe's, where manufacturers deal with a centralized or quasi-centralized authority for these negotiations, resulting in certain economies of scale in terms of transaction costs.

Structural Barriers in the U.S. Health Care System

Unlike the national health care systems in Europe, the U.S. health care system is fragmented and siloed. The fragmented delivery system does not support participation and coordination of stakeholders either across the health care system or from a net health benefit perspective. Innovative pricing arrangements are likely to work better in integrated delivery systems where payers and providers are aligned and benefit from providing high value care. The European experience supports this theory, as their national health systems function more like an integrated delivery system.

Another structural barrier is the internal separation between clinical and pharmacy benefits within most payer organizations. Many payers now outsource their drug coverage to pharmacy benefit managers who are strictly focused on the bottom line. Innovative pricing arrangements require a net health benefit perspective which many payers' organizational structures do not support.

Movement of patients between different payers in the commercial market, often referred to as churn, also poses a significant barrier as many performance-based agreements depend on clinical endpoints months or years in the future. The frequent turnover of patients between health care payers makes it difficult for a single payer to invest in a deal when they may not realize the financial benefit in the future. National payers have begun to shift their focus towards net health benefit as part of the larger trend in the U.S. to incentivize value in health care. However, this population health perspective is not as pervasive as it is in Europe.

Defining Clinical Endpoints that Indicate Performance

An accurate and easily measured clinical endpoint is critical to a successful performance-based agreement. Ideally, an endpoint should already be assessed routinely by providers. However, for many therapies, defining an endpoint is a complex process. Issues arise if providers are not already

⁴ Carlson, B (2009). Satisfaction Guaranteed or Your Money Back. *Biotechnology Healthcare*, October/November 2009. Retrieved from: <http://www.biotechnologyhealthcare.com/journal/fulltext/6/4/BH0604014.pdf?CFID=100756455&CFTOKEN=31341059>. Accessed November 2011.

⁵ Carlson, J (2009). Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals, *Journal of Managed Care Pharmacy*, Vol. 15, No. 8 October 2009. Retrieved from: <http://www.amcp.org/data/jmcp/683-687.pdf>. Accessed November 2011.

⁶ Mohr, P. and Tunis, S. (2010). Access with Evidence Development the U.S. Experience. *Pharmacoeconomics* Vol. 28, No. 2 2010. Accessed November 2011.

collecting or submitting the clinical data. It is also difficult to define a consistent endpoint for a heterogeneous patient population. In turn, a new concept of “risk-sharing fatigue” has emerged in Europe due to the difficulties of defining and collecting these clinical endpoints. Many payers are saying it is too time consuming and expensive to collect outcomes and are choosing to engage in financial-based models instead.

Lack of Provider Incentives for Data Collection

Providers are critical stakeholders in many innovative pricing arrangements, yet their role is often overlooked. Arrangements built around clinical outcomes require providers to collect and submit data. If these endpoints are not currently part of the standard of care, providers will be burdened with additional work that most likely is not reimbursed. In an environment where reimbursement rates are decreasing, it will be difficult to engage providers in this crucial role. Recent movement toward bundled payments and accountable care organizations may ease this problem, but in the near future misaligned provider incentives will remain a significant barrier.

Nascent Health Information Technology Infrastructure

Along with financial incentives, providers need adequate IT infrastructure to enter and track clinical data. Not only are integrated health systems aligned to provide high value care, they generally have comprehensive data infrastructure to collect and track health outcomes for their patients, making them great candidates for these arrangements. In the fragmented U.S. system, payers also need data infrastructure to track clinical outcomes to substantiate reimbursement. At this point in time, most payers have limited data infrastructure to track health outcomes and this kind of data collection and management may only be feasible for national payers beginning to invest in this infrastructure.⁷

Confidentiality

Manufacturers would argue that confidentiality is required for U.S.-based innovative pricing arrangements. With ever growing pressures from global reference pricing, keeping the terms of these arrangements private is critical from the manufacturer’s perspective in order to maintain prices abroad.

Additionally, data confidentiality may be an issue from the patient’s perspective, as they may be skeptical of the payer’s motives to collect additional clinical data, especially in cases of genetic testing.

Accounting Uncertainty

Innovative pricing arrangements that use clinical outcomes present cash flow issues and revenue recognition challenges for many manufacturers. For agreements that track clinical performance, manufacturers are not reimbursed until a therapy is proven effective or required to pay back funds if the drug is ineffective.⁸ In many cases, clinical performance cannot be measured for months or years after administration, creating significant accounting challenges. Limited ability to predict profitability may hinder prospective planning, including research and development.

⁷ Carlson, J (2009). Paying for Outcomes: Innovative Coverage and Reimbursement Schemes for Pharmaceuticals, *Journal of Managed Care Pharmacy*, Vol. 15, No. 8 October 2009. Retrieved from: <http://www.amcp.org/data/jmcp/683-687.pdf>. Accessed November 2011.

⁸ PriceWaterhouseCoopers (2008). Pay for Performance Arrangements IFRS Revenue Recognition Guidance. White Paper Retrieved from: http://www.pwc.com/en_GX/gx/pharma-life-sciences/pdf/pay-for-performance.pdf. Accessed November 2011.

Anti-Trust Issues

Due to anti-trust laws in the U.S., payers need to avoid discussing reimbursement and agreement details with other payers. Otherwise, payers could force the upper hand in negotiations with manufacturers, resulting in coercion.⁹ What this means is that every detail of an agreement from the clinical endpoint to the financial exchange needs to be reinvented for each payer, increasing the complexity and transaction costs for manufacturers and providers as the terms of each agreement may differ. Limited or targeted anti-trust protection, often seen in other industries, may alleviate some of the complexity associated with multiple negotiations.

Alternatives to Innovative Pricing Arrangements

Experts continue to explore alternative approaches to innovative pricing arrangements. Some believe that these arrangements should use proxies for clinical performance to reduce complexities associated with these arrangements, offering more balanced risk and rewards for both payers and manufacturers. Measuring clinical processes and medication adherence would sidestep issues associated with defining and negotiating clinical outcomes and limit confounding factors like disease progression and medication adherence that influence drug performance.

Others suggest that innovative pricing arrangements are purely an intermediary solution to personalized medicine. As researchers continue to make strides in identifying biomarkers and patient sub-populations, the effectiveness of a therapy will be ascertained upstream of the treatment rather than downstream, and patients who will likely respond to the therapy will be identified prior to drug administration.

Finally, some experts suggest that at a minimum, innovative pricing arrangements may provide a means for the health care system to promote on-label use of costly therapies and discourage off-label experimentation. Currently, providers can prescribe FDA approved therapies for “off-label” conditions not studied in clinical trials and approved by the FDA. Physician prescribed off-label use is often credited with the discovery of novel applications for an approved therapy; however, it is also costly as expensive therapies are prescribed in cases where it may not work. Where there is an innovative pricing arrangement, control of off-label use in cases of limited clinical evidence can be achieved through limiting reimbursement.

The Future of Innovative Pricing Arrangements

If innovative pricing arrangements are to grow in the U.S., understanding the common themes derived from experiences abroad and in the U.S. will be critical to overcoming the many barriers now in place. Naturally, negotiations that can be reduced to simple, clearly defined agreements, with robust, well-accepted endpoints and clear benefits for all stakeholders, will prove to be the best candidates.

However, even in the best scenarios, innovative pricing arrangements are few and far between in the U.S. Many experts suggest that one or more seismic shifts in the health care industry need to occur before these arrangements will be seen on a large scale. Some suggest that the number of

⁹ Mohr, P. and Tunis, S. (2010). Access with Evidence Development the U.S. Experience. *Pharmacoeconomics* Vol. 28, No. 2 2010. Accessed November 2011.

these agreements will only increase when there are greater financial pressures, including the threat of restricted market access along the lines already seen in Europe. Another possible catalyst would be a sustained recession causing a fundamental change in the payer model. If either occurs, payers will need to make significant coverage decisions, which will open the door to new arrangements.

Arguably, such a shift is already underway in the U.S health care system with the movement toward the creation of ACOs and integrated delivery systems. As many of the barriers suggest, stakeholder alignment and incentives for high value care are crucial. The establishment of new ACOs and integrated delivery systems may make these arrangements more feasible. Along these same lines, improved data infrastructure and expanded use of electronic health records will enhance the ability to track patient outcomes over time. Furthermore, increased competition in high cost therapeutic areas may provide the impetus for more innovative pricing arrangements, as new entrants will need to establish and differentiate themselves from their competitors. Many experts agree that oncology is an ideal therapeutic class for these arrangements as therapies are very expensive and have variable efficacy in patients.

Innovative pricing arrangements may not be the panacea to rising health care costs; however, the impetus to investigate alternative payment models can not be overlooked. The balance between cost containment and innovation continues to be tested and innovative pricing arrangements are one approach of many that maintains patient access to life saving therapies in a sustainable way.

Paying for Value: *An Expert Roundtable Discussion*

Background

Innovative pricing arrangements have been met with both fanfare and skepticism as a way to create value in biopharmaceutical reimbursement. To discuss both the challenges and opportunities for innovative pricing arrangements, NEHI held an expert roundtable on March 7, 2012. The event captured perspectives from across the health care system and featured the following national experts: Laurie Amirpoor of WellPoint Inc., Priya Chandran of The Boston Consulting Group, Chris Haney of Merck, Rob Glik of IMS Consulting Group and Peter Neumann, ScD of Tufts Medical Center.



Roundtable Participants

Left to Right: Priya Chandran, Boston Consulting Group; Valerie Fleishman, NEHI; Rob Glik, IMS Consulting Group; Chris Haney, Merck; Peter Neumann, ScD, Tufts Medical Center; Maria Buckley, Nutter McClennen & Fish LLP; Laurie Amirpoor, WellPoint; Brian Schuetz, NEHI.

Challenges

The panelists unanimously agreed that while innovative pricing arrangements offer the potential to incorporate value concepts into the pricing models for biopharmaceuticals, there are significant challenges to their implementation. The group noted, however, that many of the barriers can be overcome with forward thinking and experience. The barriers include:

Measurement Issues

In cases of outcomes-based innovative pricing arrangements, measurement of clinical endpoints has proven to be a significant barrier to widespread implementation. Not only are appropriate clinical endpoints difficult to define and agree upon, they are often difficult to collect and monitor the data in real-world clinical settings. The data may not be routinely collected by providers and reimbursement for additional testing is often not provided. To promote the adoption of these arrangements, it is necessary to identify and utilize clinical endpoints that are easily measured, collected routinely as part of current clinical practice and measured within a short timeframe, ideally less than a year. Longer clinical outcomes time horizons are more difficult to collect, monitor and analyze.

Structural Barriers in the Health Care System

Payers face significant structural barriers to the adoption of innovative pricing arrangements, including membership turnover and outsourcing of pharmacy benefits, both of which further complicate measurement challenges. Churn of membership between multiple health plans limits a payer's ability to monitor clinical outcomes over time and can result in the benefits of an arrangement accruing to a different insurer. Additionally, many payers have significantly outsourced their pharmacy management activities to pharmacy benefit managers, making coordination of pharmacy and medical benefits more challenging. This divide creates data

collection and coordination challenges pharmacy because medical claims data may be collected in multiple, non-integrated systems.

Legal/Antitrust Issues

There are several legal issues stakeholders must address when participating in innovative pricing arrangements, though the roundtable agreed that these challenges will become less onerous as organizations gain experience with these arrangements. Panelists noted that deals structured to pay for success rather than punish failure may be more desirable from the health plan perspective. Health plans may encounter legal issues or challenges from their membership if they are reimbursing a therapy with a known failure rate. It's also critical that manufacturers operate within discount safe harbors set by the U.S. government. If a manufacturer offers a discount to one health plan, it should be prepared to enter into similar arrangements with other health plans; otherwise, the manufacturer's actions may be construed as anti-competitive.



Opportunities

Despite the many challenges in implementing these arrangements, the roundtable panelists agreed there are significant opportunities for stakeholders to benefit from these arrangements. Among them:

Paying for Process Rather Than Clinical Outcomes

Many of the measurement challenges associated with innovative pricing arrangements can be overcome by tying reimbursement to process measures like diagnostics, medication adherence and patient education, rather than clinical outcomes. It is possible to identify process measures proven to enhance clinical performance of biopharmaceuticals that are far more easily tracked than clinical outcomes. Arrangements that focus solely on clinical performance are often subject to confounding factors that influence performance. By promoting process measures, stakeholders may be able to limit confounding factors such as adherence. Payers already incentivize process measures through value-based insurance design, where customers are offered discounts and incentives for participating in educational and disease management programs. Innovative pricing arrangements must be compatible with these incentive structures.

Using Data Infrastructure to Target Biopharmaceuticals

As information technology infrastructure continues to evolve and more data is collected, payers and manufacturers have a greater ability to predict who will likely benefit from different therapies and which patients are most likely to need support in the form of training or outreach for disease management or medication adherence. Pairing the power of data analytics with innovative pricing arrangements may allow stakeholders to target strategies to patients who need them the most, improving clinical performance.

Targeting Appropriate Disease Areas

The group identified two disease areas which may be best suited for innovative pricing arrangements: chronic diseases and oncology. Chronic diseases like diabetes, COPD, CHF and asthma have measurable clinical endpoints that are easily and routinely measured. By promoting diagnostics, adherence and patient education, manufacturers can expand the use of their therapies and payers can avoid costly complications and hospitalizations. Oncology, a disease area characterized by small patient populations, high-cost therapies and variable clinical outcomes, is also a candidate for innovative pricing arrangements. In an era of budgetary pressures, payers increasingly are interested in limiting costs by reimbursing biopharmaceuticals only in cases where the patient will benefit, while manufacturers need to continue to find ways to maintain prices to support future innovation, all the while maintaining patient access to life-saving therapies.

Identifying Biomarkers Early On in Drug Development

To ease the measurement challenges associated with innovative pricing arrangements, manufacturers should begin to think about paired diagnostics and clinical endpoints early in the development process. Manufacturers have an opportunity to identify biomarkers and clinical endpoints in early-stage research and validate those findings in later clinical trials. An enhanced early understanding of a drug's performance allows manufacturers to more accurately predict real world performance and minimizes the downside risk of innovative pricing arrangements.

Conclusion

Innovative pricing arrangements have proven difficult to implement in the U.S. and uptake has been limited. The panelists agree that new and innovative approaches to reimbursement are needed to create value in the health care system; however, these arrangements should be viewed as one part of a larger strategy, not as a stand-alone panacea. Other approaches like diagnostics, adherence and patient education can achieve many of the same goals, often for less effort. As a result, innovative pricing arrangements are likely to have limited near-term growth in the U.S. as other more easily implementable strategies are pursued in parallel to create value in health care.